

Corporate Blvd., Rockville, MD 20850, 301-594-5072, FAX 301-480-4224.

SUPPLEMENTARY INFORMATION: FDA, in cooperation with HIMA, is holding a public workshop to discuss the implementation of a different process for the premarket approval of class III devices by means of a PDP. Section 515(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e (f)) (the act) provides for a product development protocol as an alternate means of premarket approval of class III medical devices. Although the PDP has existed as a means of approval of a medical device since the Medical Device Amendments of 1976 (Pub. L. 94-295) to the act, the PDP has never been completely implemented. As part of its reengineering initiative, the Center for Devices and Radiological Health (CDRH) of FDA established the PDP Reengineering Team, comprised of FDA staff, in consultation with industry representatives, to develop an efficient, practical PDP process.

The intent of the PDP process is to substitute the conventional device approval model, the sequential process of clinical investigation followed by a premarket approval application, with an early interaction between the sponsor and FDA to produce a focused product development plan that merges the two steps. A PDP team has developed guidelines for creating this focused development protocol that will be described at the public workshop. Workshop participants will have ample opportunity to ask questions as the new PDP process is described and case studies on particular examples of class III devices are presented. Background information, a detailed flow chart, and a descriptive narrative regarding the proposed PDP process can be found at the FDA/CDRH Web site at the address below.

Additional information is available on the FDA Web page (www.fda.gov/cdrh/

pdp/pdp.html) or the HIMA Web page (www.himanet.com).

Dated: September 30, 1997.

Joseph A. Levitt,

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

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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) will publish periodic summaries of proposed projects being developed for submission to 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 Projects

1. Project To Assess Bi/Multilingual Services Offered at Selected Community and Migrant Health Centers—NEW

Recognizing the importance of language-appropriate services to full and effective health care provision, the Office of Minority and Women's Health in the Bureau of Primary Health Care [BPHC], Health Resources and Services Administration [HRSA], proposes to conduct a voluntary telephone survey to assess the composition and provision of bi/multilingual services at a sample of 40 Community and Migrant Health Centers [C/MHCs] selected from those C/MHCs identified as likely to be serving high percentages of people who speak languages other than English. This effort was developed so that information could be gathered to assist the field, funding agency staff, and policymakers in better understanding what methods are being used to provide services to these populations, what works, what does not, and barriers and facilitators to effective health service provision for speakers of languages other than English.

The information gathered will provide HRSA with an information base upon which to build in making future program decisions regarding C/MHC resource and staffing needs in order to reduce or eliminate the barriers to health care often faced by non-or limited-English-speaking populations. The end result of the program will be to assist the funding agency to help C/MHCs and by extension, other providers of health care for non-or limited-English speaking populations to provide appropriate services. An estimate of the hour burden for the 40 C/MHC Directors selected for the survey is shown below.

Form	Number of respondents	Responses per respondent	Hours per response	Total hour burden
Bi/Multilingual Services Survey	40 C/MHC Directors	1	2	80

Send comments to Patricia Royston, HRSA Reports Clearance Officer, Room 14-36, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: October 9, 1997.

Jane Harrison,

Acting Director, Division of Policy Review and Coordination.

[FR Doc. 97-27429 Filed 10-15-97; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Council; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), announcement is

made of the following National Advisory body scheduled to meet during the month of November 1997:

Name: National Advisory Council on Nurse Education and Practice.

Date and Time: November 20, 1997, 8:30 a.m. to 5:00 p.m.; November 21, 1997, 8:30 a.m. to 3:00 p.m.

Place: Chesapeake Room, Silver Spring Holiday Inn, 8777 Georgia Avenue, Silver Spring, Maryland 20910.

The meeting is open to the public.

Agenda: Updates on and discussion of Agency, Bureau and division activities, and the legislative and budget status of programs; overview and review of clinical nurse specialist workforce trends, implication and options for the future; review of diversity workgroup with recommendations for a national agenda.

Anyone wishing to obtain a roster of members, minutes of meetings, or other relevant information should write or contact Ms. Elaine G. Cohen, Executive Secretary, National Advisory Council on Nurse Education and Practice, Parklawn Building, Room 9-35, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone (301) 443-5786.

