## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Care Financing Administration

**[HCFA–1078–N]**

### Medicare Program; September 27 and 28, 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 September 27, 1999, from 8:30 a.m. until 5 p.m., and September 28, 1999, from 8:30 a.m. until 1:00 p.m., e.d.t.

**ADDRESSES:** The meeting will be held in the Multipurpose Room/Auditorium, 1st Floor, Health Care Financing Administration Building, 7500 Security Boulevard, Baltimore, Maryland 21244 on the 27th and in the 1st Floor Media Room on the 28th.

**FOR FURTHER INFORMATION CONTACT:** Aron Primack, MD, MA, FACP, 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 no 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, M.D.; Richard Bronfman, D.P.M.; Wayne R. Carlsen, D.O.; Mary T. Herald, M.D.; Sandral Hullett, M.D.; Stephen A. Imbeau, M.D.; Jerilynn S. Kaibel, DC; Marie G. Kuffner, M.D.; Derrick K. Latos, M.D.; Dale Lervick, O.D.; Sandra B. Reed, M.D.; Susan Schooley, M.D.; Maisie Tam, M.D.; Victor Vela, M.D.; and Kenneth M. Viste, Jr., M.D. The Council chairperson is Marie G. Kuffner, M.D.

Council members will be updated on Managed Care Provider Protections under Medicare+Choice, Documentation Guidelines, Program Fraud and Abuse, Physicians Regulatory Issues Team (PRIT), and Medicare Reform Packet Summary Information.

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

- Practice Expense and Medicare Fee Schedule Changes for 2,000
- Rural Health Clinic Issues
- Carrier Advisory Committees and Provider Input
- Nursing Home Quality of Care Initiatives
- Insurance Plan Conflicts Regarding Co-payments

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, September 8, 1999, to be scheduled. 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, September 15, 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 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: August 30, 1999.

**Michael M. Hash,**

*Deputy Administrator, Health Care Financing Administration.*

[FR Doc. 99–23121 Filed 9–3–99; 8:45 am]

**BILLING CODE 4120–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### National Heart, Lung, and Blood Institute; Proposed Collection; Comment Request; Women's Health Initiative Observational Study

**SUMMARY:** In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, Office of the Director, the National Heart, Lung, and Blood Institute (NHLBI), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

**Proposed collection**

*Title:* Women's Health Initiative (WHI) Observational Study. *Type of Information Collection Request:* Revision OMB #0925–0414 exp: 06/00. *Need for Use of Information Collection:* This study will be used by the NIH to evaluate risk factors for chronic disease among older women by developing and following a large cohort of postmenopausal women and relating subsequent disease development to baseline assessments of historical, physical, psychosocial, and physiologic characteristics. In addition, the observational study will complement the clinical trial (which has received clinical exemption) and provide additional information on the common causes of frailty, disability and death for postmenopausal women, namely, coronary heart disease, breast and colorectal cancer, and osteoporotic fractures. *Frequency of Response:* On occasion. *Affected Public:* Individuals and physicians. *Type of Respondents:* Women, next-of-kin, and physician's

office staff. The annual reporting burden is as follows:

| Type of respondents | Estimated number of respondents | Estimated number of responses per respondent | Average burden hours per response | Estimated total annual burden hours requested |
|---|---|---|---|---|
| OS Participants | 82,044 | .96876 | .4557 | 36,219 |
| Next-of-kin | 2,741 | 1 | .0835 | 229 |
| Physician's Office Staff | 226 | 1 | .0835 | 19 |
| Total | | | | 36,467 |

The annualized cost burden is $365,428.

There are no annual Capital Costs, Operating Costs and/or Maintenance Costs to report.

**Request for Comments**

Written comments and/or suggestions from the public and affected agencies should address one or more of the following points: (1) Evaluate whether the proposed collection is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

**FOR FURTHER INFORMATION CONTACT:** To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Dr. Linda Pottern, Project Officer, Women's Health Initiative Program Office, 6705 Rockledge Drive, 1 Rockledge Centre, Suite 300, MSC 7966, Bethesda, MD 20892–7966, or call (301) 402–2900 or E-mail you request, including your address to: Linda__Pottern@nih.gov.

**Comments Due Date**

Comments regarding this information collection are best assured of having their full effect if received on or before November 8, 1999.

Dated: August 27, 1999.

**Donald P. Christoferson,**

*Executive Officer, National Heart, Lung, and Blood Institute.*

[FR Doc. 99–23220 Filed 9–3–99; 8:45 am]

**BILLING CODE 4140–01–M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Public Health Service

### National Institute of Environmental Health Sciences, National Toxicology Program, Request for Data and Suggested Expert Panelists for Evaluation of the Current Status of the Frog Embryo Teratogenesis Assay—Xenopus (FETAX)

**Background**

The Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM), with participation by 14 Federal regulatory and research agencies and programs, was established in 1997 to facilitate cross-agency communication and coordination on issues relating to validation, acceptance, and national/international harmonization of toxicological test methods. The Committee seeks to promote the scientific validation and regulatory acceptance of toxicological test methods that will enhance agencies' ability to assess risks and make decisions, and that will refine, reduce, and replace animal use whenever possible. The National Toxicology Program Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM), provides administrative and technical support for ICCVAM, and serves as a communication and information resource. NICEATM and ICCVAM collaborate to carry out related activities needed to develop, validate, and achieve regulatory acceptance of new and improved test methods applicable to Federal agencies. These activities may include:

Test Method Workshops, which are convened as needed to evaluate the adequacy of current methods for assessing specific toxicities, to identify areas in need of improved or new testing methods, and to identify research efforts that may be needed to develop a new test method.

Expert Panel Meetings, which are typically convened to evaluate the validation status of a method following the completion of initial development and pre-validation studies. An Expert Panel is asked to recommend additional validation studies that might be helpful in further characterizing the usefulness of a method, and to identify any additional research and development efforts that might enhance the effectiveness of a method.

Independent Peer Review Panel Meetings, which are typically convened following the completion of comprehensive validation studies on a test method. Peer review panels are asked to develop scientific consensus on the usefulness and limitations of test methods to generate information for specific human health and/or ecological risk assessment purposes. Following the independent peer review of a test method, ICCVAM forwards recommendations on their usefulness to agencies for their consideration. Federal agencies then determine the regulatory acceptability of a method according to their mandates.

**Evaluation of FETAX**

ICCVAM and NICEATM are currently planning an Expert Panel Meeting to assess the current validation status of the Frog Embryo Teratogenesis Assay—*Xenopus* (FETAX), a method proposed for evaluating the developmental toxicity potential of chemicals (Bantle JA, 1995, FETAX—A Developmental Toxicity Assay Using Frog Embryos, *Fundamentals of Aquatic Toxicology,* 2nd ed., G.M. Rand, ed, Taylor and Francis, USA. pp. 207–230). Possible applications of FETAX to human health and environmental assessments may include screening and prioritizing compounds for further testing, evaluating complex mixtures and environmental samples, and as supplemental information in a weight-of-evidence evaluation of toxicity hazards. NICEATM is preparing a background document summarizing the initial studies and the performance characteristics of FETAX. The Expert Panel will evaluate the conclusions presented in the background document