Program; No. 93.773 Medicare—Hospital Insurance Program; and No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: August 7, 2008.

Kerry Weems,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. E8–18971 Filed 8–21–08; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–1405–N]

Medicare Program; Medicare Provider Feedback Group Town Hall Meeting—September 22, 2008

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

ACTION: Notice of meeting.

SUMMARY: This notice announces the annual Medicare Provider Feedback Group (MPFG) Town Hall meeting. This meeting is open to all Medicare fee-for-service (FFS) providers and suppliers that participate in the Medicare program, including physicians, hospitals, home health agencies, third-party billers, and interested parties, to present their individual views and opinions on selected FFS Medicare topics. In addition, we will be soliciting input on how we can improve communications to better serve the Medicare providers and suppliers.

DATES: *Meeting Date:* The Town Hall meeting announced in this notice will be held on Monday, September 22, 2008 from 2 p.m. to 4 p.m. EDT.

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

FOR FURTHER INFORMATION CONTACT: Colette Shatto, (410) 786–6932. You may also send inquiries about this meeting via e-mail to *MFG@cms.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Since 2005, CMS has held four Medicare Provider Feedback Group (MPFG) Town Hall meetings. The purpose of these meetings is to capture individual provider and supplier feedback on relevant Fee-For-Service (FFS) Medicare policy and operational issues. These meetings allow us to further advance our efforts to strengthen the Medicare program and enhance our relationship with providers and suppliers. The meetings also provide a venue to allow us to continue a process of communication with individual providers and suppliers through the following year.

II. Meeting Format and Agenda

The meeting will begin with an overview of the goals and objectives of the MPFG efforts to gather feedback from individual Medicare providers and suppliers. This meeting will be held on-site at CMS and by teleconference. The meeting agenda and discussion materials will be available to download by September 19, 2008. These materials can be located at *http://www.cms.hhs.gov/center/provider.asp.*

The feedback provided during this meeting will assist us as we evaluate FFS Medicare policy, operational issues, and CMS' provider and supplier communication activities. Topics to be discussed include, but are not limited to, 5010 (possible next version of HIPAA standards for claims and other transactions), Medicare Administrative Contract Transitions, and Recovery Auditing.

There will be a question and answer session that offers meeting participants an opportunity to provide feedback on how CMS services physicians, providers and suppliers, as well as make suggestions on how this process can be improved. Time for participants to ask questions or provide feedback will be limited according to the number of registered participants; however, written submissions will be accepted. Individuals who wish to provide written feedback should e-mail that feedback to Colette Shatto at *MFG@cms.hhs.gov.* Written feedback will be accepted through September 30, 2008.

Consideration will be given to feedback received on the topics discussed at the meeting, but written responses will not be provided. The meeting is open to the public, but on-site attendance is limited to space available. Registered participants from the meeting will be included in the MPFG and may be contacted throughout the year for follow-up meetings to solicit additional opinions or clarify any issues that may arise from the September 22, 2008 meeting.

III. Registration Instructions

The Division of Provider Relations and Evaluations, Provider Communications Group, Center for Medicare Management is coordinating the meeting registration. While there is no registration fee, individuals, providers, and suppliers must register to participate both on-site and by teleconference. Individuals must complete the on-line registration located at *http://registration.intercall.com/go/cms2.*

The on-line registration system will capture contact information and practice characteristics (for example, names, e-mail addresses, and provider, and supplier types). Registration will be open beginning August 29, 2008 and will close on September 17, 2008. Registration after 5 p.m. EDT on September 17, 2008 will not be accepted.

The on-line registration system will generate a confirmation page to indicate the completion of your registration. Participants should print this page as his or her registration receipt. Teleconference instructions will be issued as part of the confirmation page once participants have registered through the on-line registration instrument. If seating capacity has been reached for on-site participants, notification will be sent that the meeting has reached capacity; however, those wishing to participate may still do so by teleconference.

