

- Using single and multiple procedure claims data.
- Addressing other APC structure technical issues.

**Note:** The subject matter before the Panel will be limited to these and related topics. Issues related to calculation of the OPPS conversion factor, charge compression, pass-through payments, and wage adjustments are not within the scope of the Panel's purpose. Therefore, these issues will not be considered for presentations and/or comments. There will be no exceptions to this rule. We appreciate your cooperation on this matter.

The Panel may use data collected or developed by entities and organizations, other than DHHS and CMS, in conducting its review. We urge organizations to submit data for the Panel's and CMS staff's review.

### III. Written Comments and Suggested Agenda Topics

Send hardcopy and electronic written comments and suggested agenda topics to the DFO at the address indicated above. The DFO must receive these items by 5 p.m. (e.s.t.), Thursday, February 7, 2008. There will be no exceptions. We appreciate your cooperation on this matter.

The written comments and suggested agenda topics submitted for the March 2008 APC Panel meeting must fall within the subject categories outlined in the Panel's Charter and as listed in the Agenda section of this notice.

### IV. Oral Presentations

Individuals or organizations wishing to make 5-minute oral presentations must submit hardcopy and electronic versions of their presentations to the DFO by 5 p.m. (e.s.t.), Thursday, February 7, 2008, for consideration.

The number of oral presentations may be limited by the time available. Oral presentations should not exceed 5 minutes in length for an individual or an organization.

The Chairperson may further limit the time allowed for presentations due to the number of oral presentations, if necessary.

### V. Presenter and Presentation Information

All presenters must submit Form CMS-20017 (revised 01/07). Hardcopies are required for oral presentations; however, electronic submissions of Form CMS-20017 are optional. The DFO must receive the following information from those wishing to make oral presentations:

- Form CMS-20017 completed with all pertinent information identified on the first page of the presentation.
- One hardcopy of presentation.

- Electronic copy of presentation.
- Personal registration information as described in the Meeting Attendance section below.
- Those persons wishing to submit comments only must send hardcopy and electronic versions of their comments, but they are not required to submit Form CMS-20017.

### VI. Oral Comments

In addition to formal oral presentations, there will be opportunity during the meeting for public oral comments, which will be limited to 1 minute for each individual and a total of 3 minutes per organization.

### VII. Meeting Attendance

The meeting is open to the public; however, attendance is limited to space available. Attendance will be determined on a first-come, first-served basis.

Persons wishing to attend this meeting, which is located on Federal property, must e-mail the Panel DFO to register in advance no later than 5 p.m. (e.s.t.), Wednesday, February 27, 2008. A confirmation will be sent to the requester(s) via return e-mail.

The following personal information must be e-mailed to the DFO by the date and time above:

- Name(s) of attendee(s),
- Title(s),
- Organization,
- E-mail address(es), and
- Telephone number(s).

### VIII. Security, Building, and Parking Guidelines

The following are the security, building, and parking guidelines:

- Persons attending the meeting—including presenters—must be registered and on the attendance list by the prescribed date.
- Individuals who are not registered in advance will not be permitted to enter the building and will be unable to attend the meeting.
- Attendees must present photographic identification to the Federal Protective Service or Guard Service personnel before entering the building.
- Security measures include inspection of vehicles, inside and out, at the entrance to the grounds.
- In addition, all persons entering the building must pass through a metal detector.
- All items brought into CMS—including personal items such as desktops, cell phones, palm pilots—are subject to physical inspection.
- The public may enter the building 30–45 minutes before the meeting convenes each day.

- All visitors must be escorted in areas other than the lower and first-floor levels in the Central Building.
- The main-entrance guards will issue parking permits and instructions upon arrival at the building.

### IX. Special Accommodations

Individuals requiring sign-language interpretation or other special accommodations must send a request for these services to the DFO by 5 p.m. (e.s.t.), Wednesday, February 27, 2008.

**Authority:** Section 1833(t)(9) of the Act (42 U.S.C. 1395l(t)). The Panel is governed by the provisions of Pub. L. 92–463, as amended (5 U.S.C. Appendix 2).

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

Dated: November 20, 2007.

**Kerry Weems,**

*Acting Administrator, Centers for Medicare & Medicaid Services.*

[FR Doc. E7–24265 Filed 12–27–07; 8:45 am]

**BILLING CODE 4120–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[CMS–1490–N]

### Medicare Program; Town Hall Meeting on the Fiscal Year 2009 Applications for New Medical Services and Technologies Add-on Payments Under the Hospital Inpatient Prospective Payment System, February 21, 2008

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

**ACTION:** Notice of meeting.

**SUMMARY:** This notice announces a Town Hall meeting in accordance with section 503 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) to discuss fiscal year (FY) 2009 applications for add-on payments for new medical services and technologies under the hospital inpatient prospective payment system (IPPS). Interested parties are invited to this meeting to present their comments, recommendations, and data regarding whether the FY 2009 new medical services and technologies applications meet the substantial clinical improvement criterion.

