

(BPAC) whether FDA should support conversion from the ABC Codabar system to the ISBT 128 system. BPAC voted in favor of FDA supporting the transition to the new coding system. The change to ISBT 128 is also supported by the American Association of Blood Banks (AABB), American Red Cross (ARC), America's Blood Centers (ABC), and the Department of Defense (DoD).

In December 1996, ICCBBA held an ISBT 128 Consensus Conference in Washington, DC, to provide an opportunity for dialogue among the affected industry groups and FDA. Although consensus was obtained for use of ISBT 128 as proposed in the draft document, concerns were expressed regarding implementation timeframes and costs of implementation to hospital transfusion services. The ICCBBA submitted a draft of the industry consensus document to FDA with the recommendation that it serve as the basis for current FDA guidance on blood and blood component labeling. The agency is making this draft document describing the use of ISBT 128 in the labeling of blood and blood components available for public comment to assist the agency in determining whether to update its guidance on blood labeling.

Under FDA's "Good Guidance Practices" (GGP's), published in the **Federal Register** on February 27, 1997 (62 FR 8961), this draft document is being made available for public comment. The GGP's provide that members of the public may comment on and suggest areas for guidance development or revision and submit draft guidance for possible adoption by the agency. In its discretion, FDA may choose to publish for comment such a draft document as the agency considers whether or not to develop or revise guidance. In this instance, FDA believes it would be helpful to obtain public comment on the ISBT 128 coding system as the agency considers updating its guidance on blood labeling.

## II. Request for Comments

FDA is making available for comment this draft document entitled "United States Industry Consensus Standard for the Uniform Labeling of Blood and Blood Components Using *ISBT 128*." In addition to comments about the adoption of ISBT 128 as a blood coding system and the proposed label format, FDA specifically requests comments on the following: (1) The proposed "rule-based" system for naming blood components since adoption of ISBT 128 would entail changing some of the currently accepted names of blood components, e.g., Platelets, Pheresis

would become Apheresis Platelets; and (2) timeframes and procedures for the transition and full implementation of ISBT 128. FDA notes that its intent would be to initiate changes to language in order to permit the use of the new system if FDA determines the ISBT 128 is an acceptable coding system. Thus, in a future document FDA may consider changes to accommodate the new system of blood component bar coding, identification, and naming.

This draft document is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this draft document. Written comments may be submitted at any time, however, comments should be submitted by February 25, 1999, to ensure adequate consideration in the preparation of guidance. Received comments will be considered in determining whether to issue 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. A copy of the draft document and received comments are available for public examination in the office above between 9 a.m. and 4 p.m., Monday through Friday.

## III. Electronic Access

Persons with access to the Internet may obtain the draft document using the World Wide Web (WWW). For WWW access, connect to CBER at "http://www.fda.gov/cber/guidelines.htm".

Dated: November 18, 1998.

**William B. Schultz,**

*Deputy Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Care Financing Administration

[HCFA-R-50 and HCFA-1515/1572]

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

**AGENCY:** Health Care Financing Administration, HHS.

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, is publishing the

following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this 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: Medical Records Review Under PPS and Supporting Regulations in 42 CFR 412.40-412.52; Form No.: HCFA-R-0050 (OMB# 0938-0359); Use: Peer Review Organizations (PRO) are authorized to conduct medical review activities under the Prospective Payment System (PPS). In order to conduct the medical review activities we depend upon hospitals to make available medical records. PROs ensure that admissions are medically necessary, provided in the appropriate setting, and that they meet acceptable standards of quality.; Frequency: When records are reviewed; Affected Public: Business or other for profit; Number of Respondents: 7,053; Total Annual Responses: 895,419; Total Annual Hours: 26,865.

2. Type of Information Collection Request: Extension of a currently approved collection; Title of Information Collection: Home Health Agency Survey and Deficiencies Report, Home Health Functional Assessment Instrument and Supporting Regulations in 42 CFR 484.10-484.52; Form No.: HCFA-1515/1572 (OMB# 0938-0355); Use: In order to participate in the Medicare program as a Home Health Agency (HHA) provider, the HHA must meet Federal Standards. These forms are used to record information about patients' health and provider compliance with requirements.; Frequency: Annually; Affected Public: Business or other for-profit, Not-for-profit institutions; Number of Respondents: 9,942; Total Annual Responses: 19,884; Total Annual Hours: 19,884.

