The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** Notices pertaining to announcements of meetings and other committee management activities for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: February 23, 2005.

Alvin Hall,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 05–5019 Filed 3–14–05; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–1269–N3]

Medicare Program; Emergency Medical Treatment and Labor Act (EMTALA) Technical Advisory Group (TAG) Meeting and Announcement of Members

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

ACTION: Notice of meeting.

SUMMARY: In accordance with section 10(a) of the Federal Advisory Committee Act (FACA) (5 U.S.C. Appendix 2), this notice announces the first 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. This notice also announces the newly appointed members of the EMTALA TAG. Interested parties are invited to this meeting to present their comments on the EMTALA regulations and implementation.

DATES: *Meeting Date:* The meetings of the EMTALA TAG announced in this notice will be held on Wednesday, March 30, 2005 and Thursday, March 31, 2005, from 9 a.m. until 5 p.m. each day.

Registration Deadline for All Participants: All presenters must register by March 22, 2005.

Comment Deadline: Comments or statements must be received by March 22, 2005.

ADDRESSES: *Meeting Address:* The EMTALA TAG meeting will be held in Room 305 A at the Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201.

Mailing and E-mail Addresses for Inquiries or Comments: Inquiries or comments regarding this meeting may be sent to—Beverly J. Parker, 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 *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/emtalatag/emtalatagpage.asp.*

Mailing Address for Copies of the EMTALA TAG Charter: Written requests for copies of the EMTALA TAG Charter should be sent to—Marianne M. Myers, Division of Acute Care, Centers for Medicare & Medicaid Services, Mailstop C4–08–06, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Submission of Comments or Statements: Comments or statements regarding EMTALA may be sent by postal mail or e-mail to the inquiry/comment addresses listed above. We will accept written comments/statements of three single-spaced, typed pages or less that are received by March 22, 2005.

FOR FURTHER INFORMATION CONTACT: Beverly J. Parker, (410) 786–5320.

Press inquiries are handled through the CMS Press Office at (202) 690–6145.

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. 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 emergency medical conditions, as well as necessary stabilizing treatment or appropriate transfer. In addition, section 1867(h) of the Act specifically prohibits a delay in providing required screening or stabilization services in order to inquire about the individual's payment method or insurance status. Section 1867(d) of the Act provides for the imposition of civil monetary penalties on hospitals and physicians responsible for negligently violating a requirement of that section.

These provisions, taken together, frequently referred to as the Emergency Medical Treatment and Labor Act (EMTALA), are also known as the patient antidumping statute. EMTALA was passed in 1986 as part of the Consolidated Omnibus Budget Reconciliation Act of 1985 (COBRA). Congress enacted these antidumping provisions in the Social Security Act because of its concern with an ''increasing number of reports'' that hospital emergency rooms were refusing to accept or treat individuals with emergency conditions if the individuals did not have insurance.

Regulations implementing the EMTALA legislation are set forth at 42 CFR 489.20(l), (m), (q) and (r)(1), (r)(2), (r)(3), and 489.24. These regulations incorporate changes made by a final rule published in the September 9, 2003 **Federal Register** (68 FR 53222). We published a final rule to clarify policies relating to the responsibilities of Medicare-participating hospitals and physicians, under the provisions of EMTALA, in treating individuals with emergency medical conditions who present to a hospital.

Section 945 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (P.L. 108–173), requires 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.

Section 945 of the MMA also specifies the structure of the EMTALA TAG. It states that the EMTALA TAG will be composed of 19 members including the Administrator of the Centers for Medicare & Medicaid Services (CMS) and the Inspector General of the Department of Health and Human Services (DHHS) in addition to the number and type of individuals as specified in each of the following categories:

• Four representatives of hospitals, including at least one public hospital, that have experience with the application of EMTALA and, at least, two hospitals that have not been cited for EMTALA violations;

• Seven practicing physicians drawn from the fields of emergency medicine, cardiology or cardio-thoracic surgery, orthopedic surgery, neurosurgery, pediatrics or a pediatric subspecialty, obstetrics-gynecology and psychiatry, with not more than one physician from any particular field;

• Two representatives of patients;

• Two staff persons involved in EMTALA investigations from different CMS regional offices;

• One representative from a State survey agency involved in EMTALA investigations and one representative from a Quality Improvement Organization, both of whom shall be from areas other than the regions represented by the CMS regional offices.

The EMTALA TAG, as chartered under the legal authority of 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.

II. Membership Selection

The following individuals have been selected by the Secretary, to serve on the EMTALA TAG along with Mark McClellan, M.D., Adminstrator, CMS and Daniel R. Levinson, Acting Inspector General, DHHS:

• Hospital Representatives—Julie Mathis Nelson, J.D., Coopersmith, Gordon, Schnermer, Owens & Nelson, P.L.C.; Carlos Perez, South Manhattan Healthcare Network; Richard T. Perry, M.D., P.C., F.A.C.S.; and Brian C. Robinson, Hospital Corporation of America's Las Vegas Market/Sunrise Hospital and Medical Center.

• Physicians—Cesar A. Aristeguieta, M.D., Los Angeles County Paramedic Training Institute; Carol Lynn Bayer, M.D., East Jefferson General Hospital Metairie, Louisiana; James L. Biddle, M.D., Rio Grande Regional Hospital and McAllen Medical Center; John A. Kusske, M.D., University of California; James Nepola, M.D. Health Policy Committee Orthopedic Trauma Association; Michael J. Rosenberg, M.D., Assistant Professor/Private Practice; and David W. Tuggle, M.D., University Oklahoma College of Medicine

• Patient Representatives—Warren A. Jones, M.D., Office of the Governor, State of Mississippi; and Mark Pearlmutter, M.D., St. Elizabeth's Medical Center.