**DATES:** *Meeting Date:* The Town Hall meeting announced in this notice will be held on Thursday, February 21, 2008 at 1:30 p.m., e.s.t. and check-in will begin at 1 p.m. e.s.t.

**Deadline for Registration of Presenters of the Town Hall Meeting:** All presenters for the Town Hall Meeting, whether attending in person or by phone, must register and submit their agenda item(s) by February 7, 2008.

**Deadline for Submission of Comments on the Town Hall Meeting:** Written comments for discussion at the Town Hall Meeting must be received by February 7, 2008. All other written comments on whether the service or technology represents a substantial clinical improvement must be received by March 10, 2008 for consideration before publication of the FY 2009 IPPS proposed rule.

**Deadline for Registration of All Other Participants and Submitting Requests for Special Accommodations:** All other participants must register by February 14, 2008. Requests for special accommodations must be received no later than 5 p.m., e.s.t. on February 14, 2008.

**ADDRESSES: Meeting Location:** The Town Hall meeting will be held in the main Auditorium in the central building of the Centers for Medicare and Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244-1850.

**Registration and Special Accommodations:** Individuals wishing to participate in the meeting must register by following the on-line registration instructions located in section III of this notice or by contacting staff listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice. Individuals who need special accommodations should contact staff listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice.

Registration information and special accommodation requests may also be mailed to the address listed in the **ADDRESSES** section of this notice.

**Submission of Agenda Item(s) or Written Comments:** Each presenter must submit an agenda item(s) regarding whether a FY 2009 application meets the substantial clinical improvement criterion. Agenda items or written comments, questions, or other statements must not exceed three single-spaced typed pages and must be sent to: Division of Acute Care, New Technology Team, Mailstop C4-07-08, Centers for Medicare and Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244-1850, Attention: Tiffany Swygert or Michael Treitel.

Agenda items or written comments may also be sent via e-mail to [newtech@cms.hhs.gov](mailto:newtech@cms.hhs.gov).

**FOR FURTHER INFORMATION CONTACT:** Tiffany Swygert, (410) 786-4642,

[tiffany.swygert@cms.hhs.gov](mailto:tiffany.swygert@cms.hhs.gov), or Michael Treitel, (410) 786-4552, [michael.treitel@cms.hhs.gov](mailto:michael.treitel@cms.hhs.gov) or you may forward regular mail to the address listed in the **ADDRESSES** section of this notice.

#### **SUPPLEMENTARY INFORMATION:**

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

Sections 1886(d)(5)(K) and (L) of the Social Security Act (the Act) require the Secretary to establish a process of identifying and ensuring adequate payments to acute inpatient hospitals for new medical services and technologies under Medicare. Effective for discharges beginning on or after October 1, 2001, section 1886(d)(5)(K)(i) required the Secretary to establish (after notice and opportunity for public comment) a mechanism to recognize the costs of new services and technologies under the inpatient hospital prospective payment system (IPPS). In addition, section 1886(d)(5)(K)(vi) of the Act specifies that a medical service or technology will be considered "new" if it meets criteria established by the Secretary (after notice and opportunity for public comment). (See the FY 2002 proposed rule (66 FR 22693, May 4, 2001) and the final rule (66 FR 46912, September 7, 2001) for a more detailed discussion.)

In the September 7, 2001 final rule (66 FR 46914), we noted that we evaluate a request for special payment for a new medical service or technology against the following criteria in order to determine if the new technology meets the substantial clinical improvement requirement:

- The device offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments.
- The device offers the ability to diagnose a medical condition in a patient population where that medical condition is currently undetectable or offers the ability to diagnose a medical condition earlier in a patient population than allowed by currently available methods. There must also be evidence that use of the device to make a diagnosis affects the management of the patient.

- Use of the device significantly improves clinical outcomes for a patient population as compared to currently available treatments. Some examples of outcomes that are frequently evaluated in studies of medical devices are the following:

- ++ Reduced mortality rate with use of the device.
- ++ Reduced rate of device-related complications.

- ++ Decreased rate of subsequent diagnostic or therapeutic interventions (for example, due to reduced rate of recurrence of the disease process).

- ++ Decreased number of future hospitalizations or physician visits.

- ++ More rapid beneficial resolution of the disease process treatment because of the use of the device.

- ++ Decreased pain, bleeding, or other quantifiable symptoms.

- ++ Reduced recovery time.

In addition, we indicated that the requester is required to submit evidence that the technology meets one or more of these criteria.

Section 503 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) revised the process for evaluating new medical services and technology applications by requiring the Secretary to do the following:

- Provide for public input regarding whether a new service or technology represents an advance in medical technology that substantially improves the diagnosis or treatment of Medicare beneficiaries before publication of a proposed rule.

- Make public and periodically update a list of all the services and technologies for which an application is pending.

- Accept comments, recommendations, and data from the public regarding whether the service or technology represents a substantial improvement.

- Provide for a meeting at which organizations representing hospitals, physicians, manufacturers and any other interested party may present comments, recommendations, and data to the clinical staff of CMS whether the service or technology represents a substantial improvement before publication of a proposed rule.

