

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN ¹

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
801.420(c)	40	24	960	102	97,920
801.421(b)	9,900	162	1,600,000	0.30	480,000
801.421(c)	9,900	5	49,700	0.17	8,449
Total					586,369

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN ¹

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
801.421(d)	9,900	162	1,600,000	0.25	400,000
Total					400,000

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Section 801.420(c) estimate assumes that 40 hearing aid manufacturers or distributors each will distribute 5 different models of hearing aids. Thus, the 40 hearing aid manufacturers or distributors will provide 5 different user instructional brochures to sellers for distribution to prospective users and users. The completion of each user instructional brochure is estimated to require 102 staff hours.

Section 801.421(b) estimate assumes that 9,900 hearing aid dispensers will have 162 sales annually. For all such sales, the dispenser must provide the prospective user a copy of the user instructional brochure and the opportunity to read and review the contents with him or her orally, or in the predominant method used during the sale. FDA estimates that this exchange will involve .30 staff hours.

Section 801.421(c) estimate assumes that 40 hearing aid manufacturers or distributors and 9,900 dispensers will provide copies of the user instructional brochure to any health care professional, user, or prospective user who requests a copy in writing. It is estimated that five written requests for copies of the brochures will be received by each hearing aid manufacturer or distributor and dispenser annually. It is estimated that each request for a brochure will take .17 staff hours to complete. This effort consists of the hearing aid manufacturer or distributor or hearing aid dispenser locating the appropriate user instructional brochure for the specific model and mailing the brochure to the requester.

Section 801.421(d) recordkeeping estimate assumes that 9,900 hearing aid dispensers will each retain 162 records. Each record documents the dispensing of a hearing aid to a hearing aid user.

The recordkeeping entry is estimated to require 0.25 staff hours.

Dated: November 10, 1999.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 99-30302 Filed 11-19-99; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N-4491]

Reuse of Single Use Devices; FDA's Proposed Strategy; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meeting.

The Food and Drug Administration (FDA) is announcing the following meeting: Reuse of Single Use Devices—FDA's Proposed Strategy. The topic to be discussed is the current practice of reprocessing and reusing devices that are labeled, or otherwise intended, for only one use and FDA's proposed strategy to address concerns regarding this practice.

Date and Time: The meeting will be held on December 14, 1999, 8 a.m. to 5:30 p.m.

Location: The meeting will be held at the University of Maryland Auditorium, 9640 Gudelsky Dr., Rockville, MD.

FOR FURTHER INFORMATION CONTACT: Heather Howell, Center for Devices and Radiological Health (HFZ-205), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD, 20850, 301-594-3252, FAX 301-443-7185, Internet site: <http://www.fda.gov/cdrh/reuse>, e-mail: reuse@cdrh.fda.gov.

Registration and Requests for Oral Presentations: Please register online on the Internet at <http://www.fda.gov/cdrh> reuse by December 1, 1999. There is no charge to attend this meeting, but advance registration is requested due to limited seating. Those desiring to make formal oral presentations should submit a brief statement of the general nature of their presentation, the names and addresses of the proposed participants, and an indication of the approximate time requested to make their presentation. The time allotted for each presentation is limited.

Written comments may be submitted to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, by December 1, 1999.

If you need special accommodations due to a disability, please contact Heather Howell at least 7 days in advance of the meeting.

SUPPLEMENTARY INFORMATION:

I. Background

FDA announced the availability of a document entitled "FDA's Proposed Strategy on Reuse of Single-Use Devices" in the **Federal Register** of November 3, 1999 (64 FR 59782). The document presents the agency's current thinking about the best way to address the concerns regarding the practice of reprocessing and reusing devices that are labeled, or otherwise intended, for only one use. The agency is interested in discussing this proposed strategy, and it is soliciting comments, proposals for alternative approaches, and information on this issue.

II. Electronic Access

In order to receive "FDA's Proposed Strategy on Reuse of Single Use

Devices" via your fax machine, call the CDRH Facts-On-Demand system at 800-899-0381 or 800-827-0111 from a touch-tone telephone. At the first voice prompt press 1 to access DSMA Facts, at the second voice prompt press 2, and then enter the document number 2525 followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of "FDA's Proposed Strategy on Reuse of Single Use Devices" 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 access to the Internet. Updated on a regular basis, the CDRH home page includes "FDA's Proposed Strategy on Reuse of Single Use Devices," 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>.

