DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D–0297]

Medical Devices; Availability of Information Given to Advisory Committee Members in Connection with CDRH Open Public Panel Meetings; Draft Guidance for Industry and FDA Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''Availability of Information Given to Advisory Committee Members in Connection with CDRH Open Public Panel Meetings; Draft Guidance for Industry and FDA Staff.'' This document provides guidance to the Center for Devices and Radiological Health (CDRH) staff and to industry whose device is the subject of an open advisory committee meeting. The Federal Advisory Committee Act (FACA) generally requires FDA to make available to the public the information given to panel members, except for material that is exempt under the Freedom of Information Act (FOIA). This draft guidance describes the process CDRH intends to follow when making this information publicly available. This draft guidance also describes how these materials should be assembled and timeframes for their availability. This draft guidance is neither final nor is it in effect at this time.

DATES: Submit written or electronic comments concerning this guidance by October 16, 2001.

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the draft guidance document entitled ''Availability of Information Given to Advisory Committee Members in Connection with CDRH Open Public Panel Meetings; Draft Guidance for Industry and FDA Staff'' to the Division of Small Manufacturers Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments on the document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments.

FOR FURTHER INFORMATION CONTACT: Nancy J. Pluhowski, Center for Devices and Radiological Health (HFZ–400), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2022.

SUPPLEMENTARY INFORMATION:

I. Background

FACA provides at section 10(b) that materials that are made available to an advisory committee in connection with an open advisory committee meeting shall also be made available to the public, if the materials are not exempt from disclosure under FOIA. This FACA provision is intended to facilitate meaningful public participation at such meetings. CDRH has now developed a process to make materials provided to advisory committee members in connection with open public meetings available for public disclosure, whenever practicable before or at the time of the meeting. This process also ensures that those materials exempt from disclosure under FOIA are protected. This draft guidance is designed to minimize the amount of time and resources spent in reviewing, redacting (the deletion of nondisclosable information), and publishing this information so that panel meetings can proceed when they are scheduled and in compliance with the requirements of FACA.

II. Significance of Guidance

This draft guidance document represents the agency's current thinking on the availability of information given to advisory committee members in connection with CDRH open public panel meetings. 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 applicable statutes and regulations.

The agency has adopted good guidance practices (GGPs), and published the final rule, which set forth the agency's regulations for the development, issuance, and use of guidance documents (21 CFR 10.115; 65 FR 56468, September 19, 2000). This draft guidance document is issued as a level 1 guidance in accordance with the GGP regulations.

III. Electronic Access

In order to receive ''Availability of Information Given to Advisory Committee Members in Connection with CDRH Open Public Panel Meetings; Draft Guidance for Industry and FDA Staff'' via your fax machine, call the CDRH Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt press 1 to order a document. Enter the document number 1341 followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the draft guidance may also do so using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes the civil money penalty guidance documents package, device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH home page may be accessed at http://www.fda.gov/cdrh.

IV. Comments

Interested persons may submit to Dockets Management Branch (address above) written or electronic comments regarding this draft guidance by October 16, 2001. Submit two copies of any comments, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance document and any received comment may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 12, 2001.

Linda S. Kahan,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 01–17976 Filed 7–17–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–R–312 and HCFA–R–263]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

In compliance with the requirement of section 3506(c)(2)(A) of the

Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, has submitted to the Office of Management and Budget (OMB) the following proposal for the collection of information. Interested persons are invited to send comments regarding the burden estimate 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 accuracy of the estimated 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.

(1) *Type of Information Collection Request:* Extension of a currently approved collection;

Title of Information Collection: Conflict of Interest and Ownership and Control Information;

Form No.: HCFA–R–312 (OMB# 0938–0795);

Use: This Conflict of Interest questionnaire is sent to all Medicare Fiscal Intermediaries (FIs) and Carriers to collect full and complete information on any entity's or individual's ownership interest (defined as a 5 per centum or more) in an organization that may present a potential conflict of interest in their role as a Medicare FI or Carrier. The information gathered is used to ensure that all potential, apparent and actual conflicts of interest involving Medicare contracts are appropriately mitigated and that employees of the contractors, including officers, directors, trustees and members of their immediate families, do not utilize their positions with the contractor for their own private business interest to the detriment of the Medicare program.;

Frequency: Annually;

Affected Public: Not-for-profit institutions, and Business or other for-profit;

Number of Respondents: 37;

Total Annual Responses: 37;

Total Annual Hours: 11,100.

