

ACTION: Notice of meeting.

SUMMARY: This notice announces a Town Hall meeting to solicit input from the public on the proposed use of a Skilled Nursing Facility Advance Beneficiary Notice (SNFABN). Interested persons are invited to comment on the SNFABN Notice (CMS-10055 form) collection instrument, the associated burden or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the associated time burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden. The meeting is open to the public, but attendance is limited to space available.

DATES: The Town Hall meeting will be held on Wednesday, March 16, 2004, from 1 p.m. to 4 p.m., e.s.t.

ADDRESSES: The Town Hall meeting will be held in the Multi-Purpose Room at the Centers for Medicare & Medicaid Services (CMS), 7500 Security Boulevard, Baltimore, Maryland 21244.

FOR FURTHER INFORMATION CONTACT: E. Joan Collins by phone at (410) 786-4618, via e-mail at ecollins1@cms.hhs.gov, or by fax at (410) 786-9963.

SUPPLEMENTARY INFORMATION:

I. Background

The Skilled Nursing Facility Advance Beneficiary Notice (SNFABN) replaces the Skilled Nursing Facility (SNF) Notices Of Non-Coverage previously used for notification purposes. SNFs must also meet the advance beneficiary notice (ABN) Standards in § 40.3 of chapter 30, Financial Liability Protections, of the IOM Pub. 100-4 at http://www.cms.hhs.gov/manuals/104_claims/clm104c30.pdf in completing and delivering SNFABNs.

A SNFABN is a CMS-approved written notice that the SNF gives to a Medicare beneficiary, or to their authorized representative, before extended care services or items are furnished, reduced, or terminated when the SNF, the Utilization Review entity, the Quality Improvement Organization, or the Medicare contractor believes that Medicare will not pay for, or will not continue to pay for, extended care services that the SNF furnishes and that a physician ordered on the basis of one of the following statutory exclusions:

- Not reasonable and necessary ("medical necessity") for the diagnosis

or treatment of illness, injury, or to improve the functioning of a malformed body member—section 1862(a)(1) of the Social Security Act (the Act); or

- Custodial care ("not a covered level of care")—section 1862(a)(9) of the Act.
- These exclusions provide the only statutory authority for application of the limitation on liability (LOL) provision at section 1879 of the Act to denied SNF claims.

The SNFABN (CMS-10055 form) is for use with SNF Prospective Payment System services. This form satisfies the requirements under LOL for advance beneficiary notice and the beneficiary's agreement to pay. The use of any other notices or of modified SNFABNs may be ineffective in protecting users from liability. The SNFABN must be prepared with an original and at least one patient copy, a SNF copy containing the signature of the patient or authorized representative, an attending physician copy, and (when necessary) a Medicare contractor copy. SNFs may produce SNFABNs using self-carboning paper and other methods of producing copies, including photocopying, printing, and electronic generation, but they must conform to the Form CMS-10055 design.

This Town Hall meeting is intended to provide a forum for all interested individuals to comment on and discuss the SNFABN. The SNFABN form and instructions may be reviewed prior to the public meeting by accessing <http://www.cms.hhs.gov/medicare/bni> on the Internet. This information is available for immediate review.

II. Meeting Format

Registered persons from the public may discuss and make individual recommendations concerning the Skilled Nursing Facility Advance Beneficiary Notice. Individuals who wish to make formal presentations must include that information when registering. Presentations must be brief, and three written copies must be submitted to accompany the oral presentation. Presenters may also make copies available for approximately 70 meeting participants.

III. Registration Instructions

Representatives of providers and suppliers furnishing skilled nursing facility services, health care consumer advocacy groups, and other members of the public who wish to participate in the public meeting are asked to notify us, in advance, of their interest in attending. Interested persons may register by providing notification to E. Joan Collins either by telephone at (410) 786-4618, fax at (410) 786-9963, or by

e-mail at ecollins1@cms.hhs.gov. Please submit the following information when registering: name, company name, address, telephone number, and e-mail address and an indication of whether you wish to make a formal presentation.

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 on March 10, 2004. In order to gain access to the building and grounds, participants must show to the Federal Protective Service or guard service personnel government-issued photo identification and a copy of their registration confirmation. 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 be held from 12 noon until 1 p.m., followed by opening remarks. Please allow sufficient time to arrive to go through the security checkpoints. It is suggested that you arrive at 7500 Security Boulevard no later than 12 noon so that you will be able to arrive promptly at the meeting by 1 p.m. All items brought to us, whether personal or for the purpose of demonstration or to support a presentation, are subject to inspection.

Individuals requiring sign language interpretation or other special accommodations must provide that information upon registering for the meeting.

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

Dated: February 12, 2004.

