

her term until a successor has been sworn in.

A Federal official, designated by the Secretary or the Administrator, must serve as the Chair and facilitate the Panel meetings. The Chair's term must usually be for a period of 4 years, but it may be extended at the discretion of the Administrator or his or her duly appointed designee.

In order to conduct the business of the Panel, a quorum is required. A quorum exists when a majority of currently appointed members is present at full Panel or subcommittee meetings or is participating in conference calls.

With the approval of the Secretary or designee, subcommittees consisting of two or more Panel members may be established to perform functions within the Panel's jurisdiction. One of the members will be designated by his or her peers as chair of the subcommittee. The Department Committee Management Officer will be notified upon establishment of each subcommittee and will be provided information on its name, membership, function, and estimated frequency of meetings. The advice or recommendations of a subcommittee or working group must be deliberated by the Panel. A subcommittee may not report directly to a Federal official, but rather it must report to the parent Panel.

The FACA provides that a Designated Federal Officer (DFO) must be appointed to a Federal advisory committee to attend each Panel meeting and to ensure that all procedures adhere to applicable statutory, regulatory, and DHHS General Administration Manual directives. The DFO approves and prepares all meeting agendas; calls all Panel or subcommittee meetings; adjourns any meeting when he or she determines adjournment to be in the public interest; and chairs meetings when directed to do so by the Secretary or the Administrator. The DFO or his or her designee must be present at all full Panel and subcommittee meetings. The CMS must also provide management and support services to the Panel.

#### *E. APC Panel Meetings*

Meetings must be held up to three times a year at the call of the DFO. The agenda, which sets the boundaries for discussion, is developed by CMS and approved by the DFO. Meetings are open to the public, except as determined otherwise by the Secretary or other official to whom the authority has been delegated in accordance with the Government in the Sunshine Act (5 U.S.C. 552b(c)) and FACA. The Panel Chair must facilitate all Panel meetings.

Adequate advance notice of all meetings must be published in the **Federal Register**, as required by applicable laws and departmental regulations, stating reasonably accessible and convenient locations and times. Meetings must be conducted, and records of the proceedings kept, as required by applicable laws and departmental regulations. The records of the Panel and established subcommittees must be managed in accordance with General Records Schedule 26, Item 2, or other approved Agency records disposition schedule. These records must be available for public inspection and copying, subject to the Freedom of Information Act (5 U.S.C. 552).

#### *F. Compensation*

All members must serve on a voluntary basis, without compensation, pursuant to advance written agreement. Members of the Panel must be entitled to receive reimbursement for travel expenses and per diem in lieu of subsistence, in accordance with Standard Government Travel Regulations.

#### *G. Annual Cost Estimate*

Estimated fiscal year (FY) 2011 annual cost for operating the Panel, including travel expenses for members but excluding staff support, is \$77,000. The estimated annual person-years of staff support required for the APC Panel is 1.0 full-time equivalent (FTE) at an estimated annual cost of \$105,575. Estimated FY 2012 annual cost for operating the Panel, including travel expenses for members but excluding staff support, is \$80,000. The estimated annual person-years of staff support required for the APC Panel is 1.0 FTE at an estimated annual cost of \$107,650.

#### *H. Termination Date*

Unless renewed by appropriate action prior to its expiration, the APC Panel must terminate 2 years from the date the charter is filed.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance Program; and No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: December 2, 2010.

**Donald M. Berwick,**

*Administrator, Centers for Medicare & Medicaid Services.*

[FR Doc. 2010–31372 Filed 12–14–10; 8:45 am]

**BILLING CODE 4120–01–P**

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Centers for Medicare & Medicaid Services**

[CMS–3236–N]

#### **Medicare Program; Town Hall Meeting on Physician Quality Reporting System**

**AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS.

**ACTION:** Notice of meeting.

**SUMMARY:** This notice announces a Town Hall Meeting to discuss the Physician Quality Reporting System (previously known as the Physician Quality Reporting Initiative (PQRI)). The purpose of the Town Hall Meeting is to solicit input from participating stakeholders on the individual quality measures and measures groups being considered for possible inclusion in the proposed set of quality measures for use in the 2012 Physician Quality Reporting System and key components of the design of the Physician Quality Reporting System. Measure developers, eligible professionals, professional associations, such as medical specialty societies, and other interested stakeholders are invited to participate, in person or by teleconference. The meeting is open to the public, but attendance is limited to space and teleconference lines available.

