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' website address at website address at *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html.*

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: William Parham 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–10691 Data Request and Attestation for PDP Sponsors

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

Type of Information Collection Request: New collection (request for a new OMB control number); *Title of Information Collection:* Data Request and Attestation for PDP Sponsors; *Use:* Section 50354 of the Bipartisan Budget Act of 2018 (BBA) provides that the Secretary shall establish a process under which the sponsor of a Prescription Drug Plan (PDP) that provide prescription drug benefits under Medicare Part D may request, beginning in plan year 2020, that the Secretary provide on a periodic basis and in an electronic format standardized extracts of Medicare claims about its plan enrollees. Section 50354 of the BBA further specifies that PDP sponsors receiving such Medicare claims data for their corresponding PDP plan enrollees may use the data for: (1) Optimizing therapeutic outcomes through improved medication use, (2) improving care coordination so as to prevent adverse healthcare outcomes, such as preventable emergency department visits and hospital readmissions, and (3) for any other purposes determined appropriate by the Secretary. Section 50354 also states that the PDP sponsor may not use the data: (1) To inform coverage determinations under Part D, (2) to conduct retroactive review of medically accepted conditions, (3) to facilitate enrollment changes to a different PDP or a MA–PD plan offered by the same parent organization, (4) to inform marketing benefits; and (5) for any other purpose the Secretary determines is necessary to include in order to protect the identity of individuals entitled to or enrolled in Medicare, and to protect the security of personal health information. This proposed information collection request would allow the PDP sponsor to submit a request to CMS for claims data for its enrollees and to attest that it will adhere to the permitted uses and limitations on the use of the Medicare claims data that are listed in 42 CFR 423.153. *Form Number:* CMS–10691 (OMB control number: 0938–TBD); *Frequency:* Occasionally; *Affected Public:* Private sector; *Number of Respondents:* 63; *Total Annual Responses:* 68; *Total Annual Hours:* 1.36. (For policy questions regarding this collection contact Kari Gaare at 410–786–8612.)

Dated: November 27, 2018.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2018–26052 Filed 11–29–18; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3374–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 MEDCACs 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, January 7, 2019.

ADDRESSES: You may mail nominations for membership to the following address: Centers for Medicare & Medicaid Services, Center for Clinical Standards and Quality, Attention: Leah Cromwell or 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 website 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, Public Law 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: 90 at-large standing members (10 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, 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 June 2019, there will be 20 membership terms expiring. Of the 20 memberships expiring, 1 is an industry representative and the remaining 19 membership openings are for the at-large standing MEDCAC membership.

All nominations must be accompanied by curricula vitae. Nomination packages should be sent to Leah Cromwell or 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.

III. 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. 3501 *et seq.*).

Dated: November 21, 2018.

Kate Goodrich,

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

[FR Doc. 2018–26090 Filed 11–29–18; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–1446]

Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the draft guidance for industry and FDA staff entitled ''Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use.'' This draft guidance document describes studies and information that FDA recommends be used when submitting premarket notifications (510(k)s) for self-monitoring blood glucose test