tracking under tracking provisions revised by FDAMA. 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 statute, regulations, or both. This is a Level 1 guidance. Public comment prior to implementation of this guidance document is not required because the guidance is needed to implement new statutory tracking requirements enacted by FDAMA. The agency is providing for a comment period of 60 days after the date of publication of the **Federal Register** notice of availability for the document.

II. Electronic Access

In order to receive the guidance entitled ''Guidance on Medical Device Tracking'' via your fax machine, call the CDRH Facts-On-Demand (FOD) system at 800.899.0381 or 301.827.0111 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 (169) followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so by using the World Wide Web (WWW). The Center for Devices and Radiological Health (CDRH) maintains an entry on the WWW for easy access to information including text, graphics, and files that may be downloaded to a PC with access to the WWW. Updated on a regular basis, the CDRH Home Page includes ''Guidance on Medical Device Tracking,'' 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. ''Guidance on Medical Device Tracking'' will be available at http://www.fda.gov/cdrh.

A text-only version of the CDRH Web site is also available from a computer or VT-100 compatible terminal by dialing 800–222–0185 (terminal settings are 8/1/N). Once the modem answers, press Enter several times and then select menu choice 1: FDA BULLETIN BOARD SERVICE. From there follow instructions for logging in, and at the BBS TOPICS PAGE, arrow down to the FDA home page (do not select the first CDRH entry). Then select Medical Devices and Radiological Health. From there select CENTER FOR DEVICES AND RADIOLOGICAL HEALTH for general information, or arrow down for specific topics.

III. Comments

Interested persons may, by or before May 4, 1998 submit to the Dockets Management Branch (address above) written comments regarding this guidance. Two copies of any comments are to be submitted, 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 guidance document and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 25, 1998.

D.B. Burlington,

Director, Center for Devices and Radiological Health.

[FR Doc. 98–5519 Filed 2–27–98; 3:14 pm]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–1036–N]

Medicare Program; March 16–17, 1998, 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 March 16, 1998, from 9:00 a.m. until 5 p.m., March 17, 1998, from 8:30 a.m. until 12:00 noon e.s.t.

ADDRESSES: The meeting will be held in Room 800, 8th Floor, Hubert H. Humphrey Building, 200 Independence Avenue, SW, Washington, DC 20201.

FOR FURTHER INFORMATION CONTACT: Jeffrey Kang, M.D., Executive Director, Practicing Physicians Advisory Council, Room 435–H, Hubert H. Humphrey Building, 200 Independence Avenue, S.W., Washington, DC 20201, (202) 690–7874.

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: Richard Bronfman, D.P.M.; Wayne R. Carlsen, D.O.; Gary C. Dennis, M.D.; Mary T. Herald, M.D.; Ardis Hoven, M.D.; Sandral Hullett, M.D. (Renominated-Pending Selection); Jerilynn S. Kaibel, D.C.; Marie G. Kuffner, M.D.; Marc Lowe, M.D.; Derrick K. Latos, M.D.; Susan Schooley, M.D.; Maisie Tam, M.D.; and Kenneth M. Viste, Jr., M.D. (Renominated-Pending Selection). The chairperson is Kenneth M. Viste, Jr., M.D.

Council members will receive an update on Medicare+Choice Program and Children's Health Initiative. The agenda will provide for discussion and comment on the following topics:

- Documentation Guidelines.
- Practice Expense.
- Physician Supervision of Allied Health Professions.

Individuals or organizations that wish to make 5-minute oral presentations on the agenda issues should contact the Executive Director by 12 noon, March 6, 1998, to be scheduled. The number of oral presentations may be limited by the time available. A written copy of the oral remarks should be submitted to the Executive Director no later than 12 noon, March 12, 1998. Anyone who is

not scheduled to speak may submit written comments to the Executive Director by 12:00 noon, March 12, 1998. 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 Pub. L. 92–463 (5 U.S.C. App. 2, section 10(a)); 45 CFR 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: February 26, 1998.

Nancy-Ann Min DeParle,

Administrator, Health Care Financing Administration.

[FR Doc. 98–5637 Filed 2–27–98; 4:20 pm]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request; ''Transmission and Linkage Analysis of Alcoholism in a Southwestern American Indian Tribe; Collection of EEG Phenotypes Associated With Alcoholism''

SUMMARY: Under the provisions of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the National Institute on Alcohol Abuse and Alcoholism (NIAAA), National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection was previously in the **Federal Register** on July 1, 1997, and allowed 60 days for public comment. There were two or three telephone inquiries asking which tribes were involved, who was doing the work, and which data collection instruments were being used, no public comments were received. The purpose of this notice is to allow an additional 30 days for public comment.

The NIH may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after Dec. 31, 1999, unless it displays a currently valid OMB control number.

Proposed Collection

Title: ''Transmission and Linkage Analysis of Alcoholism in a Southwestern American Indian Tribe; Collection of EEG Phenotypes Associated with Alcoholism''. Type of Information Collection request: New. Need and Use of Information Collection: The information proposed for collection in this study will be used by the NIAAA to determine resting EEG and ERP phenotypes in large American Indian families, correlate this information with psychiatric diagnoses from previous studies, and perform linkage analysis in order to map the genes for these phenotypes which appear to confer vulnerability to alcoholism in Caucasians. There are obvious great advantages in studying the large families the NIAAA already contacted, psychiatrically interviewed, and genotyped. The NIAAA hypothesizes that this EEG family study will enable elucidation of the transmission and linkage of alcoholism vulnerability in this tribe. The intent is to identify subgroups of American Indian alcoholics who may be more responsive to particular treatment of prevention strategies.

Frequency of Response: On Occasion. Affected Public: Individuals. *Type of Respondents:* Native American adults. *Estimated Number of Respondents:* 400. *Estimated Number of Responses per Respondent:* 1. *Average Burden Hours per Response:* 3.25. *And Estimated Total Annual Burden Hours Requested:* 1300. There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

The annual burden estimates are as follows:

Type and number of respondents	Responses per respondent	Total responses	Hour	Total hours
Clients—400	1	400	3.25	1300
Total Number of Respondents: 400.				
Total Number of responses: 400.				
Total Hours: 1300.				

Request for Comments

Comments are invited on: (a) Whether the proposed collection is necessary, including whether the information has practical use; (b) ways to enhance the clarity, quality, and use of the information to be collected; (c) the accuracy of the agency estimate of burden of the proposed collection; and (d) ways to minimize the collection burden of the respondents. Send written comments to Ms. Ronni Nelson, Laboratory of Neurogenetics, Division of Intramural Clinical and Biological Research, NIAAA, NIH, 12420 Parklawn Drive, Suite 451, Rockville, Maryland 20852.

Direct Comments To OMB

Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time should be directed to the Office of Management and Budget, Office of Regulatory Affairs, New Executive Office Building, Room 10235, Washington, D.C. 20503, Attention: Desk Officer for NIH.

FOR FURTHER INFORMATION: To request more information on the proposed project or to obtain a copy of the data collection plans, contact Ms. Ronni Nelson, Laboratory of Neurogenetics, Division of Intramural Clinical and Biological Research (DICBR), NIAAA, 12420 Parklawn Drive, Suite 451, Rockville, Maryland 20852, or call non-toll-free number (301) 443–5781.

COMMENTS DUE DATE: Comments regarding this information collection are best assured of having their full effect if received on or before April 3, 1998.

Dated: February 18, 1998.

Martin K. Trusty,

Executive Officer, NIAAA.

[FR Doc. 98–5587 Filed 3–3–98; 8:45 am]

BILLING CODE 4140–01–M