DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–1382–N]

Medicare Program; Town Hall Meeting on the Fiscal Year 2008 Applications for New Medical Services and Technologies and Informational Workshop on Payment for New Technologies Under the Inpatient Prospective Payment System (IPPS) and the Outpatient Prospective Payment System (OPPS), Processes for Diagnosis-Related Group (DRG) Assignment; and Requesting New International Classification of Diseases, 9th Revision, Clinical Modification (ICD–9–CM) Codes Under the IPPS—February 22, 2007 (CMS–1382–N)

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

ACTION: Notice of meetings.

SUMMARY: This notice announces a Town Hall Meeting to discuss fiscal year (FY) 2008 applications for add-on payments for new medical services and technologies under the Inpatient Prospective Payment System (IPPS). Interested parties are invited to this meeting to present their comments, recommendations, and data regarding whether the FY 2008 new medical services and technologies applications meet the substantial clinical improvement criteria. Additionally, we will hold an Informational Workshop for all interested parties on the application process and criteria for new medical services and technologies add-on payments under the IPPS, the transitional pass-through payment and new technology ambulatory payment classification (APC) assignment application processes under the Outpatient Prospective Payment System (OPPS) and the processes of Diagnosis-Related Group (DRG) assignment and requesting new ICD–9 codes under the IPPS.

DATES: *Meeting and Informational Workshop Date:* Both the Town Hall Meeting and Informational Workshop will be held on Thursday, February 22, 2007. The Informational Workshop will begin at 9 a.m. e.s.t. The Town Hall Meeting will begin at 1:30 p.m. e.s.t.

Registration Deadline for All Participants for the Town Hall Meeting and the Informational Workshop: All participants must register by February 15, 2007.

Registration Deadline for 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 6, 2007.

Comment Deadline for the Town Hall Meeting: Written comments for discussion at the Town Hall Meeting must be received by February 6, 2007. All other written comments on whether the service or technology represents a substantial clinical improvement must be received by March 9, 2007 for consideration before publication of the FY 2008 IPPS proposed rule.

Agenda Item(s) Deadline for the Town Hall Meeting: Agenda items for the Town Hall Meeting must be received by February 6, 2007.

ADDRESSES: *Meeting Location:* The Information Workshop and 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.

Registration and Special Accommodations: Individuals wishing to participate or who need special accommodations or both must register by completing the on-line registration located at *newtech@cms.hhs.gov* or by contacting Tiffany Swygert (410) 786–4642 or Michael Treitel at (410) 786–4552. Registration information may also be mailed to the New Technology Team, Division of Acute Care, Center for Medicare Management, Centers for Medicare & Medicaid Services, Mail stop C4–08–06, 7500 Security Boulevard, Baltimore, MD 21244–1850 or faxed to the New Technology Team at (410) 786–0169.

Written Comments for the Town Hall Meeting: We will accept written questions or other statements, not to exceed three single-spaced, typed pages that are received by the date specified in the ''**DATES**'' section. Written comments may be sent electronically to *newtech@cms.hhs.gov* (please make the subject of the e-mail new technology comments); sent via mail to the New Technology Team, Division of Acute Care, Center for Medicare Management, Centers for Medicare & Medicaid Services, Mail stop C4–08–06, 7500 Security Boulevard, Baltimore, MD 21244–1850; or sent via fax to the New Technology Team at (410) 786–0169.

Agenda Item(s) for the Town Hall Meeting: Agenda items for the Town Hall Meeting regarding whether a FY 2008 application meets the substantial clinical improvement criteria may be sent by mail, fax, or electronically. Agenda items must be received by the date specified in the ''**DATES**'' section. Agenda item(s) may be sent electronically to *newtech@cms.hhs.gov* (please make the subject of the e-mail new technology agenda item(s)); sent via mail to the attention of the New Technology Team, Division of Acute Care, Center for Medicare Management, Centers for Medicare & Medicaid Services, Mail stop C4–08–06, 7500 Security Boulevard, Baltimore, MD 21244–1850; or faxed to the New Technology Team at (410) 786–0169.

