decision or dismissal is not supported by the preponderance of evidence in the record or the ALJ abused his or her discretion. Since CMS and its contractor do not have explicit authority under the existing statutes and regulations to participate in or be parties to ALJ hearings in Part D cases, we believe it is appropriate and consistent with part 405, subpart I, to allow CMS or the Part D IRE to refer Part D cases to the MAC to consider review under its own motion authority based on the standards for referral that apply when CMS or its contractor did not participate in the ALJ proceedings or appear as a party.

Similar to how § 405.1110 sets forth different referral standards depending on whether or not CMS or its contractor participate in the ALJ hearing, the regulations provide differing standards for review. Section 405.1110(c)(1) provides that when a referral is made in instances where CMS or its contractor participated or appeared as a party, the MAC exercises its own motion authority if there is an error of law material to the outcome of the case, an abuse of discretion by the ALJ, the decision is not consistent with the preponderance of the evidence of record, or there is a broad policy or procedural issue that may affect the public interest. In deciding whether to accept review under this standard, the MAC will limit its consideration of the ALJ's action to those exceptions raised by CMS.

Section 405.1110(c)(2) provides that when referral is made in instances where CMS or its contractor did not participate or appear as a party, the MAC will accept review if the decision or dismissal contains an error of law material to the outcome of the case, or presents a broad policy or procedural issue that may affect the public interest. In deciding whether to accept review, the MAC will limit its consideration of the ALJ's action to those exceptions raised by CMS.

As previously noted, since neither the Part D statute nor the current Part D regulations explicitly allow a Part D plan sponsor, CMS, or a CMS contractor to participate in or be parties to appeals at the ALJ level, we consider it appropriate to implement the standard of referral and review in § 405.1110 that applies when CMS and its contractor do not participate in or are not parties to the ALJ hearing. Accordingly, under this Ruling, CMS or the Part D IRE may refer a Part D case to the MAC and the MAC will accept review of a Part D case if the ALJ's decision or dismissal contains an error of law material to the outcome of the case or presents a broad policy or procedural issue that may affect the general public interest. In deciding whether to accept review, the MAC will limit its consideration of the ALJ's action to those exceptions raised by CMS or the Part D IRE.

C. Other Issues Regarding MAC Own Motion Review of Part D Cases

For the most part, the other provisions set forth under § 405.1110 apply appropriately to Part D cases. The requirements related to the 60-day time frame for filing the written referral and for providing notice to other interested parties set forth in § 405.1110(b)(2) are processes that are appropriate to apply to Part D cases. See also 42 CFR 405.1110(a). Written referrals must state the reasons why CMS or its contractors believe the MAC must review the case on its own motion. CMS or its contractors will send a copy of its referral to all parties to the ALJ's action and to the ALJ. Similarly, the requirements in § 405.1110(b)(2) regarding the filing of exceptions to the referral by submitting written comments to the MAC within 20 days of the referral notice, and sending such comments to CMS, appropriately apply to Part D cases.

We also believe it is appropriate to apply to Part D cases those requirements in § 405.1110(d) regarding the MAC's action. This provision states that if the MAC decides to review a decision or dismissal on its own motion, it will mail the results of its action to all the parties to the hearing and to CMS if it is not already a party to the hearing. The notice of the referral in § 405.1110(b)(2) requires that the enrollee will be notified that the ALJ's decision may not be the final action in the case. If the MAC accepts review, it may adopt, modify, or reverse the decision or dismissal, may remand the case to an ALJ for further proceedings or may dismiss a hearing request. The MAC must issue its action no later than 90 days after receipt of the CMS referral, unless the 90-day period has been extended as provided in 405 CFR subpart I. The MAC may not, however, issue its action before the 20-day comment period has expired, unless it determines that the agency's referral does not provide a basis for reviewing the case. If the MAC does not act within the applicable adjudication deadline, the ALJ's decision or dismissal remains the final action in the case. We believe it is appropriate to apply these procedures to Part D cases that the MAC reviews on its own motion.