Dated: November 12, 1999.

David W. Feigal, Jr.,

Director, Center for Devices and Radiological Health.

[FR Doc. 99-30303 Filed 11-19-99; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration [HCFA-1079-N]

Medicare Program; December 13, 1999, Meeting of the Practicing Physicians Advisory Council

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice of meeting.

SUMMARY: In accordance with section 10(a) of the Federal Advisory Committee Act, this notice announces a meeting of the Practicing Physicians Advisory Council. This meeting is open to the public.

DATES: The meeting is scheduled for December 13, 1999, from 8:00 a.m. until 5 p.m., e.s.t.

ADDRESSES: The meeting will be held in the Multi-purpose Room, Room 705-A, 7th Floor, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201.

FOR FURTHER INFORMATION CONTACT: Paul Rudolf, Executive Director, Practicing Physicians Advisory Council, Room 435-H, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, (202) 690-7874. News media representatives should contact the HCFA Press Office, (202) 690-6145.

SUPPLEMENTARY INFORMATION: The Secretary of the Department of Health and Human Services (the Secretary) is mandated by section 1868 of the Social Security Act to appoint a Practicing Physicians Advisory Council (the Council) based on nominations submitted by medical organizations representing physicians. The Council meets quarterly to discuss certain proposed changes in regulations and carrier manual instructions related to physicians' services, as identified by the Secretary. To the extent feasible and consistent with statutory deadlines, the consultation must occur before publication of the proposed changes. The Council submits an annual report on its recommendations to the Secretary and the Administrator of the Health Care Financing Administration not later than December 31 of each year.

The Council consists of 15 physicians, each of whom has submitted at least 250 claims for physicians' services under Medicare or Medicaid in the previous year. Members of the Council include both participating and nonparticipating physicians, and physicians practicing in rural and underserved urban areas. At least 11 members must be doctors of medicine or osteopathy authorized to practice medicine and surgery by the States in which they practice. Members have been invited to serve for overlapping 4-year terms. In accordance with section 14 of the Federal Advisory Committee Act, terms of more than 2 years are contingent upon the renewal of the Council by appropriate action before the end of the 2-year term. The Council held its first meeting on May 11, 1992.

The current members are: Jerold M. Aronson, Richard Bronfman, Wayne R. Carlsen, Mary T. Herald, Sandra Hullett, Stephen A. Imbeau, Jerilynn S. Kaibel, Marie G. Kuffner, Derrick K. Latos, Dale Lervick, Sandra B. Reed, Susan Schooley, Maisie Tam, Victor Vela, and Kenneth M. Viste, Jr. The Council chairperson is Marie G. Kuffner.

Council members will be updated on the, Physician Fee Schedule (Practice Expense) Issues, Impact of the Balanced Budget Act of 1997, and New Coverage Process-How It Is Working.

The agenda will provide for discussion and comment on the following topics:

- New Initiatives in Provider Education/Communication.
 - Provider Involvement in Beneficiary Education.
 - Co-payment Follow Up.
 - Physician/Beneficiary Interaction in Medicare+Choice.
 - Program Fraud and Abuse Issues.
- For additional information and clarification on the aforementioned topics, call the contact person listed above.

Individual physicians or medical organizations that represent physicians that wish to make 5-minute oral presentations on agenda issues should contact the Executive Director by 12 noon, November 29, 1999, to schedule the presentation. Testimony is limited to listed agenda issues only. The number of oral presentations may be limited by the time available. A written copy of the presenters' oral remarks should be submitted to the Executive Director no later than 12 noon, December 6, 1999, for distribution to Council members for review prior to the meeting. Physicians and organizations not scheduled to speak may also submit written comments to the Executive Director and Council members. The meeting is open to the public, but attendance is limited to the space available.

(Section 1868 of the Social Security Act (42 U.S.C. 1395ee) and section 10(a) of Public Law 92-463 (5 U.S.C. App. 2, section 10(a)); 45 C.F.R. Part 11)

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

Dated: November 10, 1999.

Nancy-Ann DeParle,

Administrator, Health Care Financing Administration.

[FR Doc. 99-30441 Filed 11-19-99; 8:45 am]

BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request, Training Tomorrow's Scientists: Linking Minorities and Mentors Through the Web

SUMMARY: Under the provisions of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Office of Behavioral and Social Sciences Research, Office of the Director, National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request to review