FOR FURTHER INFORMATION CONTACT: Tiffany Swygert, (410) 786–4642, *tiffany.swygert@cms.hhs.gov*. Michael Treitel, (410) 786–4552, *michael.treitel@cms.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

Sections 1886(d)(5)(K) and (L) of 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 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 IPPS proposed (66 FR 22693, May 4, 2001) and final rules (66 FR 46912, September 7, 2001) for a more detailed discussion.) In addition, we have further discussed our application of the criteria in the IPPS proposed and final rules for FYs 2003, 2004, 2005, 2006 and 2007. (See 67 FR 31427, May 9, 2002; 67 FR 50009, August 1, 2002; 68 FR 27184, May 19, 2003; 68 FR 45385, August 1, 2003; 69 FR 28236, May 18, 2004; 69 FR 49000, August 11, 2004; 70 FR 23353, May 5, 2005; 70 FR 47341, August 12, 2005; and 71 FR 47994, August 18, 2006 respectively).

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.

• 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 parties may present comments, recommendations, and data to the clinical staff of CMS whether the service or technology represents a substantial improvement.

The opinions and alternatives provided during this meeting will assist us as we evaluate the new medical services and technology applications for FY 2008. In addition, they will help us to evaluate our policy on the IPPS new technology add-on payment process.

We note that for applications for add-on payments for new technologies for FY 2008, we initially set a deadline of October 15, 2006 for an applicant to submit a formal request, including a full description of the clinical applications of the medical service, evidence that the new medical service or technology represents a substantial clinical improvement, and a significant sample of data demonstrating that the medical service or technology meets the high-cost threshold. As announced on our Web site, *http://www.cms.hhs.gov/AcuteInpatientPPS/08_newtech.asp*, we extended the October 15, 2006 deadline to December 30, 2006. Applicants must also submit a complete database demonstrating that the medical service or technology meets the high-cost threshold by December 30, 2006.

II. Informational Workshop and Town Hall Meeting Format

In addition to, the statutorily-required Town Hall Meeting on whether an IPPS new technology application meets the substantial clinical improvement criteria, we will be holding an Informational Workshop on applying for special payment for new medical services and technologies under the IPPS and OPPS. Specifically, for new technology add-on payments under the IPPS, we will discuss each criterion in detail along with other information that will be helpful in guiding an applicant through the new technology add-on payment process. We will also discuss the processes of DRG assignment and requesting new ICD–9 codes under the IPPS. (Information on DRGs can be found on the IPPS Web site at *http://www.cms.hhs.gov/AcuteInpatientPPS/01_overview.asp#TopOfPage* and information on ICD–9–CM coding can be found on our Web site at *http://www.cms.hhs.gov/ICD9ProviderDiagnosticCodes/02_newrevisedcodes.asp*.)

In addition, to facilitate the public's knowledge of OPPS new technology application processes, the Informational Workshop will also include information on several processes for applying for special payment under the OPPS. One topic concerns the process and criteria for applying for a new category of devices for pass-through payment. Interested parties may apply for a new device category, in accordance with section 1833(t)(6) of the Act. As background information, we have posted application and process background information on our Web site at *http://www.cms.hhs.gov/HospitalOutpatientPPS/Downloads/catapp.pdf*. Furthermore, under section 1833(t)(6) of the Act interested parties may also apply for transitional pass-through payment for certain new drugs, biological or radiopharmaceutical agents. As background information, we have posted application and process background information on our Web site, *http://www.cms.hhs.gov/HospitalOutpatientPPS/Downloads/drugapplication.pdf*. Finally, we provide the opportunity for the public to apply for new services to be placed in new technology APC groups in the OPPS, in accordance with our criteria and discussion in our November 30, 2001 final rule (66 FR 59897). We plan to discuss all three of these OPPS application processes at the Informational Workshop that will be held on February 22, 2007.

The Informational Workshop is open to all interested parties including organizations representing hospitals, physicians and manufacturers. We encourage all interested parties to attend, especially those who are not familiar with these processes. Individuals who want to attend this Informational Workshop must register by the date specified in the ''**DATES**'' section of this notice. Registration information is available below.

For participants who cannot come to CMS for the meeting, an open toll-free phone line, (888) 577–8990, has been made available. If you are calling in, the operator will ask you for the conference code. The conference code is ''New Tech.''

We are required to provide for a Town 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 for which an application has been submitted for new technology add-on treatment under the IPPS represents a substantial improvement. This meeting will allow for a discussion of the substantial clinical improvement criteria to each of the FY 2008 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.*

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 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 want to be presenters must register and submit their agenda item(s) by the date specified in the ''**DATES**'' section. Once the agenda is completed, it will be posted on the IPPS Web site at *http://www.cms.hhs.gov/AcuteInpatientPPS/08_newtech.asp#TopOfPage*. Comments from participants will be heard (time permitting) after the completion of the presentations.