As described in this section, the provisions in § 405.1110 are procedural rules that apply appropriately to Part D appeals. Further, applying these regulatory processes to Part D appeals does not conflict with existing Part D requirements.

Authority: Sections 1852, 1860D–4(g)–(h), and 1869 of the Social Security Act (42 U.S.C. 1395w–22, 1395w–104 and 1395ff).

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program; No. 93.773 Medicare—Hospital Insurance Program; and No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: March 15, 2007.

Leslie V. Norwalk,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. E7–5304 Filed 3–22–07; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–1481–N3]

Medicare Program; Emergency Medical Treatment and Labor Act (EMTALA) Technical Advisory Group (TAG) Meeting—May 3–4, 2007

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

ACTION: Notice of meeting.

SUMMARY: This notice announces the sixth meeting of the Emergency Medical Treatment and Labor Act (EMTALA) Technical Advisory Group (TAG). The purpose of the EMTALA TAG is to review regulations affecting hospital and physician responsibilities under EMTALA to individuals who come to a hospital seeking examination or treatment for medical conditions. The primary purpose of the sixth meeting is to enable the EMTALA TAG to hear additional testimony and further consider written responses from medical societies and other organizations on specific issues considered by the EMTALA TAG at previous meetings. The public is permitted to attend this meeting and, to the extent that time permits and at the discretion of the Chairperson, the EMTALA TAG may hear comments from the floor.

DATES: *Meeting Date:* The meetings of the EMTALA TAG announced in this notice are as follows:

Thursday, May 3, 2007, 9 a.m. to 5 p.m.
Friday, May 4, 2007, 9 a.m. to 5 p.m.

Registration Deadline: All individuals must register in order to attend this meeting. Individuals who wish to attend the meeting but do not wish to present testimony must register by April 26,

2007. Individuals who wish to attend the meeting and to present their testimony must register by April 12, 2007 and must submit copies of their testimony in writing by April 19, 2007. See section III for more detailed registration instructions.

Comment Deadline: Written comments/statements to be presented to the EMTALA TAG must be received by April 19, 2007.

Special Accommodations: Individuals requiring sign-language interpretation or other special accommodations should send a request for these services to Eric Ruiz by 5 p.m. by April 19, 2007 at the address listed below.

ADDRESSES: *Meeting Address:* The EMTALA TAG meeting will be held in Room 705a of the Hubert Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20001.

Mailing and E-mail Addresses for Inquiries or Comments: Inquiries or comments regarding this meeting may be sent to—Eric Ruiz, Division of Acute Care, Centers for Medicare & Medicaid Services, Mail Stop C4–08–06, 7500 Security Boulevard, Baltimore, MD 21244–1850. Inquiries or comments may also be e-mailed to *Eric.Ruiz@cms.hhs.gov* or *EMTALATAG@cms.hhs.gov.*

Web Site Address for Additional Information: For additional information on the EMTALA TAG meeting agenda topics, updated activities, and to obtain Charter copies, please search our Internet Web site at (*http://www.cms.hhs.gov/faca/07_emtalatag.asp*).

FOR FURTHER INFORMATION CONTACT: Eric Ruiz, (410) 786–0247. George Morey, (410) 786–4653.

SUPPLEMENTARY INFORMATION:

I. Background

Sections 1866(a)(1)(I), 1866(a)(1)(N), and 1867 of the Social Security Act (the Act) impose specific obligations on Medicare-participating hospitals that offer emergency services. These obligations concern individuals who come to a hospital emergency department and request or have a request made on their behalf for examination or treatment for a medical condition. The Emergency Medical Treatment and Labor Act (EMTALA) applies to all these individuals, regardless of whether or not they are beneficiaries of any program under the Act. Section 1867 of the Act sets forth requirements for medical screening examinations for medical conditions, as well as necessary stabilizing treatment or appropriate transfer.