Agenda items are subject to change as priorities dictate.

Dated: October 9, 1997.

Jane M. Harrison,

Acting Director, Division of Policy Review and Coordination.

[FR Doc. 97-27430 Filed 10-15-97; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Announcement of Technical Assistance Workshops for Programs Administered by the Division of Disadvantaged Assistance, Bureau of Health Professions

SUMMARY: The Health Resources and Services Administration (HRSA) announces that technical assistance workshops will be held for new and renewal applicants for the fiscal year (FY) 1998 competitive grant cycles for the Health Careers Opportunity Program.

FOR FURTHER INFORMATION CONTACT: Division of Disadvantaged Assistance, Bureau of Health Professions, Health Resources and Services Administration, Parklawn Building, Room 8A-09, 5600 Fishers Lane, Rockville, Maryland 20857, (301) 443-4493 or (301) 443-2100.

SUPPLEMENTARY INFORMATION: The Division of Disadvantaged Assistance will be conducting application preparation technical assistance workshops for new and renewal applicants for the FY 1998 competitive grant cycles for the Health Careers Opportunity Program. The workshops are scheduled as follows:

DoubleTree Hotel, Rockville, MD, (301) 468-1100, October 9-10, 1997; Harvey Hotel, Atlanta, GA, (770) 955-1700, October 16-17, 1997; Embassy Suites, Houston, TX, (713) 995-0123, October 20-21, 1997; and Embassy Suites Airport, Los Angeles, CA, (310) 215-1000, October 23-24, 1997.

The program will commence at 8:30 a.m. each day. Attendees must make their own hotel reservations. Please reference the "Health Careers Opportunity Program Technical Assistance Workshops." Expenses incurred by the attendees will not be supported by the Federal Government. Participation in the technical assistance workshops does not assure approval and funding of applications submitted for competitive review.

Dated: October 9, 1997.

Jane M. Harrison,

Acting Director, Division of Policy Review and Coordination.

[FR Doc. 97-27428 Filed 10-15-97; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of AIDS Research; Notice of Meeting of the Office of AIDS Research Advisory Council

Pursuant to the Federal Advisory Committee Act, as amended, notice is hereby given of the Fifth meeting of the Office of AIDS Research Advisory Council (OARAC) on Friday, October 17, 1997. The meeting will be held at the National Institutes of Health (NIH), 9000 Rockville Pike, Building 31, C-Wing, Sixth Floor, Conference Room 10.

The Office of AIDS Research (OAR) is responsible for planning, coordination, and evaluation of the NIH AIDS research program. The OARAC was established to advise the Director, OAR, regarding these activities.

The Council meeting will be open to the public on October 17 from 9:00 a.m. until 4:00 p.m. The agenda includes: FY 1998 budgets for NIH AIDS research;

updates on various OAR sponsored workshops and conferences; reports on activities of Advisory Council Working Groups and the NIH Vaccine Research Committee; and a presentation by the Director, Center for Scientific Review (CSR), who will discuss recent changes and future plans at the CSR.

In accordance with the provisions set forth in section 552b(c)(9)(B), Title 5 United States Code and section 10(d) of the Federal Advisory Committee Act, Public Law 92-463, as amended, the meeting will be closed to the public from 4:00 p.m. until adjournment for discussions of which the premature disclosure is likely to significantly frustrate implementation of NIH's research initiatives by impeding the timely announcement of those initiatives.

Copies of the meeting agenda and the roster of council members will be furnished upon request by Ms. Linda Jackson, Program Coordinator, Office of AIDS Research, National Institutes of Health, Building 31, Room 4B54, 9000 Rockville Pike, Bethesda, Maryland 20892, Telephone (301) 402-3357, FAX (301) 402-3360. Individuals who plan to attend the open session and need special assistance, such as sign language interpretation or other reasonable accommodations, should contact Ms. Jackson.

This notice is published less than 15 days prior to the meeting due to the urgent need to meet timing limitations imposed by the review and funding cycle.

Dated: October 10, 1997.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 97-27451 Filed 10-15-97; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meeting

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting that is being held to review grant applications:

Health Promotion and Disease Prevention Initial Review Group