For presenters or participants who cannot come to CMS for the meeting, an open toll-free phone line, (888) 577–8990, has been made available. If you are calling in, the operator will ask you for the conference code. The conference code is ''New Tech.'' In addition, written comments will also be accepted and presented at the meeting if they are received by the date specified in the ''**DATES**'' section. 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 the date specified in the ''**DATES**'' section.

III. Registration Instructions

The Division of Acute Care in CMS is coordinating the meeting registration for both the Informational Workshop and Town Hall Meeting. While there is no registration fee, individuals must register to attend the Town Hall Meeting on substantial clinical improvement and for the Informational Workshop (two separate registrations).

Individuals may present their comments for the Town Hall Meeting either in person or by phone. These individuals must register and submit their agenda item(s) by the date specified in the ''**DATES**'' section. All other participants for the Town Hall Meeting must register by the date specified in the ''**DATES**'' section.

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 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 who plan to come to CMS, we prefer that these persons register on-line. In addition, we would prefer that registrants who plan to participate by phone register by phone or fax.

A. On-line Registration

Registration may be completed on-line at the following Web address: *http://www.cms.hhs.gov/AcuteInpatientPPS/08_newtech.asp#TopOfPage*. Select the link ''Register to Attend the New Technology Town Hall Meeting'' and/or ''Register to attend the New Technology Informational Workshop.'' After completing the registration, on-line registrants should print the confirmation page and bring it with them to the meeting(s).

B. Registration by Phone, Fax or Mail

Registration for both meetings may also be completed by contacting Tiffany Swygert at (410) 786–4642 or Michael Treitel at (410) 786–4552. Registration may also be completed by fax to the attention of the New Technology Team at (410) 786–0169. If registration is completed by phone fax or mail, please provide your name, address, and telephone number, meetings, which you are registering for Town Hall Meeting and/or Informational Workshop and, if available, e-mail address and fax number. Please send mail in registration to address specified in the **''ADDRESSES''** section.

IV. Security Information

Because this meeting will be located on Federal property, for security reasons, any persons wishing to attend this Informational Workshop and Town Meeting must register by close of business on February 15, 2007. Individuals who have not registered in advance will not be allowed to enter the building to attend the meeting. Seating capacity is limited to the first 250 registrants.

The on-site check-in for visitors will begin at 8:30 a.m. Please allow sufficient time to go through the security checkpoints. It is suggested that you arrive at central building by 8:30 a.m. so that you will have enough time to check-in before the session begins. Individuals that will only attend the Town Hall Meeting must check-in at 1 p.m. Security measures will include inspection of vehicles, inside and out, at the entrance to the grounds. In addition, all persons entering the building must check in by name, provide a government-issued identification, and pass through a metal detector. All items brought to CMS, 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. Participants attending the Informational Workshop will be able to attend the Town Hall meeting without an additional check-in unless they exit the building. In this case, a participant will need to repeat the security check-in and procedures.

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: November 30, 2006.

Leslie V. Norwalk,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 06–9838 Filed 12–20–06; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

AGENCY: Administration for Native Americans (ANA), HHS.

ACTION: Notice of Public Comment on the Proposed Adoption of ANA Program Policies and Procedures; Correction

SUMMARY: Pursuant to section 814 of the Native American Programs Act of 1974 (the Act) 42 U.S.C. 2992b–1, ANA herein describes its proposed interpretive rules, statements of general policy and rules of agency procedure or practice in relation to the Social and Economic Development Strategies (hereinafter referred to as SEDS), Native Language Preservation and Maintenance (hereinafter referred to as Native Language), Environmental Regulatory Enhancement (hereinafter referred to as Environmental), Environmental Mitigation (hereinafter referred to as Mitigation), Improving the Well-Being of Children—Native American Health Marriage Initiative (hereinafter referred to as Healthy Marriage) programs and any Special Initiatives. Under the statute, ANA is required to provide members of the public an opportunity to comment on proposed changes in interpretive rules, statements of general policy and rules of agency procedure or practice and to give notice of the final adoption of such changes at least thirty (30) days before the changes become effective. This Notice also provides additional information about ANA's plan for administering the programs.

FOR FURTHER INFORMATION CONTACT: Sheila K. Cooper, Director of Program Operations, toll-free at (877) 922–9262.

In the **Federal Register** Notice published on November 21, 2006 (Vol.