• CMS Regional Office Representatives—Gretchen A. Kane CMS, and Charlotte S. Yeh, M.D., FACEP.

• State Survey Agency Representative—Azzie Conley, RN, State of North Carolina.

• QIO Representative—David Siegel, M.D., J.D., FACEP, FACP, FCLM Senior Physician Consultant and Clinical Coordinator.

III. Meeting Format, Agenda, and Suggested Presentation Topics

A. Meeting Format

The initial portion of the meeting will involve opening remarks, introductions and the swearing in of the EMTALA TAG members by Michael O. Leavitt, Secretary, DHHS. After which and in accordance with section 945 of MMA, the EMTALA TAG members will elect their chairperson. The afternoon portion of the first day and the morning portion of the second day will be reserved for statements from registered presenters. The afternoon portion of the second day will be reserved for the EMTALA TAG members to ask questions, prioritize the topics presented, and to conduct other necessary business.

The time allotted for each presentation will be approximately 5 minutes but will be based on the number of registered presenters. Presenters will speak in their assigned order. If there are individuals who cannot attend the meeting, we will accept and present their comments/statements at the meeting if their comments/statements are received via postal mail or email at the address list in the **ADDRESSES** section of this notice by March 22, 2005. Comments from other participants (individuals that are not registered presenters) may be heard after the scheduled statements, if time permits.

B. Tentative Meeting Agenda

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

Day 1

• Welcome, call to order, introductions, and opening remarks

• Administrative and housekeeping issues

• Swearing in of members and self-introductions

• Comments from registered presenters

Day 2

• Comments from registered presenters

• Discussion of current business

C. Suggested Presentation Topics

The following are suggested presentation topics:

• Inpatient Transfers—Under current EMTALA regulations, if a hospital admits an individual in good faith for stabilizing treatment on an inpatient basis, the admission ends the hospital's EMTALA obligation to that individual. Does the fact that an individual no longer is covered by EMTALA at the time transfer is sought make it more difficult to find a suitable specialty hospital transfer?

• Specialty Hospitals and EMTALA—Some specialty hospitals apparently accept patients on an appointment basis only, and will accept patients only for treatment of particular medical conditions or for a narrow range of services. There are reports that such hospitals are refusing to accept transfers of patients from general or community hospitals, on the basis that because the specialty hospital does not have a dedicated emergency department as defined in the new regulations, it has no obligations under EMTALA.

• On-Call Issues—Some concerns have been expressed that the revised regulations regarding physician on-call responsibilities are reducing the willingness of physicians to take call, especially at receiving hospitals, thus leading to delays in arranging appropriate transfers and thereby delaying stabilization of patients.

• Psychiatric Patients—There continues to be much concern about determining stability for patients who have a psychiatric condition, even if the emergency medical condition is not based on a psychiatric disorder.

• Certified Nurse Midwives—Under current regulations, certified nurse midwives (CNMs) are not able to certify that a patient is in false labor. Current regulations state that only a physician may certify that a patient is in false labor. There is concern that this policy is not cost effective and is in conflict with the authority provided CNMs by state law.

IV. Registration Instructions

The Center for Medicare Management is coordinating meeting registration. While there is no registration fee, individuals must register to attend. As specified in the **DATES** section of this notice, individuals who wish to attend or make a presentation at the meeting or both must register by March 22, 2005. You may register by sending an e-mail to *EMTALATAG@cms.hhs.gov*, sending a fax to the attention of Ronda Allen at fax number (410) 786–0681 or (410) 786–0169, or calling (410) 786–4548. All registration requests must include your name, name of the organization (if applicable), address, telephone and fax numbers, e-mail address (if available), and topic to be addressed (if you want to do a presentation). You will receive a registration confirmation with instructions for your arrival at the Hubert H. Humphrey Building. If seating capacity has been reached, you will be notified that the meeting has reached capacity. All registered presenters must submit a hard copy of their presentation to the EMTALA TAG at the first meeting.

V. 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, participants must bring a government-issued photo identification (driver's license, passport, etc.) and a copy of your confirmation of registration 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 HHS, 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 10, 2005.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 05–5028 Filed 3–14–05; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0083]

Agency Information Collection Activities; Proposed Collection; Comment Request; General Licensing Provisions: Biologics License Application, Changes to an Approved Application, Labeling, Revocation and Suspension, and Forms FDA 356h and 2567

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection requirements relating to the general licensing provisions regarding biologics license application, changes to an approved application, labeling, and revocation and suspension, and the use of Forms FDA 356h and 2567.

DATES: Submit written or electronic comments on the collection of information by May 16, 2005.

ADDRESSES: Submit electronic comments on the collection of information to: *http://www.fda.gov/dockets/ecomments*. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

General Licensing Provisions: Biologics License Application, Changes to an Approved Application, Labeling, Revocation and Suspension, and Forms FDA 356h and 2567 (OMB Control Number 0910–0338)—Extension

Under Section 351 of the Public Health Services Act (the PHS Act) (42 U.S.C. 262), manufacturers of biological products must submit a license application for FDA review and approval before marketing a biological product in interstate commerce. Licenses may be issued only upon showing that the establishment and the products for which a license is desired meets standards prescribed in regulations designed to insure the continued safety, purity, and potency of such products. All such licenses are issued, suspended, and revoked as prescribed by regulations in part 601 (21 CFR part 601).