To obtain copies of the supporting statement and any related forms 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, phone number, OMB number, and HCFA document identifier, to Paperwork@hcf.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: OMB Human Resources and Housing Branch, Attention: Allison Eydt, New Executive Office Building, Room 10235, Washington, D.C. 20503.

Dated: November 17, 1998.

**John P. Burke III,**

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

[FR Doc. 98-31578 Filed 11-25-98; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Cancer Institute; Notice of 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 meeting of the National Cancer Advisory Board.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(6) and 552b(c)(9)(B), Title 5 U.S.C. and section 10(d) of the Federal Advisory Committee Act, as amended, for discussions pertaining to NCI personnel and programmatic issues. These discussions could reveal information of a personal nature where disclosure would constitute a clearly unwarranted invasion of personal privacy and would be likely to significantly frustrate the subsequent implementation of personnel and programmatic recommendations made during these discussions.

*Name of Committee:* National Cancer Advisory Board.

*Date:* December 8-9, 1998.

*Open:* December 8, 1998, 8:30 am to 4:00 pm and December 9, 1998, 8:30 am to 1:00 pm.

*Agenda:* Report of the Director, National Cancer Institute; Overview of Board of Scientific Advisors activities; Intramural and Extramural Program Overviews and Updates; Presentations by various NCI working groups on current and proposed program activities, projects and initiatives; other NCAB business.

*Place:* National Cancer Institute, 9000 Rockville Pike, Building 31, C Wing, 6th Floor, Conference Room 10, Bethesda, MD 20892.

*Closed:* December 8, 1998, 4:00 pm to 5:30 pm.

*Agenda:* To review and evaluate discussion of Intramural site visits, proprietary, programmatic and personnel issues. Review and discussion of Extramural proprietary, programmatic and personnel issues.

*Place:* National Cancer Institute, 9000 Rockville Pike, Building 31, C Wing, 6th Floor, Conference Room 10, Bethesda, MD 20892.

*Contact Person:* Dr. Marvin R. Kalt, Executive Secretary, Division of Extramural Activities, National Cancer Institute, National Institutes of Health, Executive Plaza North, Suite 600, 6130 Executive Boulevard, Rockville, MD 20892, (301) 496-5147.

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

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: November 19, 1998.

**LaVerne Y. Stringfield,**

*Committee Management Officer, NIH.*

[FR Doc. 98-31635 Filed 11-25-98; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Nation Human Genome Research Institute; National Bioethics Advisory Commission; Notice of Workshop

Notice is hereby given of the meeting on Involving Diverse Communities in Genetics Research, sponsored by the National Human Genome Research Institute (NHGRI), and the National Bioethics Advisory Commission, November 23, 1998, 8:30 a.m. to 5:30 p.m., at the Natcher Building, Room D, on the NIH campus. Registration is required.

To register and for further information, contact Ms. Hope Kott, 301 770-3153.

Individuals who plan to attend and need special assistance, such as sign

language interpretation or other reasonable accommodations, should contact Ms. Kott, 301 770-3153 by November 19.

(Catalogue of Federal Domestic Assistance Program No. 93.172, Human Genome Research.)

Date: November 12, 1998.

**Kathy Hudson,**

*Assistant Director for Policy and Public Affairs, NHGRI.*

[FR Doc. 98-31639 Filed 11-25-98; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute on Aging; Notice of Closed Meetings

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 meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Institute on Aging Special Emphasis Panel, Degenerative and Dementing Diseases of Aging.

*Date:* December 1, 1998.

*Time:* 12:00 pm to 5:00 pm.

*Agenda:* To review and evaluate grant applications.

*Place:* Chevy Chase Holiday Inn, Chevy Chase, MD 20815.

*Contact Person:* Paul Lenz, Scientific Review Administrator, The Bethesda Gateway Building, 7201 Wisconsin Avenue/Suite 2C212, Bethesda, MD 20892, (301) 496-9666.

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

*Name of Committee:* National Institute on Aging Special Emphasis Panel, Patient-Oriented Research in Aging.

*Date:* December 4, 1998.

*Time:* 3:00 pm to 4:00 pm.

*Agenda:* To review and evaluate grant applications.

*Place:* Gateway Building, Room 2C-212, National Institute on Aging, National Institutes of Health, Bethesda, MD 20892 (Telephone Conference Call).

*Contact Person:* Mary Ann Guadagno, Scientific Review Administrator, The