

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.

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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

participate in a meeting when statutory criteria are met; for example, when the need for the individual's services outweighs the potential for a conflict of interest created by the financial interest involved. FDA administers several laws and regulations that govern conflict of interest determinations; these laws are not entirely consistent and set out different standards. FDA's Waiver Criteria 2000 guidance, which this draft guidance would replace, attempted to comprehensively address the complex set of variables that can be applied in reaching a determination about an individual advisory committee participant. However, because of its complexity and discretionary elements, FDA staff found it difficult to achieve consistent results that the public could readily understand. As part of FDA's recent internal assessment of its advisory committee process, the agency has targeted its assessment of potential conflicts of interest and granting of waivers as an area that needs improvement. This draft guidance will implement a more stringent approach for considering eligibility for participation in FDA advisory committee meetings. The purpose of this draft guidance is to simplify and streamline the process by which FDA considers meeting participation, increase the transparency, clarity, and consistency of the process, and enhance public trust in this important function.

We welcome comments on the draft guidance and specifically seek comment on (1) whether the draft approach, due to its stringency, could unduly restrict eligibility of needed experts for advisory committee meetings, (2) whether the \$50,000 figure generally employed as the maximum amount for disqualifying financial interests, after applying certain exemptions, is appropriate or, alternatively, whether a different figure (higher or lower) should be used, and (3) whether and what additional examples should be provided for the steps described in this draft guidance for determining conflicts of interest and eligibility for participating in an advisory committee meeting.

This draft guidance is being issued consistent with FDA's good guidance

practices regulation (21 CFR 10.115). The draft guidance represents the agency's current thinking on procedures for considering conflict of interest and eligibility for participation in FDA advisory committees. 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. 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 docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at: <http://www.fda.gov/opacom/morechoices/industry/guidedc.htm>

Dated: March 20, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub.

L. 104-13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, call the HRSA Reports Clearance Officer on (301) 443-1129.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: The National Health Service Corps (NHSC) Scholarship Program In-School Worksheets (OMB No. 0915-0250): Extension

The National Health Service Corps (NHSC) Scholarship program provides scholarships to students in health professions in return for service in a federally-designated Health Professional Shortage Area (HPSA). If awarded an NHSC scholarship, the program requires the schools and the awardees to review and complete data collection worksheets for each year that the student is an NHSC Scholar. The forms provide information on the following: Verification of enrollment status; current curriculum; current contact information; and verification of accuracy of student data. The worksheets require minimal burden and provide the program with information that is required to determine if scholars are maintaining their status of eligibility as required by Federal statute.

The annual estimate of burden is as follows:

Instrument	Number of respondents	Responses per respondent	Total responses	Hours per response (minutes)	Total burden hours
Scholar Worksheet	800	1	800	10	134
School Verification Worksheet	300	1	300	10	50
School Contact Information	550	1	550	10	92
Total	1,650		1,650		276