### IV. Oral Presentations

Individuals or organizations wishing to make 5-minute oral presentations must contact the DFO. The DFO must receive hardcopy presentations by 5 p.m. (e.s.t.), on Wednesday, January 26, 2005, in order to be scheduled.

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

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

### V. Presenter and Presentation Criteria

The additional criteria below must be supplied to the DFO by the January 26, 2005 deadline (along with hardcopies of presentations).

- Required personal information regarding presenter(s):
  + Name of presenter(s);
  + Title(s);
  + Organizational affiliation;
  + Address;
  + E-mail address, and
  + Telephone number(s).
- All presentations must contain, at a minimum, the following supporting information and data:
  + Financial relationship(s) of presenter(s), if any, with any company whose products, services, or procedures that are under consideration;
  + Physicians' Current Procedural Terminology (CPT) codes involved;
  + APC(s) affected;
  + Description of the issue(s);
  + Clinical description of the service under discussion (with comparison to other services within the APC);
  + Recommendations and rationale for change;
  + Expected outcome of change; and
  + Potential consequences of not making the change(s).

### VI. Oral Comments

In addition to formal oral presentations, there will be opportunity during the meeting for public oral comments that will be limited to 1 minute for each individual and a total of 5 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 call or e-mail the Panel DFO to register in advance no later than 5 p.m. (e.s.t.), Wednesday, February 9, 2005.

The following information must be e-mailed or telephoned 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

Persons attending the meeting must present photographic identification to the Federal Protective Service or Guard Service personnel before they will be allowed to enter the building.

*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 30–45 minutes prior to the convening of the meeting each day. (Please note that the meeting on Wednesday, February 23, 2005 does not convene until 1 p.m.)

All visitors must be escorted in areas other than the lower and first-floor levels in the Central Building.

Parking permits and instructions are issued upon arrival by the guards at the main entrance.

### 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 9, 2005.

**Authority:** Section 1833(t) of the Act (42 U.S.C. 1395l(t), as amended by section 201(h) of the BBRA of 1999 (Pub. L. 106–113). 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: December 9, 2004.

**Mark B. McClellan,**

*Administrator, Centers for Medicare & Medicaid Services.*

[FR Doc. 04–28151 Filed 12–29–04; 8:45 am]

**BILLING CODE 4120–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

**[CMS–1292–N]**

### Medicare Program; Town Hall Meeting on the Fiscal Year 2006 Applications for New Medical Services and Technologies Add-on Payments Under the Hospital Inpatient Prospective Payment System Scheduled for February 23, 2005

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

**ACTION:** Notice of meeting.

**SUMMARY:** This notice, in accordance with section 503 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), announces a Town Hall meeting to discuss fiscal year (FY) 2006 applications for add-on payments for new medical services and technologies under the hospital inpatient prospective payment system (IPPS). Applicants, supporters, opponents, and other interested parties are invited to this meeting to present their comments, recommendations, and data regarding whether the FY 2006 new medical services and technologies applications meet the substantial clinical improvement criteria.

**DATES:** *Meeting Date:* The Town Hall meeting announced in this notice will be held on Wednesday, February 23, 2005 at 9 a.m. and check-in will begin at 8:30 a.m. EST.

*Registration Deadline for Presenters:* All presenters, whether attending in person or by phone, must register and submit their agenda item(s) by February 15, 2005.

*Registration Deadline for All Other Participants:* All other participants must register by February 17, 2005.

*Comment Deadline:* Written comments for discussion at the meeting must be received by February 15, 2005. All other written comments for consideration before publication of the IPPS proposed rule must be received by March 15, 2005.

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

*Agenda Items or Written Comments:* Agenda items and written comments regarding whether a FY 2006 application meets the substantial clinical improvement criterion may be sent by mail, fax, or electronically.

Agenda items must be received by February 15, 2005. We will accept written questions or other statements, not to exceed three single-spaced, typed pages that are received by March 15, 2005. Send written comments, questions, or other statements to—

Division of Acute Care, Mail stop C4–07–05, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244–1850. Attention: Meredith Walz or Michael Treitel, Fax: (410) 786–0169. E-mail: *newtech@cms.hhs.gov*

**FOR FURTHER INFORMATION CONTACT:** Meredith Walz, (410) 786–9421, *mwalz@cms.hhs.gov;* Michael Treitel, (410) 786–4552, *mtreitel@cms.hhs.gov.*

**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 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 May 4, 2001 proposed rule (66 FR 22693) and the September 7, 2001 final rule (66 FR 46912) 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 symptom.

++ 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:

- Before publication of a proposed rule, 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.
- 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.
- Before publication of a proposed rule, 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.

The opinions and alternatives provided during this meeting will assist us as we evaluate the new medical services and technology applications for FY 2006. 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 2006 IPPS proposed rule.

## II. Meeting Format

This meeting will allow for a discussion of the substantial clinical improvement criteria for each of the FY 2006 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/providers/hipps/newtech.asp.* In addition, we believe some of the issues raised in public comments during the FY 2005 rulemaking cycle warrant further investigation to determine whether our definition of ''substantial clinical improvement'' should be revised (69 FR 49001 through 49006). We also believe that the definition of ''substantial similarity'' may need to be revisited. (*See* the IPPS FY 2005 final rule (69 FR 49011) and the September 7, 2001 (66 FR 46915) final rule). Although we do not expect to have a general discussion of these topics during the timeframe of the town hall meeting, we are inviting comment as part of this town hall meeting notice. So that we can consider these comments in development of our proposed rule, we will accept comments through the deadline for other written comments specified in the **DATES** section of this notice. We will also solicit comments during the rulemaking process.