(2)*Type of Information Collection Request:* Revision of a currently approved collection;

Title of Information Collection: On Site Inspection for Durable Medical Equipment (DME) Supplier Location & Supporting Regulations in 42 CFR, 424.57;

Form Nos.: HCFA–R–263 (OMB# 0938–0749);

Use: To identify and implement measures to prevent fraud and abuse in the Medicare program. Controlling the entry of suppliers of durable medical equipment, prosthetics, orthotics, or supplies (DMEPOS) to Medicare has been identified as one of the most effective ways to prevent fraud and abuse. To meet this challenge, HCFA is moving forward with a plan to improve the quality of the process for enrolling and reenrolling DMEPOS suppliers into the Medicare program by enhancing procedures for verifying supplier information collected on the Form HCFA–855S (DMEPOS Supplier Enrollment Application, OMB Approval No. 0938–0685). This form will be used to complete information on DMEPOS suppliers' compliance with regulations found in 42 CFR 424.57.

Frequency: On occasion;

Affected Public: Business or other for-profit, Not-for-profit institutions, and State, Local or Tribal Government;

Number of Respondents: 20,000;

Total Annual Responses: 20,000;

Total Annual Hours: 10,000.

To obtain copies of the supporting statement for the proposed paperwork collections referenced above, access HCFA's Web Site Address at http://www.hcfa.gov/regs/prdact95.htm, or E-mail your request, including your address and phone number, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 30 days of this notice directly to the OMB Desk Officer designated at the following address:

OMB Human Resources and Housing Branch, Attention: Allison Eydt, New Executive Office Building, Room 10235, Washington, D.C. 20503.

Dated: June 19, 2001.

John P. Burke III,

HCFA Reports Clearance Officer, HCFA, Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards.

[FR Doc. 01–17959 Filed 7–17–01; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Program Announcement for Delta State Rural Development Network Grants

AGENCY: Health Resources and Services Administration, DHHS.

ACTION: Notice of availability of funds; request for applications.

SUMMARY: The Office of Rural Health Policy (ORHP) in the Health Resources and Services Administration (HRSA) announces that applications are being accepted for grants for Delta State Rural Development Networks (DSRDN). One grant will be awarded in each of the eight States designated by Congress for inclusion in the service area of the Delta Regional Authority: Alabama, Arkansas, Illinois, Kentucky, Louisiana, Missouri, Mississippi and Tennessee. Public Law 104–299, enacted in 1996, authorizes the Rural Health Outreach, Network Development and Telemedicine Grant program. The Consolidated Appropriations Act, 2001, Public Law 106–554 includes, in the Rural Health Outreach appropriation line, funding for a special initiative. ORHP will use these special initiative funds to award grants to rural networks in the eight Delta States. Grants will be for a three-year project period, with annual renewal dependant on availability of funds and evaluation of grantee performance.

Application Requests, Dates and Addresses: The application form and guidance for this Grant Program are available at the ORHP web site address at *http://ruralhealth.hrsa.gov.* Applicants may request a hard copy of these materials from the HRSA Grants Application Center (GAC) at 1815 North Fort Myer Drive, Suite 300, Arlington, VA 22209; telephone number 1–877–477–2123. The GAC email address is *hrsagac@hrsa.gov.*

In order to be considered for competition, an original and one copy of the applications for this grant program must be received by August 15, 2001. To be considered submitted on time applications must be OFFICIALLY POSTMARKED BY 11:59 P.M. August 14, 2001. Postmarked means Official Post Office cancellation mark, Federal Express Shipping Receipt Form, United States Parcel Company receipt or other carrier that Officially records the pick-up or drop-off time of a package. PRIVATE POSTAGE METER CANCELLED PACKAGES WILL NOT BE ACCEPTED UNLESS THE PACKAGE ARRIVES ON OR BEFORE THE DUE DATE.

Applications must be mailed or delivered to: HRSA Grants Application Center (GAC), 1815 North Fort Myer Drive, Suite 300, Arlington, VA 22209.

Applications postmarked after the deadline date or sent to any address other than the address above will be returned to the applicant and not reviewed.