

researchers or CMS contractors request CMS PII/PHI data, they enter into a Data Use Agreement (DUA) with CMS. The DUA stipulates that the recipient of CMS data must properly protect the data according to all applicable data security standards and provide for its appropriate destruction at the completion of the project/study or the expiration date of the DUA.

CMS is permitted to disclose data files for approved research purposes in compliance with 45 CFR 164.512(I). Researchers requesting limited data set files (LDS) must, as part of the request process, complete a research request packet that provides CMS with information pertaining to the research study, including describing how the research results/findings will be disseminated, as well as the data files being requested. Should CMS approve the research request, the data requestor enters into a Data Use Agreement (DUA). This data collection is necessary to ensure that disclosures of data for research purposes comply with Federal laws and regulations as well as CMS policy. *Form Number:* CMS–R–235 (OMB control number 0938–0734); *Frequency:* Occasionally; *Affected Public:* Private Sector—State, Local, or Tribal Governments; and Business or other for-profits, Not-for-profits institutions and Federal Government *Number of Respondents:* 7,805; *Total Annual Responses:* 7,805; *Total Annual Hours:* 4,234. (For policy questions regarding this collection contact Rebecca Dorman at 410–786–2095 or [rebecca.dorman@cms.hhs.gov](mailto:rebecca.dorman@cms.hhs.gov).)

**3. Type of Information Collection Request:** Revision of a currently approved collection; *Title of Information Collection:* Administrative Simplification HIPAA Compliance Review; *Use:* The purpose of this collection is to retrieve information necessary to conduct a compliance review and carry out the authority delegated to CMS as described in CMS–0014–N (68 FR 60694). These forms will be submitted to the Centers for Medicare & Medicaid Services (CMS), National Standards Group, from entities covered by HIPAA Administrative Simplification regulations. This collection is not applicable to HIPAA Privacy and Security Rules. *Form Number:* CMS–10662 (OMB control number 0938–1390); *Frequency:* Annually; *Affected Public:* Private Sector—State, Local, or Tribal Governments; and Business or other for-profits, Not-for-profits institutions and Federal Government; *Number of Respondents:* 100; *Total Annual Responses:* 140; *Total Annual Hours:* 3,040. (For policy questions regarding

this collection contact Kevin Stewart at 410–786–6149 or [Kevin.stewart@cms.hhs.gov](mailto:Kevin.stewart@cms.hhs.gov).)

**William N. Parham, III,**

*Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10203]

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

**AGENCY:** Centers for Medicare & Medicaid Services, Health and Human 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 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 on the collection(s) of information must be received by the OMB desk officer by February 13, 2025.

**ADDRESSES:** Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to [www.reginfo.gov/public/do/PRAMain](http://www.reginfo.gov/public/do/PRAMain). Find this particular information collection by selecting "Currently under 30-day Review—Open for Public Comments" or by using the search function.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, please access the CMS PRA website by copying and pasting the following web address into your web browser: <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing>.

**FOR FURTHER INFORMATION CONTACT:** William Parham at (410) 786–4669.

**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:* Medicare Health Outcomes Survey; *Use:* The HOS is a longitudinal patient-reported outcome measure (PROM) that assesses self-reported beneficiary quality of life and daily functioning. As a PROM, the HOS measures the impact of services provided by MAOs, whereas process and patient experience measures only provide a snapshot of activities or experiences at a specific point in time. PROM data collected by the HOS allows CMS to continue to assess the health of the Medicare Advantage population. This older population is at increased risk of adverse health outcomes, including chronic diseases and mobility impairments that may significantly hamper quality of life. The HOS supports CMS's commitment to improve health outcomes for beneficiaries while reducing burden on providers. CMS accomplishes this by focusing on high-priority areas for quality measurement and improvement established in the agency's Meaningful Measures Framework. The HOS uses quality

measures that ask beneficiaries about health outcomes related to specific mental and Physical Conditions. *Form Number*: CMS-10203 (OMB control number: 0938-0701); *Frequency*: Yearly; *Affected Public*: Individuals and Households; *Number of Respondents*: 1,275; *Total Annual Responses*: 663,150; *Total Annual Hours*: 212,208. (For policy questions regarding this collection contact Alyssa Rosen at 410-786-8559 or [Alyssa.Rosen@cms.hhs.gov](mailto:Alyssa.Rosen@cms.hhs.gov).)

**William N. Parham, III**

*Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Medicare & Medicaid Services**

[CMS-3472-N]

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

**AGENCY**: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human 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's fundamental purpose is to support the principles of an evidence-based determination process for Medicare's coverage policies. MEDCAC panels provide advice to CMS on the strength of the evidence available for specific medical treatments and technologies through a public, participatory, and accountable process.

**DATES**: Nominations must be received by Monday, February 17, 2025.

**ADDRESSES**: You may send in nominations for membership via email to [MEDCACnomination@cms.hhs.gov](mailto:MEDCACnomination@cms.hhs.gov).

**FOR FURTHER INFORMATION CONTACT**: Leah Cromwell, 410-786-2243, MEDCAC Coordinator, via email at [Leah.Cromwell1@cms.hhs.gov](mailto:Leah.Cromwell1@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 website at: <https://www.cms.gov/Regulations-and-Guidance/Guidance/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 those enrolled in the Medicare program including but not limited to, racial and ethnic groups, individuals with disabilities, and from across the gender spectrum. Therefore, we encourage nominations of qualified candidates who can represent these lived experiences.

The MEDCAC consists of a pool of 100 appointed members including: 90 at-large standing members (20 of whom are patient advocates), and 10 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, health disparities, medical ethics, geriatrics those with an understanding of sociodemographic bias and resulting limitations of scientific evidence, 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 December 2025, there will be a total of 20 membership terms expiring. Of the 20 memberships expiring, 2 are industry representatives, 10 are patient advocates and the remaining 8 membership openings are for the at-large standing MEDCAC membership.

All nominations must be accompanied by curricula vitae. Nomination packages should be addressed to Leah Cromwell and sent to the email 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
- Health disparities
- Biological and physical sciences
- Epidemiology and biostatistics
- Clinical trial design
- Health care data management and analysis
- Patient advocacy
- Health care economics
- Medical ethics
- Geriatrics
- Other relevant professions

We are looking particularly for experts in a number of fields. These include health disparities, 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, observational research design, stroke epidemiology, geriatrics, 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