Dennis G. Smith,

Acting Administrator, Centers for Medicare and Medicaid Services.

[FR Doc. 04-4275 Filed 2-26-04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-1268-N]

Medicare Program; Town Hall Meeting on the Fiscal Year 2005 Applications for New Medical Services and Technologies Add-On Payments Under the Hospital Inpatient Prospective Payment System

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) 2005 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 2005 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 Monday, March 15, 2004 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 March 8, 2004.

Registration Deadline for All Other Participants: All other participants must register by March 10, 2004.

Comment Deadline: Written comments for discussion at the meeting must be received by March 8, 2004. All other written comments for consideration before publication of the IPPS proposed rule must be received by March 26, 2004.

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

Agenda Item(s) or Written Comments: Agenda item(s) and written comments regarding whether a FY 2005 application(s) meet the substantial clinical improvement criterion may be sent by mail, fax, or electronically. Agenda item(s) must be received by March 8, 2004. We will accept written questions or other statements, not to exceed three single-spaced, typed pages that are received by March 26, 2004. 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, Fax: (410) 786-0169, 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 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 noted that we require the requester to submit evidence that the technology meets one or more of these criteria.

Section 503 of the 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.

- 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 2005. 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 2005 IPPS proposed rule.

II. Meeting Format

This meeting will allow a discussion of the substantial clinical improvement criteria for each of the FY 2005 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/default.asp>. 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. Therefore, individuals who want to be presenters must register and submit their agenda item(s) by Monday, March 8, 2004. Once the agenda is completed, it will be posted on the IPPS Web site at <http://www.cms.hhs.gov/providers/hipps/default.asp>. Comments from all 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 phone line, 1-877 357-7851, has been made available. If you are calling in, you will be prompted to enter the conference identification number, 5601867, or the name of the meeting. In addition, written comments will also be accepted and presented at the meeting if they are received by March 8, 2004. 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 26, 2004.

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 March 8, 2004. All other participants must register by March 10, 2004. All registrants will receive confirmation with instructions for arrival at the CMS complex. 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/default.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 your confirmation of registration for the meeting. Access may be denied to persons without proper identification.

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. 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.

Authority: Section 503 of Pub. L. 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: February 23, 2004.

Dennis G. Smith,

Acting Administrator, Centers for Medicare and Medicaid Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-2200-N]

Medicare Program; Request for Nominations for the State Pharmaceutical Assistance Transition Commission

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

ACTION: Notice.

SUMMARY: This notice requests nominations for individuals to serve on the State Pharmaceutical Assistance Transition Commission (the Commission). The Commission will develop a proposal for addressing the unique transitional issues facing State pharmaceutical assistance programs and program participants due to the implementation of the voluntary prescription drug benefit program under part D of title XVIII of the Social Security Act. This Commission will be established in accordance with the Federal Advisory Committee Act, 5

U.S.C. appendix 2. We are preparing the charter and will ask the Secretary to establish this Commission.

EFFECTIVE DATE: Nominations will be considered if we receive them at the appropriate address, provided below, no later than 5 p.m. on March 12, 2004, or until the Secretary or designee selects all members of the Commission.

ADDRESSES: Mail or deliver nominations to the following address: Marge Watchhorn, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Mail stop S2-01-16, Baltimore, MD 21244-1850.

FOR FURTHER INFORMATION CONTACT: Marge Watchhorn, (410) 786-4361. Press inquiries are handled through the CMS Press Office at (202) 690-6145.

SUPPLEMENTARY INFORMATION:

I. Background

Section 106 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108-173), enacted on December 8, 2003, grants to the Secretary of the Department of Health and Human Services (the Secretary) the authority to establish a State Pharmaceutical Assistance Transition Commission (the Commission). The Commission's goal is to develop a proposal for addressing the unique transitional issues facing State pharmaceutical assistance programs (SPAPs) and program participants due to the implementation of the voluntary prescription drug benefit program under Part D of title XVIII of the Social Security Act (the Act). An SPAP is a program (other than the Medicaid program) operated by a State (or under contract with a State) that provides financial assistance as of December 8, 2003 to Medicare beneficiaries to purchase prescription drugs. Generally, SPAP participants are low-income Medicare beneficiaries.

II. Composition of the Commission

The Commission must include the following:

1. A representative of each Governor of each State that the Secretary identifies as operating, on a statewide basis, an SPAP that provides for eligibility and benefits that are comparable to, or more generous than, the low-income assistance eligibility and benefits offered under section 1860D-14 of the Act. Nominations under this category must be made by a State Governor or his designee and information must be submitted to demonstrate that the SPAP in the State provides a benefit comparable to, or more generous than, the Medicare benefit under section 1860D-14 of the