The majority of the meeting will be reserved for comments, recommendations, and data from registered presenters. The time for each presenter's comments will be approximately 10 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 want to be presenters must register and submit their agenda items by Tuesday, February 15, 2005. Once the agenda is completed, it will be posted on the IPPS Web site at *http://www.cms.hhs.gov/providers/hipps/newtech.asp.* Comments from participants will be heard (time permitting) after the completion of the presentations.

For presenters or participants that cannot come to CMS for the meeting, an open toll-free phone line, (877) 357–7851, has been made available. If you are calling in, you will be prompted to enter the conference identification number, 2940111, or the name of the meeting. In addition, written comments will also be accepted and presented at the meeting if they are received by February 15, 2005. 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 by March 15, 2005.

### III. Registration Instructions

The Division of Acute Care is coordinating meeting registration. While there is no registration fee, individuals must register to attend. Individuals may present their comments either in person or by phone. These individuals must register and submit their agenda item(s) by February 15, 2005. All other participants must register by February 17, 2005. All registrants will receive confirmation with instructions for arrival at the CMS complex (persons who register on-line will receive this confirmation upon completion of the registration process and should print the confirmation and bring it with them to the meeting). Because of limited meeting space and our desire to maintain an accurate count of registrants that plan to come to CMS, we prefer that these persons register on-line. In addition, we would prefer that registrants that plan to participate by phone, register by phone or fax.

*On-line Registration:* Registration may be completed on-line at the following web address: *http://www.cms.hhs.gov/providers/hipps/newtech.asp.* Select the link ''Register to Attend the New Technology Town Hall Meeting'' and then select ''New Technology Town Hall Meeting'' from the drop down menu and follow the instructions. After completing registration, on-line registrants should print the confirmation page and bring it with them to the meeting.

*Registration by Phone or Fax:* Registration may be completed by contacting Meredith Walz at (410) 786–9421 or Michael Treitel at (410) 786–4552. Registration may also be completed by fax to the attention of Meredith Walz or Michael Treitel at (410) 786–0169. If registration is completed by phone or fax, please provide your name, address, telephone number, and, if available, e-mail address and fax number.

### IV. Security Information

Since this meeting will be held in a Federal government building, Federal security measures are applicable. In planning your arrival time, we recommend allowing additional time to clear security. In order to gain access to the building and grounds, participants must bring a government-issued photo identification and a copy of their confirmation of registration for the meeting. Access may be denied to persons without proper identification. For security reasons, no additional meeting registrations will be accepted after the close of the registration period.

Security measures also 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 to CMS, whether personal or for the purpose of demonstration or to support a presentation, are subject to inspection. Laptops and other computer equipment must be registered with the security desk upon entry. CMS 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 presentation. Participants should e-mail presentations to CMS prior to the meeting to ensure that CMS has a back-up copy in the event of computer problems or lack of software or memory card compatibility. Please note that CMS headquarters is a smoke-free facility.

**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 16, 2004.

**Mark B. McClellan,**

*Administrator, Centers for Medicare & Medicaid Services.*

[FR Doc. 04–28153 Filed 12–29–04; 8:45 am]

**BILLING CODE 4120–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 2004N–0545]**

### Nonclinical and Clinical Datasets; Notice of Pilot Project

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA), Center for Biologics Evaluation and Research (CBER), is seeking volunteers to participate in a pilot project involving the evaluation of various analysis tools to facilitate the use of electronic datasets for analysis of animal and human data submitted to FDA by applicants of biologics license applications (BLAs). These analysis tools will allow a reviewer to more efficiently capture and evaluate nonclinical and clinical datasets submitted in electronic format.

**DATES:** Submit written requests to participate in the pilot project by February 28, 2005. Comments on this pilot project may be submitted at any time.

**ADDRESSES:** Submit written requests to participate and comments regarding the pilot project to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments.*

**FOR FURTHER INFORMATION CONTACT:** Richard Diamond, Center for Biologics Evaluation and Research (HFM–6), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–0372.

**SUPPLEMENTARY INFORMATION:**

### I. Background

Under current FDA regulations (21 CFR 601.2), applicants must provide nonclinical and clinical data in BLAs. CBER provided recommendations for the electronic submission of BLAs, as well as new drug applications (NDAs), in the ''Guidance for Industry: Providing Regulatory Submissions to the Center for Biologics Evaluation and Research (CBER) in Electronic Format—Biologics Marketing Applications'' dated November 1999. A joint CBER and Center for Drug Evaluation and Research (CDER) document entitled ''Guidance for Industry: Providing Regulatory Submissions in Electronic Format—General Considerations'' dated January 1999 provided recommendations for the file formats for nonclinical and clinical datasets.

FDA announced on July 21, 2004, a standard format, called the Study Data Tabulation Model (SDTM) developed by the Clinical Data Interchange Standards Consortium (CDISC), that sponsors of human drug clinical trials can use to submit data to the agency. It is expected that this step will lead to greater efficiencies in clinical research and FDA reviews of NDAs and BLAs. CDISC is an open, multidisciplinary, nonprofit organization including members from pharmaceutical companies, biotechnology companies, contract research organizations, and software vendors. CDISC committed to the development of industry standards to support the electronic acquisition, exchange, submission and archiving of clinical trials data and metadata for medical and biopharmaceutical product development. CDISC is currently facilitating the work on similar standards for nonclinical and clinical datasets. Where possible, the standards developed for clinical datasets and metadata should be used in the development of standardized