

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.*

[FR Doc. 2016-18545 Filed 8-4-16; 8:45 am]

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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](mailto: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.)

2. *Type of Information Collection Request:* New collection (Request for a new OMB control number); *Title of Information Collection:* The PACE Organization (PO) Monitoring and Audit Process in 42 CFR part 460; *Use:* Historically, the Programs of All-Inclusive Care for the Elderly (PACE) audit protocols have been included in the Medicare Advantage (MA) and Medicare Part D audit protocol's information collection request (CMS-10191, OMB 0938-1000). However, in examining previous submissions, we do not believe that including it with the MA and Part D audit protocols allowed for an accurate representation of the PACE burden. Due to PACE audits being substantially different from our MA and Part D audits, we have separated the PACE audit protocols from the MA and Part D protocols and created this information collection request which seeks OMB approval under a new control number.

POs are required to comply with all PACE program requirements. The growth of these PACE organizations forced CMS to develop an audit strategy to ensure we continue to obtain meaningful audit results. As a result, CMS' audit strategy reflected a move to a more targeted, data-driven and outcomes-based audit approach. We focused on high-risk areas that have the greatest potential for participant harm.

CMS has developed an audit protocol and will post it to the CMS Web site each year for use by POs to prepare for their audit. The data collected for audit is detailed in this protocol and the exact fields are located in the record layouts, at the end of the protocol. In addition, a questionnaire will be distributed as part of our audit. This questionnaire is also included in this package. *Form Number:* CMS-10630 (OMB control number: 0938-New); *Frequency:* Yearly; *Affected Public:* Private sector (Business or other for-profits and Not-for-profits institutions); *Number of Respondents:* 72; *Total Annual Responses:* 72; *Total Annual Hours:* 12,960. (For policy questions regarding this collection contact Caroline Zeman at 410-786-0116.)

Dated: August 2, 2016.

**William N. Parham, III,**

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

[FR Doc. 2016-18662 Filed 8-4-16; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2016-N-0001]

#### Cellular, Tissue, and Gene Therapies Advisory Committee; Notice of Meeting

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Cellular, Tissue, and Gene Therapies Advisory Committee. The general function of the committee is to provide advice and recommendations to the Agency on FDA's regulatory issues. At least one portion of the meeting will be closed to the public. **DATES:** The meeting will be held on September 7, 2016, from 1 p.m. to 4 p.m.

**ADDRESSES:** FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993-0002. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm>.

**FOR FURTHER INFORMATION CONTACT:** Janie Kim or Denise Royster, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Silver Spring, MD 20993-0002, 301-796-9016 or 240-402-8158, [Janie.kim@fda.hhs.gov](mailto:Janie.kim@fda.hhs.gov) or [Denise.royster@fda.hhs.gov](mailto:Denise.royster@fda.hhs.gov); or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at <http://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting. For those unable to attend in person, the meeting will also be available via Webcast. The Webcast will be available at the following link: <https://collaboration.fda.gov/ctgtac0916/>.

#### SUPPLEMENTARY INFORMATION:

*Agenda:* On September 7, 2016, the committee will meet by teleconference. In open session, the committee will hear updates of research programs in the Gene Transfer and Immunogenicity Branch, Division of Cellular and Gene Therapies, Office of Cellular, Tissue, and Gene Therapies, Center for Biologics Evaluation and Research.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee meeting link.

*Procedure:* On September 7, 2016, from 1 p.m. to 2:20 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before August 23, 2016. Oral presentations from the public will be scheduled between approximately 2:20 p.m. to 3:20 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before August 15, 2016. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by August 16, 2016.

*Closed Committee Deliberations:* On September 7, 2016, from 3:20 p.m. to 4 p.m., the meeting will be closed to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)). The committee will discuss reports of intramural research programs and make recommendations regarding personnel staffing decisions.

Persons attending FDA's advisory committee meetings are advised that the