will need to identify how and when to adapt to new science, with a full consideration of the nature of the science itself, public health implications, and our statutory and regulatory framework.

II. Public Meeting

As one step towards establishing the center's approach for incorporating new science in regulatory decisionmaking, CDRH will hold a public meeting to discuss the issues the Task Force is considering. The objective of the meeting will be to hear input on these issues from a broad range of external constituencies, including industry representatives, consumer and patient advocates, academic experts, other members of Government, and the general public.

To focus the center's strategies, CDRH requests feedback related to the following questions, which will serve as the basis for discussion at the public meeting:

A. Adapting to New Scientific Information

(1) When CDRH gains new scientific information about a particular product or type of product, what should the criteria be for changing CDRH's expectations of the evidence necessary for pre- or postmarket regulatory decisions, keeping in mind our mission to protect and promote the public health, as well as our statutory and regulatory framework? What are potential ''triggers'' for making such changes?

(2) When such changes are warranted, how should the center communicate them to industry, consumers, and other external constituencies? Should CDRH have a new regulatory paradigm for communicating with outside parties?

(3) When such changes are warranted, how should CDRH apply them to devices currently under review?

(4) When such changes are warranted, how should CDRH apply them to products currently on the market? For example, how should CDRH treat ''first-generation'' products as new and improved versions are developed?

B. Adapting to Novel Technologies or Novel Uses of Existing Technologies

(1) Assessing the safety and effectiveness of a novel technology can be challenging because the extent of information on and the level of understanding of the technology's risk-benefit profile or manufacturing process is less mature than that of a technology for which there is extensive ''real-world'' experience. What steps should CDRH take to assure that novel technologies or novel uses of existing technologies are safe and effective, without creating barriers to innovation, keeping in mind our statutory and regulatory framework?

C. Enhancing CDRH's Technical Competence and Analytical Capability

(1) With current resources, what proactive steps should CDRH take to address gaps in staff-members' knowledge about new science and reduce uncertainty in science-based regulatory decisionmaking?

During the meeting, there will be a moderated discussion between CDRH staff and invited experts from the private and public sectors about the questions presented in this document. The invited participants will not be asked to develop consensus recommendations, but rather to provide their individual perspectives. The topics for discussion will be presented in conjunction with hypothetical case studies for consideration. There will also be an opportunity for general attendees to provide feedback on the discussion topics during periodic open sessions.

In advance of the meeting, additional information, including the case studies, will be made available on the Internet. This information will be placed on file in the public docket (docket number found in brackets in the heading of this document), which is available at *http://www.regulations.gov*. This information will also be available on FDA's Medical Devices Web site at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm* (select the appropriate meeting from the list), along with the agenda for the meeting.

Transcripts: Transcripts of the public meeting may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 6–30, Rockville, MD 20857, approximately 15 working days after the public meeting at a cost of 10 cents per page. A transcript of the public meeting will be available on the Internet at *http://www.regulations.gov*.

Dated: December 11, 2009.

Jeffrey Shuren,

Acting Director, Center for Devices and Radiological Health.

[FR Doc. E9–30114 Filed 12–17–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3221–N]

Medicare Program; Physician Quality Reporting Initiative (PQRI): Listening Session-February 2, 2010.

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

ACTION: Notice of meeting.

SUMMARY: This notice announces a listening session to discuss the Physician Quality Reporting Initiative (PQRI). The purpose of the listening session is to solicit input from participating stakeholders on—

- The individual quality measures and measures groups (for example, suggestions for new measures groups or suggestions for the composition of existing measures group(s) being considered for possible inclusion in the proposed set of quality measures for use in the 2011 PQRI program and;
- Key components of the design of the PQRI program, such as possible reporting mechanisms, reporting periods, criteria for satisfactory reporting, the group practice reporting option, and public reporting of 2011 PQRI data.

Measure developers, eligible professionals, professionals associations, such as medical specialty societies, and other interested stakeholders are invited to participate, in person or by teleconference.

The opinions and alternatives provided during this meeting will assist us as we evaluate the PQRI program for 2011. 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 2011 PQRI program on the PQRI section of the CMS Web site at *http://www.cms.hhs.gov/PQRI* by January 18, 2010.

The meeting is open to the public, but attendance is limited to space and teleconference lines available.

DATES: *Meeting Date:* The listening session will be held on Tuesday, February 2, 2010 from 10 a.m. until 4:30 p.m. Eastern Standard Time (E.S.T).