Regulations implementing the EMTALA legislation are set forth at 42 CFR 489.20(l), (m), (q), and (r) and § 489.24. Section 945 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173), mandates that the Secretary establish a Technical Advisory Group (TAG) for advice concerning issues related to EMTALA regulations and implementation.

Section 945 of the MMA specifies that the EMTALA TAG—

- Shall review the EMTALA regulations;
- May provide advice and recommendations to the Secretary concerning these regulations and their application to hospitals and physicians;
- Shall solicit comments and recommendations from hospitals, physicians, and the public regarding implementation of such regulations; and
- May disseminate information concerning the application of these regulations to hospitals, physicians, and the public.

The EMTALA TAG, as chartered under section 945 of the MMA, is also governed by the provisions of the Federal Advisory Committee Act (FACA) (5 U.S.C. Appendix 2) for the selection of members and the conduct of all meetings.

In the May 28, 2004 **Federal Register** (69 FR 30654), we specified the statutory requirements regarding the charter, general responsibilities, and structure of the EMTALA TAG. That notice also solicited nominations for members based on the statutory requirements for the EMTALA TAG. In the August 27, 2004 **Federal Register** (69 FR 52699), we solicited nominations again for members in two categories (patient representatives and a State survey agency representative) for which no nominations were received in response to the May 28, 2004 **Federal Register** notice. In the March 15, 2005 **Federal Register** (70 FR 12691), we announced the inaugural meeting of the EMTALA TAG and the membership selection. In the May 18, 2005 **Federal Register** (70 FR 28541), the September 23, 2005 **Federal Register** (70 FR 55903), the April 7, 2006 **Federal Register** (71 FR 17888), and the September 29, 2006 **Federal Register** (71 FR 57543), we announced the second, third, fourth, and fifth meetings of the EMTALA TAG, respectively, with a purpose to hear public testimony and consider written responses from medical societies and other organizations on specific issues considered by the EMTALA TAG at its previous meetings. The EMTALA TAG has established the following three subcommittees:

- *On-Call Subcommittee* (Chairperson, John Kusske, M.D.) charged with reviewing the testimony and other materials provided to the TAG to identify some specific issues related to on-call requirements.
- *Action Subcommittee* (Chairperson, Julie Nelson, J.D.) charged with identifying issues other than on-call issues.
- *Framework Subcommittee* (Chairperson, Charlotte Yeh, M.D.) charged with clarifying the historical context and conceptual basis for the TAGs recommendations and developing a document for review and approval by the TAG.

II. Meeting Format, Agenda, and Presentation Topics

A. Meeting Format

The initial portion of the meeting, which will convene at 9 a.m. on May 3, will involve opening remarks and a limited period of public testimony on issues related to EMTALA and its implementation. TAG members will have the opportunity to ask questions, prioritize the topics presented, and to conduct other necessary business. At the conclusion of each day's meeting, to the extent that time is available and at the discretion of the Chairperson, the public will be permitted a reasonable time to comment on issues being considered by the TAG.

B. Tentative Meeting Agenda

The tentative agenda for the EMTALA TAG meetings is as follows:

Day 1

Convenes at 9 a.m.

- Welcome, Call to Order, and Opening Remarks.
- Administrative and Housekeeping Issues.
- Public Testimony on Issues Related to EMTALA and its Implementation.
- Subcommittee Reports.
- Public Comment.

Day 2

Convenes at 9 a.m.

- Subcommittee Reports.
- Public Comment.

C. Public Presentations

Only individuals who register and submit written testimony as specified in the Registration section of this notice will be considered registered presenters. The time allotted for each presentation will be approximately 5 minutes and will be based on the number of registered presenters. Presenters will

speak in their assigned order. If registered presenters are not given an opportunity to speak because of time restrictions, we will accept and present their written testimony to the TAG members. Time permitting, comments from other participants (individuals who are not registered presenters) may be heard after the scheduled testimonies.