**DATES:** *Meeting Date:* The Town Hall Meeting will be held on February 9, 2011, from 10 a.m. until 4 p.m. eastern standard time (e.s.t.).

*Deadline for Registration of Presenters of the Town Hall Meeting:* All presenters for the Town Hall meeting must register and submit their discussion item(s) by 5 p.m. e.s.t. on January 18, 2011.

*Deadline for Registration of All Other Participants for the Town Hall Meeting and Request for Special Accommodations:* Registration opens on December 20, 2010. All other participants must register no later than 5 p.m. e.s.t. on January 28, 2011.

Requests for special accommodations must be received by 5 p.m. e.s.t. on January 28, 2010.

*Deadline for Submission of Comments on Key Issues for the Town Hall Meeting:* Written comments on key issues for discussion at the Town Hall Meeting must be received by 5 p.m. e.s.t. on January 21, 2011.

*Deadline for Submission of Other Written Comments or Statements:* Written comments or statements on issues that were discussed at this Town Hall Meeting or other comments, may be sent via regular mail, fax, or electronically to the address specified in

the **ADDRESSES** section of this notice and must be received by 5 p.m. e.s.t. on February 25, 2011.

**ADDRESSES: Meeting Location:** The Town Hall Meeting will be held in the main auditorium of the Central Building of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244-1850.

**Registration and Special Accommodations:** Persons interested in attending the meeting or participating by teleconference must register by completing the on-line registration via the Web site at <http://www.usqualitymeasures.org>.

Individuals who require special accommodations should send a request via email or regular mail to the contact specified in the **FOR FURTHER INFORMATION** section of this notice.

**Submission of Written Comments or Statements:** Written comments or statements may be sent via e-mail to [Physician\\_Reporting\\_TEMP@cms.hhs.gov](mailto:Physician_Reporting_TEMP@cms.hhs.gov), or sent via regular mail to: *Attn:* 2012 Physician Quality Reporting System Town Hall Meeting Comments, Office of Clinical Standards and Quality, Centers for Medicare & Medicaid Services, Mail Stop S3-02-01, 7500 Security Boulevard, Baltimore, MD 21244-1850.

**FOR FURTHER INFORMATION CONTACT:** Jacquelyn Kosh-Suber, (410).786-6889 via e-mail at [Jacquelyn.Koshsuber@cms.hhs.gov](mailto:Jacquelyn.Koshsuber@cms.hhs.gov), or via regular mail as specified in the **ADDRESSES** section of this notice.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

The Physician Quality Reporting System is a voluntary reporting program in which eligible professionals and group practices report data on quality measures. An eligible professional who satisfactorily reports data on quality measures may qualify to earn a Physician Quality Reporting System incentive payment based on a percentage of the eligible professional's (or, in the case of a group practice, the group's) total estimated allowed Medicare Part B charges for covered professional services furnished during a specified reporting period. Under section 1848(k)(3)(B) of the Social Security Act (the Act), the term "eligible professional" means any of the following:

- A physician.
- A practitioner described in section 1842(b)(18)(C) of the Act.
- A physical or occupational therapist or a qualified speech-language pathologist or qualified audiologist.

Detailed information about the Physician Quality Reporting System is

available on the CMS Web site at <http://www.cms.hhs.gov/PQRI>.

Our goals for the 2012 Physician Quality Reporting System include increasing participation in light of a payment adjustment that begins in 2015, leveraging the benefits of alternative reporting mechanisms, such as registry-based reporting, EHR-based reporting, and the group practice reporting option, and increasing alignment with other programs, such as the EHR Incentive Program.