Meeting Registration and Request for Special Accommodations Deadline: Registration opens on Monday, December 21, 2009. For security reasons, registration must be completed no later than 5 p.m. E.S.T. on Wednesday, January 27, 2010. Requests

for special accommodations must be received by 5 p.m. E.S.T. on Wednesday, January 27, 2010.

Submission of Written Comments or Statements Deadline: Written comments or statements on the issues that were discussed at this listening session may be sent via 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 Friday February 12, 2010.

ADDRESSES: *Meeting Location:* The listening session 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.

Written Comments or Statements: Written comments or statements may be sent via e-mail to *PQRITEMP@cms.hhs.gov* or sent via regular mail to: Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244–1850, Mail Stop S3–02–01, Attn: 2011 PQRI Listening Session Comments. All persons planning to make a statement in person at the listening session are urged to submit statements in writing during the listening session and should subsequently submit the information electronically by the timeframe specified in the **DATES** section of this notice.

FOR FURTHER INFORMATION CONTACT: Regina Chell, Centers for Medicare & Medicaid Services, Office of Clinical Standards and Quality, Mailstop S3–02–01, Attn: 2011 PQRI Listening Session, 7500 Security Boulevard, Baltimore, MD 21244 or contact Ms. Chell by phone at 410–786–6551, or via e-mail at *Regina.Chell@cms.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The PQRI is a voluntary reporting program in which eligible professionals (and beginning in 2010, group practices) report data on quality measures to CMS. For 2010 and prior years, an eligible professional who satisfactorily reports data on quality measures may qualify to earn a PQRI incentive payment based on a percentage of the eligible professional's total estimated allowed Medicare Part B charges for covered professional services furnished during a specified reporting period. CMS is authorized to provide PQRI incentive payments through 2010, although changes being considered by Congress, if passed, could extend that authority beyond 2010. 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

The PQRI was first implemented in 2007 as a result of section 101(b) of Division B–Medicare Improvements and Extension Act of 2006 of the Tax Relief and Health Care Act of 2006 (Pub.L. 109–432) (MIEA–TRHCA), which was enacted on December 20, 2006. The PQRI was extended and further enhanced as a result of the Medicare, Medicaid, and SCHIP Extension Act of 2007 (Pub.L. 110–173) (MMSEA), which was enacted on December 29, 2007, and the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (Pub. L. 110–275), which was enacted on July 15, 2008. Changes to the PQRI as a result of these laws, as well as information about the PQRI in 2007, 2008, 2009, and 2010, are discussed in detail in the Calendar Year (CY) 2008 Medicare Physician Fee Schedule (PFS) proposed rule (72 FR 38196 through 38204), CY 2008 PFS final rule with comment period (72 FR 66336 through 66353), CY 2009 PFS proposed rule (73 FR 38558 through 38575), CY 2009 PFS final rule with comment period (73 FR 69817 through 69847), CY 2010 PFS proposed rule (74 FR 33559 through 33589) and CY 2010 PFS final rule with comment period(74FR 61788 through 61844). In addition, detailed information about the PQRI is available on the CMS Web site at *http://www.cms.hhs.gov/PQRI.*

Section 1848(k)(2)(D) of the Act requires that, for the 2009 PQRI and subsequent years, for each quality measure adopted by the Secretary of the Department of Health and Human Services (the Secretary), the Secretary shall ensure that the eligible professionals have the opportunity to provide input during the development, endorsement, or selection of measures applicable to services they furnish. To satisfy this requirement with respect to the selection of 2011 PQRI measures, we intend to publish a proposed set of quality measures for the 2011 PQRI in the **Federal Register** via the CY 2011 PFS proposed rule. To assist us with identifying new measures or measures groups for the proposed set of 2011 PQRI quality measures, on November 16, 2009, we solicited suggestions for individual measures and measure groups [*e.g.,* suggestions for new measures groups and/or suggestions for the composition of existing measures group(s)] for possible inclusion in the proposed set of 2011 PQRI quality measures. The ''2011 PQRI Call for Measures'' was posted on the CMS Web site at *http://www.cms.hhs.gov/apps/QMIS/CallforMeasures.asp.* The deadline for submitting quality measures suggestions in response to the ''2011 PQRI Call for Measures'' was 5 p.m. E.S.T. on Wednesday, December 16, 2009.