The opinions and alternatives provided during this meeting will assist us as we evaluate the new medical services and technology applications for FY 2009. In addition, they will help us to evaluate our policy on the IPPS new technology add-on payment process before the publication of the FY 2009 IPPS proposed rule.

##### **II. Meeting Format**

As noted in section I. of this notice, we are required to provide for a meeting at which organizations representing hospitals, physicians, manufacturers and any other interested party may present comments, recommendations, and data to the clinical staff of CMS concerning whether the service or technology represents a substantial improvement. This meeting will allow

for a discussion of the substantial clinical improvement criteria on each of the FY 2009 new medical services and technology add-on payment applications. Information regarding the applications can be found on our Web site at [http://www.cms.hhs.gov/AcuteInpatientPPS/08\\_newtech.asp#TopOfPage](http://www.cms.hhs.gov/AcuteInpatientPPS/08_newtech.asp#TopOfPage).

The majority of the meeting will be reserved for presentations of comments, recommendations, and data from registered presenters. The time for each presenter's comments will be approximately 10 to 15 minutes and will be based on the number of registered presenters. Presenters will be scheduled to speak in the order in which they register and grouped by new technology applicant. Therefore, individuals who would like to present must register and submit their agenda item(s) to the address specified in the **ADDRESSES** section of this notice by the date specified in the **DATES** section of this notice. Comments from participants will be heard after scheduled statements if time permits. Once the agenda is completed, it will be posted on the CMS IPPS Web site at [http://www.cms.hhs.gov/AcuteInpatientPPS/08\\_newtech.asp#TopOfPage](http://www.cms.hhs.gov/AcuteInpatientPPS/08_newtech.asp#TopOfPage).

For presenters or participants unable to attend the CMS for the meeting, an open toll-free phone line, (888) 970-4128, is available. Persons who call in will be asked for the conference code by the conference operator. The conference code is "New Tech."

In addition, written comments will also 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. Written comments may also be submitted after the meeting. If the comments are to be considered before the publication of the proposed rule, the comments must be received at the address specified in the **ADDRESSES** section of this notice by the date specified in the **DATES** section of this notice.

### III. Registration Instructions

The Division of Acute Care in CMS is coordinating the meeting registration for the Town Hall Meeting. While there is no registration fee, individuals must register to attend the Town Hall Meeting.

Registration may be completed on-line at the following Web address: [http://www.cms.hhs.gov/AcuteInpatientPPS/08\\_newtech.asp#TopOfPage](http://www.cms.hhs.gov/AcuteInpatientPPS/08_newtech.asp#TopOfPage). Select the link at the bottom of the page "New Technology Town Hall Meeting" to

complete the on-line registration. After completing the registration, on-line registrants should print the confirmation page and bring it with them to the meeting.

If you are unable to register on-line, you may register by sending an email to the contacts listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice. Please include your name, address, telephone number, email address and fax number. If seating capacity has been reached, you will be notified that the meeting has reached capacity.

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

Because this meeting will be located on Federal property, for security reasons, any persons wishing to attend this meeting must register by close of business by the date listed in the **DATES** section of this notice. Please allow sufficient time to go through the security checkpoints. It is suggested that you arrive at 7500 Security Boulevard no later than 1 p.m., e.s.t. so that you will be able to arrive promptly at the meeting by 1:30 p.m., e.s.t.

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 30 to 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 6, 2007.

**Kerry Weems,**

*Acting Administrator, Centers for Medicare and Medicaid Services.*

[FR Doc. E7-24267 Filed 12-27-07; 8:45 am]

**BILLING CODE 4120-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

#### Statement of Organization, Functions, and Delegations of Authority

Part F of the Statement of Organization, Functions, and Delegations of Authority for the Department of Health and Human Services, Centers for Medicare & Medicaid Services (CMS), (**Federal Register**, Vol. 72, No. 123, pp. 35246–35247, dated Wednesday, June 27, 2007) is amended to reflect the abolishment of the 10 Regional Offices and the establishment of the Consortium for Medicare Health Plans Operations, the Consortium for Financial Management and Fee for Service Operations, the Consortium for Medicaid and Children's Health Operations, and the Consortium for Quality Improvement and Survey and Certification Operations.

Part F is described below:

• Section F.10. (Organization) reads as follows:

1. Office of External Affairs (FAC)
2. Center for Beneficiary Choices (FAE)
3. Office of Legislation (FAF)
4. Center for Medicare Management (FAH)
5. Office of Equal Opportunity and Civil Rights (FAJ)
6. Office of Research, Development, and Information (FAK)
7. Office of Clinical Standards and Quality (FAM)
8. Office of the Actuary (FAN)
9. Center for Medicaid and State Operations (FAS)
10. Consortium for Medicare Health Plans Operations (FAU)
11. Consortium for Financial Management and Fee for Service Operations (FAV)
12. Consortium for Medicaid and Children's Health Operations (FAW)
13. Consortium for Quality Improvement and Survey and Certification Operations (FAX)
14. Office of Operations Management (FAY)