This Town Hall meeting will be hosted to solicit input from eligible professionals and other interested parties on the individual quality measure and measures group suggestions received in response to the "2012 Physician Quality Reporting System Call for Measures" and on other changes being considered for the future with regard to the key components of the Physician Quality Reporting System described in this notice.

##### **II. Town Hall Meeting Format**

The Town Hall meeting will begin with an overview of the objectives for the session. The remainder of the meeting will be devoted to presenting and receiving input on each of the major components of the Physician Quality Reporting System including the following:

- The individual quality measures and measures group suggestions received in response to the "2012 Physician Quality Reporting System Call for Measures" (for more information, see the CMS Measures Management System Web site at [http://www.cms.gov/MMS/13\\_Call%20for%20Measures.asp#TopOfPage](http://www.cms.gov/MMS/13_Call%20for%20Measures.asp#TopOfPage)).
- Reporting mechanism.
- Reporting period.
- Criteria for satisfactory reporting.
- The group practice reporting option.
- The Maintenance of Certification Program Incentive.

Following each presentation, the meeting agenda will provide opportunities for brief comments on each of the key issues from on-site session attendees. The time for each presenter's comments will be approximately 2 minutes and will be based on the number of registered presenters. As time allows, telephone participants will also have the opportunity to provide brief comments of no more than 2 minutes on each of the key issues. Presenters will be scheduled to speak in the order in which they register. Therefore, individuals who would like to present must register and submit their

comment(s) to the address specified in the **ADDRESSES** section of this notice by the date specified in the **DATES** section of this notice. All other written submissions will be accepted and presented at the meeting if they are received at the address specified in the **ADDRESSES** section of this notice by the date specified in the **DATES** section of this notice.

We anticipate posting an audio download and/or transcript of the Town Hall meeting on the CMS PQRI Web site after completion of the meeting. See Web site at <http://www.cms.hhs.gov/PQRI>. The opinions and alternatives provided during this meeting will assist us as we develop the Physician Quality Reporting System for 2012. We anticipate posting a summary of the individual quality measures and measures groups for possible inclusion in the proposed set of quality measures, as well as possible program design options under consideration for use in the 2012 Physician Quality Reporting System on the Physician Quality Reporting System section of the CMS Web site at <http://www.cms.hhs.gov/PQRI> by January 21, 2011.

##### **III. Registration Instructions**

While there is no registration fee, for security reasons, any persons wishing to attend this meeting must register by the date listed in the **DATES** section of this notice. Persons interested in attending the meeting or participating by teleconference must register by completing the online registration via the Web site at <http://www.usqualitymeasures.org>. The online registration system will generate a confirmation page to indicate the completion of your registration. Please print this page as your registration receipt. If seating capacity has been reached, you will be notified that the meeting has reached capacity. Individuals may also participate in the Town Hall meeting by teleconference. Registration is required as the number of call-in lines will be limited. The call-in number will be provided upon confirmation of registration. Individuals may also register via telephone by calling the contact listed in the **FOR FURTHER INFORMATION** section of this notice or via regular mail to the address listed in the **ADDRESSES** section of this notice.

##### **IV. Security, Building, and Parking Guidelines**

This meeting will be held in a Federal government building; therefore, Federal security measures are applicable. In planning your arrival time, we recommend you to arrive at the central

building no later than 9 a.m. e.s.t. to allow for enough time to clear security and to check in before the meeting begins. The on-site check-in for visitors will begin at 9:30 a.m. e.s.t. All items brought to the building, whether personal or for the purpose of demonstration or to support a presentation, including items such as laptops, cell phones, and palm pilots, are subject to physical inspection.

Security measures include the following:

- Presentation of government-issued photographic identification to the Federal Protective Service or Guard Service personnel.
- Interior and exterior inspection of vehicles (this includes engine and trunk inspection) at the entrance to the grounds. Parking permits and instructions will be issued after the vehicle inspection.
- Passing through a metal detector and inspection of items brought into the building.