If there are individuals who cannot attend the meeting but wish to submit comments/statements regarding issues related to the EMTALA TAG, we will accept and present their written comments/statements at the meeting if their comments/statements are received by postal mail or e-mail at the address listed in the **ADDRESSES** section of this notice by April 19, 2007.

III. Registration Instructions

The Center for Medicare Management of CMS is coordinating meeting registration. While there is no registration fee, all individuals must register to attend due to limited seating. As specified in the **DATES** section of this notice, individuals who wish to attend the meeting but do not plan to present testimony must register by April 26, 2007. Individuals who would like both to attend and to present testimony on issues relating to the EMTALA TAG must register by April 12, 2007 and must state specifically in their registration request that they wish to present testimony for EMTALA TAG consideration. A copy of the presenter's written testimony must be received by CMS at the address specified in the **ADDRESSES** section of this notice by April 19, 2007.

You may register by e-mail to Marianne Myers at *Marianne.Myers@cms.hhs.gov*, by fax to the attention of Marianne Myers at (410) 786–0681, or by telephone at (410) 786–5962. All registration requests must include your name, name of the organization (if applicable), address, telephone and fax numbers, e-mail address (if available). Individuals will receive a registration confirmation with instructions for your arrival at the Hubert Humphrey Building. If seating capacity has been reached, registrants will be notified that the meeting has reached capacity. All registrants are asked to arrive at the Hubert Humphrey Building no later than 20 minutes before the scheduled starting time of each meeting session they wish to attend.

IV. Security Information

Since this meeting will be held in a Federal government building, Federal security measures are applicable. As noted above, in planning your arrival time, we recommend allowing additional time to clear security. In order to gain access to the building, participants must bring a government-issued photo identification such as a driver's license or a passport and a copy of your registration information for the meeting. Access may be denied to persons without proper identification.

All persons entering the building must pass through a metal detector. In addition, all items brought to CMS, whether personal or for the purpose of demonstration or to support a presentation, 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 presentation.

Authority: Section 945 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA).

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

Dated: March 16, 2007.

Leslie V. Norwalk,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. E7–5329 Filed 3–22–07; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007D–0101]

Draft Guidance for the Public, FDA Advisory Committee Members, and FDA Staff on Procedures for Determining Conflict of Interest and Eligibility for Participation in FDA Advisory Committees; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft document for the public, FDA advisory committee members, and FDA staff entitled ''Guidance for the Public, FDA Advisory Committee Members, and FDA Staff: Procedures for Determining Conflict of Interest and Eligibility for Participation in FDA Advisory Committees'' dated March 2007. This draft guidance describes the factors and analyses that should be used in considering whether an advisory committee member has a potential conflict of interest and whether participation in a meeting is appropriate. This guidance is intended to help the public, FDA advisory committee members, and FDA staff to understand and implement FDA policy in applying the applicable statutory and regulatory requirements. This draft guidance, when finalized, will replace the guidance document entitled ''FDA Waiver Criteria 2000.''

DATES: Submit written or electronic comments on the draft guidance by May 21, 2007. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Office of Policy (HF–11), Office of the Commissioner, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit phone requests to 800–835–4709 or 301–827–1800. 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.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Jill Hartzler Warner, Office of Policy and Planning (HF–11), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3370.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft document, entitled ''Guidance for the Public, FDA Advisory Committee Members, and FDA Staff; Procedures for Determining Conflict of Interest and Eligibility for Participation in FDA Advisory Committees,'' dated March 2007. FDA's advisory committees provide independent and expert advice on scientific, technical, and policy matters related to the development and evaluation of products regulated by FDA.

FDA is committed to strictly adhering to the laws and regulations governing the process for selecting advisory committee members. FDA for many years has screened, prior to each meeting, all advisory committee members who are special government employees or regular government employees, to determine whether the potential for a financial conflict of interest exists. The agency may grant a waiver to allow an individual to