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 5 p.m. EDT on September 17, 2008. Individuals who have not registered by the registration deadline will not be allowed to enter the building to attend the meeting or attend the meeting by teleconference. Seating capacity is limited to the first 250 registrants.

The on-site check-in for visitors will be held from 12:30 p.m. to 1:30 p.m. EDT. Participants should allow sufficient time to go through the security checkpoints. It is suggested that participants arrive at 7500 Security Boulevard no later than 1:30 p.m. EDT in order to arrive promptly at the meeting by 2 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 pass through a metal detector. All items brought to the building, whether personal or for the purpose of demonstration or to support a presentation, are subject to inspection. In order to gain access to the building, participants will be required to show a government-issued photo identification (for example, driver's license, or

passport), and must be listed on an approved security list before persons are permitted entrance. Persons not registered in advance will not be permitted into the CMS building and will not be permitted to attend the meeting.

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 the purpose of presentation.

Individuals requiring sign language interpretation or other special accommodation must contact the Designated Federal Officer specified in the **FOR FURTHER INFORMATION CONTACT** section of this notice by September 17, 2008.

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

Dated: August 19, 2008.

Kerry Weems,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. E8–19564 Filed 8–21–08; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0419]

Draft Guidance for Industry on Acute Bacterial Exacerbations of Chronic Bronchitis in Patients With Chronic Obstructive Pulmonary Disease: Developing Antimicrobial Drugs for Treatment; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Acute Bacterial Exacerbations of Chronic Bronchitis in Patients With Chronic Obstructive Pulmonary Disease: Developing Antimicrobial Drugs for Treatment.'' The purpose of this draft guidance is to assist clinical trial sponsors and investigators in the development of antimicrobial drugs for the treatment of acute bacterial exacerbations of chronic bronchitis in patients with chronic obstructive pulmonary disease (ABECB–COPD). The agency's thinking in this area has evolved in recent years, and this draft guidance, when finalized, will inform sponsors of the changes in our recommendations. In addition, it will fulfill a statutory requirement enacted in the Food and Drug Administration Amendments Act of 2007 (FDAAA) to publish such a guidance.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by November 20, 2008.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance 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.regulations.gov*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Steven Gitterman, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 6134, Silver Spring, MD 20993–0002, 301–796–1600.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Acute Bacterial Exacerbations of Chronic Bronchitis in Patients With Chronic Obstructive Pulmonary Disease: Developing Antimicrobial Drugs for Treatment.'' The purpose of this draft guidance is to assist clinical trial sponsors and investigators in the development of antimicrobial drugs for the treatment of ABECB–COPD. This guidance revises the draft guidance regarding ABECB published in 1998. Section 911 of FDAAA (Public Law 110–85) adds section 511 to the Federal Food, Drug, and Cosmetic Act that directs the Secretary of Health and Human Services to ''issue guidance for the conduct of clinical trials with respect to antibiotic drugs, including antimicrobials to treat * * * acute bacterial exacerbation of chronic bronchitis.''

The design of ABECB clinical trials was discussed at a meeting of the Anti-Infective Drugs Advisory Committee on February 19, 2002, and an IDSA/PhRMA/FDA workshop on November 19 and 20, 2002. In addition, other advisory committee meetings have focused on the development of specific drugs for this indication. As a result of these public discussions, as well as review of applications at FDA, the agency's thinking in this area has evolved in recent years, and this draft guidance informs sponsors of the changes in our recommendations. Specifically, this draft guidance recommends that ABECB–COPD clinical trials be designed as superiority rather than noninferiority trials, and discusses some possible study designs that might be employed in an ABECB–COPD trial designed to show superiority. This draft guidance discusses patient-reported outcome instruments for assessing clinical response, and the use of time to resolution of symptoms as a possible approach to assessing the primary endpoint in clinical studies.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on developing drugs for the treatment of ABECB–COPD. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. The Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014; the collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001; and the collections of information referred to in the guidance ''Establishment and Operation of Clinical Trial Data Monitoring Committees'' have been approved under OMB control number 0910–0581.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the