

13(e)(1)). In addition, the contractor must require its employees, by written agreements, to disclose subject inventions (FAR 52.227–11(e)(2); 52.227–13(e)(4)). The contractor also has an obligation to utilize the subject invention, and agree to report, upon request, the utilization or efforts to utilize the subject invention (FAR 52.227–11(f); 52.227–13(c)(1)(iii)).

**C. Annual Burden**

*Respondents:* 3,379.

*Total Annual Responses:* 13,200.

*Total Burden Hours:* 52,800.

*Obtaining Copies:* Requesters may obtain a copy of the information collection documents from the General Services Administration, Regulatory Secretariat Division (MVCB), 1800 F Street NW, Washington, DC 20405, telephone 202–501–4755. Please cite OMB Control No. 9000–0095, Commerce Patent Regulations, in all correspondence.

Dated: October 16, 2019.

**Janet Fry,**

*Director, Federal Acquisition Policy Division, Office of Governmentwide Acquisition Policy, Office of Acquisition Policy, Office of Governmentwide Policy.*

[FR Doc. 2019–22853 Filed 10–18–19; 8:45 am]

**BILLING CODE 6820–EP–P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Medicare & Medicaid Services**

[CMS–3392–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, November 18, 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, 7500 Security Boulevard, Mail Stop: S3–02–01, Baltimore, MD 21244 or send via email to [MEDCACnomination@cms.hhs.gov](mailto:MEDCACnomination@cms.hhs.gov).

**FOR FURTHER INFORMATION CONTACT:** Leah Cromwell, MEDCAC Coordinator, 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. Cromwell by phone (410) 786–2243 or 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: <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 2020, there will be 25 membership terms expiring. Of the 25 memberships expiring, 2 are industry representatives, 5 are patient advocates and the remaining 18 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 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: October 3, 2019.

**Kate Goodrich,**

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

[FR Doc. 2019-22947 Filed 10-18-19; 8:45 am]

**BILLING CODE 4120-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2019-D-3989]

#### Drug Master Files; Draft Guidance for Industry; 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 a draft guidance for industry entitled "Drug Master Files." Once finalized, this guidance will provide FDA's current thinking on drug master files (DMFs), which are submissions to FDA that may be used to provide confidential, detailed information about facilities, processes, or articles used in the manufacturing, processing, packaging, and storing of human drug products. DMFs are submitted solely at the discretion of their holders and are not required by statute or regulation. This draft guidance, when finalized, will revise the guidance for industry "Drug Master Files: Guidelines" that published in September 1989.

**DATES:** Submit either electronic or written comments on the draft guidance by December 20, 2019 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

**ADDRESSES:** You may submit comments on any guidance at any time as follows:

#### *Electronic Submissions*

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such

as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

#### *Written/Paper Submissions*

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

*Instructions:* All submissions received must include the Docket No. FDA-2019-D-3989 for "Drug Master Files." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- *Confidential Submissions—*To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20