We also intend to address other program components of the 2011 PQRI in the CY 2011 PFS proposed rule, such as the reporting mechanisms, reporting periods, criteria for satisfactory reporting, the group practice reporting option, and public reporting of 2011 PQRI data. We will formally propose aspects of the 2011 PQRI in the CY 2011 PFS proposed rule. Our goals for the 2011 PQRI include increasing participation in this voluntary reporting program and leveraging the benefits of alternative reporting mechanisms, such as registry-based reporting, EHR-based reporting, and the group practice reporting option.

This listening session 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 ''2011 PQRI Call for Measures'' and on other changes being considered for the future with regard to the key components of the PQRI described above. Prior to the listening session, we will post a summary of the individual quality measures and measures groups being considered for possible inclusion in the proposed set of quality measures for use in the 2011 PQRI program and the policy options related to the components of the program described above that we are considering to potentially propose for the 2011 PQRI on the CMS Web site at *http://www.cms.hhs.gov/PQRI.* We anticipate posting this summary by January 18, 2010. We will consider the input that we receive from stakeholders as a result of this listening session as we develop our policy proposals for the 2011 PQRI program. We will determine which individual measures and measures group(s) to include in the proposed set of 2011 quality measures and the

changes to the design of the PQRI to propose for 2011 and publish these proposals in the CY 2011 PFS proposed rule. After a period of public comment, we will make the determination with regard to the final set of quality measures for the 2011 PQRI and the final 2011 PQRI program requirements and publish them in the CY 2011 PFS final rule.

II. Listening Session Format

The listening session will be held on February 2, 2010 beginning at 10 a.m. E.S.T. with an overview of the objectives for the session. The remainder of the meeting will be devoted to presenting and receiving input on possible key program design changes under consideration for each of the major components of PQRI as follows—

- The individual quality measures and measure group suggestions received in response to the ''2011 PQRI Call for Measures'';
- Reporting mechanisms;
- Reporting periods;
- Criteria for satisfactory reporting;
- The group practice reporting option, and
- Policies with respect to public reporting of 2011 PQRI data.

Following each presentation, the meeting agenda will provide opportunities for brief 2-minute comments on each of the key issues from on-site session attendees. As time allows, telephone participants will also have the opportunity to provide brief 2-minutecomments on each of the key issues. A lunch break will occur at approximately 12:30 p.m. E.ST. The meeting will conclude by 4:30.p.m. E.S.T. Written submissions will also be accepted up until the timeframe specified in the **DATES** section of this notice.

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 listening session 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.

We anticipate posting an audio download and/or transcript of the listening session on the CMS PQRI website after completion of the listening session. See Web site at *http://www.cms.hhs.gov/PQRI.*

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 session 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, set-up, 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 1848(k) of the Social Security Act; Section 1848(m) of the Social Security Act.

(Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: December 10, 2009.

Charlene Frizzera,

Acting Administrator, Centers for Medicare and Medicaid Services.

[FR Doc. E9–30122 Filed 12–17–09; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–7017–N]

Medicare Program; Meeting of the Advisory Panel on Medicare Education, February 3, 2010

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

ACTION: Notice of meeting.

SUMMARY: This notice announces a meeting of the Advisory Panel on Medicare Education (the Panel) in accordance with the Federal Advisory Committee Act. The Panel advises and makes recommendations to the Secretary of Health and Human Services and the Administrator of the Centers for Medicare & Medicaid Services on opportunities to enhance the effectiveness of consumer education strategies concerning the Medicare program. This meeting is open to the public.

DATES: *Meeting Date:* Wednesday, February 3, 2010 from 8:30 a.m. to 3 p.m., eastern standard time (e.s.t.).

Deadline for Meeting Registration, Presentations and Comments: Wednesday, January 27, 2010, 5 p.m., e.s.t.

Deadline for Requesting Special Accommodations: Wednesday, January 20, 2009, 5 p.m., e.s.t.

ADDRESSES: *Meeting Location:* Hilton Washington Hotel Embassy Row, 2015 Massachusetts Avenue, NW., Washington, DC 20036, (202) 265–6800.

Meeting Registration, Presentations, and Written Comments: Lynne Johnson, Designated Federal Official, Division of Forum and Conference Development, Office of External Affairs, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Mailstop S1–05–06, Baltimore, MD 21244–1850 or contact Ms. Johnson via e-mail at *Lynne.Johnson@cms.hhs.gov.*

Registration: The meeting is open to the public, but attendance is limited to the space available. Persons wishing to attend this meeting must register by contacting Lynne Johnson at the address