We note that all items brought to CMS, whether personal or for the purpose of demonstration or to support a demonstration, are subject to inspection. We cannot assume responsibility for coordinating the receipt, transfer, transport, storage, setup, safety, or timely arrival of any personal belongings or items used for demonstration or to support a demonstration.

**Note:** *Individuals who are not registered in advance will not be permitted to enter the building and will be unable to attend the meeting. The public may not enter the building earlier than 45 minutes prior to the convening of the meeting. All visitors must be escorted in areas other than the lower and first floor levels in the Central Building. Seating capacity is limited to the first 250 registrants.*

**Authority:** Section 503 of Public Law 108–173.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program).

Dated: December 7, 2010.

**Donald M. Berwick,**

*Administrator, Centers for Medicare & Medicaid Services.*

[FR Doc. 2010–31301 Filed 12–13–10; 8:45 am]

**BILLING CODE 4120–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2009–D–0008]

#### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry on Citizen Petitions and Petitions for Stay of Action Subject to Section 505(q) of the Federal Food, Drug, and Cosmetic Act

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (PRA).

**DATES:** Fax written comments on the collection of information by January 14, 2011.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, *Attn:* FDA Desk Officer, *FAX:* 202–395–7285, or e-mailed to *oira\_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910—NEW and title “Guidance for Industry on Citizen Petitions and Petitions for Stay of Action Subject to Section 505(q) of the Federal Food, Drug, and Cosmetic Act.” Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Elizabeth Berbakos, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850. 301–796–3792. E-mail: *elizabeth.berbakos@fda.hhs.gov*.

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Guidance for Industry on Citizen Petitions and Petitions for Stay of Action Subject to Section 505(q) of the Federal Food, Drug, and Cosmetic Act

In the **Federal Register** of January 21, 2009 (74 FR 3611), FDA announced the availability of a draft guidance for industry entitled “Draft Guidance for

Industry on Citizen Petitions and Petitions for Stay of Action Subject to Section 505(q) of the Federal Food, Drug, and Cosmetic Act” (FD&C Act). FDA is now in the process of finalizing this guidance. In that **Federal Register** notice, FDA provided the public with 60 days to comment on the proposed collection of information. FDA received no comments pertaining to the information collection in the draft guidance.

#### *Description of Respondents:*

Respondents to this collection of information as it is related to citizen petitions are individuals or households, State or local governments, not-for-profit institutions, and businesses or other for-profit institutions or groups. Respondents to this collection of information as it is related to petitions for stay of Agency action are persons who choose to file a petition for an administrative stay of action.

**Burden Estimate:** Section 505(q)(1)(H) of the FD&C Act requires that citizen petitions and petitions for stay of Agency action that are subject to section 505(q) include a certification to be considered for review by FDA. Section 505(q)(1)(I) of the FD&C Act requires that supplemental information or comments to such citizen petitions and petitions for stay of Agency action include a verification to be accepted for review by FDA. This guidance describes our current thinking on the interpretation of these requirements. The guidance sets forth the criteria the Agency will use in determining if the provisions of section 505(q) apply to a particular citizen petition or petition for stay of agency action. One of the criteria for a citizen petition or petition for stay of Agency action to be subject to section 505(q) of the FD&C Act is that a related ANDA or 505(b)(2) application is pending at the time the citizen petition or petition for stay is submitted. Because petitioners or commenters may not be aware of the existence of a pending ANDA or 505(b)(2) application, the guidance recommends that all petitioners challenging the approvability of a possible ANDA or 505(b)(2) application include the certification required in section 505(q)(1)(H) of the FD&C Act and that petitioners and commenters submitting supplements or comments, respectively, to a citizen petition or petition for stay of action challenging the approvability of a possible ANDA or 505(b)(2) application include the verification required in section 505(q)(1)(I) of the FD&C Act. The guidance also recommends that if a petitioner submits a citizen petition or petition for stay of Agency action that is missing the