

comparison to a legally marketed predicate.

This draft guidance represents the agency's current thinking on labeling of diagnostic performance for new laboratory tests. 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.

The agency has adopted good guidance practices (GGP's), which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (62 FR 8961, February 27, 1997). This draft guidance is issued as a Level 1 guidance consistent with GGP's.

II. Electronic Access

In order to receive the "Draft Guidance on Labeling for Laboratory Tests" via your fax machine, call the CDRH Facts-On-Demand system at 800-899-0381 or 301-827-0111 from a touch-tone telephone.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 second voice prompt press 2, and then enter the document number (1352) followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the draft guidance may also do so using the World Wide Web (WWW). CDRH maintains an entry on the WWW for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the WWW. Updated on a regular basis, the CDRH home page includes the "Draft Guidance on Labeling for Laboratory Tests," device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved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".

III. Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this draft guidance. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments should be identified with the docket number found in brackets in the heading of this document. A copy of the draft guidance and received comments are available for public examination in the Dockets Management Branch

between 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 24, 1999.

Linda S. Kahan,

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

[FR Doc. 99-23229 Filed 9-7-99; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA-R-285]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Health Care Financing Administration, HHS.

ACTION: Comment request.

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.

Title of Information Collection Request: Extension of a currently approved collection;

Title of Information Collection: Request for Retirement Benefit Information;

Form No.: HCFA-R-285 (OMB# 0938-0769);

Use: This form will be used to obtain information regarding whether a beneficiary is receiving retirement payments based on State or local government employment, how long the claimant worked for the State or local government employer, and whether the former employer or pension plan subsidizes the beneficiary's Part A premium. The purpose in collecting this information is to determine and provide those eligible beneficiaries, with free Part A Medicare coverage;

Frequency: On Occasion;
Affected Public: State, Local or Tribal Government, and Individuals or Households;

Number of Respondents: 1,500;
Total Annual Responses: 1,500;
Total Annual Hours: 375.

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@hcfa.gov, or call the Reports Clearance Office on (410) 786-1326. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards, Attention: Dawn Willingham, Room N2-14-26, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: August 26, 1999.

John P. Burke III,

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

[FR Doc. 99-23312 Filed 9-7-99; 8:45 am]

BILLING CODE 4120-03-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Council; 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 following Health Professions and Nurse Education Special Emphasis Panel (SEP) Meetings.

Name: Residency Training in Primary Care Peer Review Group I.

Date and Time: December 6-9, 1999, 8:00 a.m. to 6:00 p.m.

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

Open on: December 6, 1999, 8:00 a.m. to 10:00 a.m.

Closed on: December 6, 1999, 10:00 a.m. to 6:00 p.m.; December 7-9, 1999, 8:00 a.m. to 6:00 p.m.

Name: Residency Training in Primary Care Peer Review Group II.

Date and Time: December 13-16, 1999, 8:00 a.m. to 6:00 p.m.

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

Open on: December 13, 1999, 8:00 a.m. to 10:00 a.m.

Closed on: December 13, 1999, 10:00 a.m. to 6:00 p.m.; December 14–16, 1999, 8:00 a.m. to 6:00 p.m.

Name: Faculty Development in Primary Care Peer Review Group.

Date and Time: January 18–21, 2000, 8:00 a.m. to 6:00 p.m.

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

Open on: January 18, 2000, 8:00 a.m. to 10:00 a.m.

Closed on: January 18, 2000, 10:00 a.m. to 6:00 p.m.; January 19–21, 2000, 8:00 a.m. to 6:00 p.m.

Name: Quentin N. Burdick Rural Health Interdisciplinary Program Peer Review Group.

Date and Time: January 24–27, 2000, 8:00 a.m. to 6:00 p.m.

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

Open on: January 24, 2000, 8:00 a.m. to 10:00 a.m.

Closed on: January 24, 2000, 10:00 a.m. to 6:00 p.m.; January 25–27, 2000, 8:00 a.m. to 6:00 p.m.

Name: Public Health Nursing/Clinical Practice Peer Review Group.

Date and Time: January 24–27, 2000, 8:00 a.m. to 6:00 p.m.

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

Open on: January 24, 2000, 8:00 a.m. to 10:00 a.m.

Closed on: January 24, 2000, 10:00 a.m. to 6:00 p.m.; January 25–27, 2000, 8:00 a.m. to 6:00 p.m.

Name: Podiatric Residency in Primary Care Peer Review Group.

Date and Time: January 31–February 3, 2000, 8:00 a.m. to 6:00 p.m.

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

Open on: January 31, 2000, 8:00 a.m. to 10:00 a.m.

Closed on: January 31, 2000, 10:00 a.m. to 6:00 p.m.; February 1–3, 2000, 8:00 a.m. to 6:00 p.m.

Name: Dentistry Public Health Peer Review Group.

Date and Time: January 31–February 3, 2000, 8:00 a.m. to 6:00 p.m.

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

Open on: January 31, 2000, 8:00 a.m. to 10:00 a.m.

Closed on: January 31, 2000, 10:00 a.m. to 6:00 p.m.; February 1–3, 2000, 8:00 a.m. to 6:00 p.m.

Name: Health Administration Traineeships and Special Projects Peer Review Group.

Date and Time: February 7–10, 2000, 8:00 a.m. to 6:00 p.m.

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

Open on: February 7, 2000, 8:00 a.m. to 10:00 a.m.

Closed on: February 7, 2000, 10:00 a.m. to 6:00 p.m.; February 8–10, 2000, 8:00 a.m. to 6:00 p.m.

Name: Predoctoral Training in Primary Care Peer Review Group.

Date and Time: February 14–17, 2000, 8:00 a.m. to 6:00 p.m.

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

Open on: February 14, 2000, 8:00 a.m. to 10:00 a.m.

Closed on: February 14, 2000, 10:00 a.m. to 6:00 p.m.; February 15–17, 2000, 8:00 a.m. to 6:00 p.m.

Name: Physicians Assistant Training Peer Review Group.

Date and Time: February 22–25, 2000, 8:00 a.m. to 6:00 p.m.

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

Open on: February 22, 2000, 8:00 a.m. to 10:00 a.m.

Closed on: February 22, 2000, 10:00 a.m. to 6:00 p.m.; February 23–25, 2000, 8:00 a.m. to 6:00 p.m.

Name: Residencies and Advanced Education in the Practice of General Dentistry Peer Review Group.

Date and Time: February 28–March 2, 2000, 8:00 a.m. to 6:00 p.m.

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

Open on: February 28, 2000, 8:00 a.m. to 10:00 a.m.

Closed on: February 28, 2000, 10:00 a.m. to 6:00 p.m.; February 29–March 2, 2000, 8:00 a.m. to 6:00 p.m.

Name: Pediatric Dentistry Peer Review Group.

Date and Time: February 28–March 2, 2000, 8:00 a.m. to 6:00 p.m.

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

Open on: February 28, 2000, 8:00 a.m. to 10:00 a.m.

Closed on: February 28, 2000, 10:00 a.m. to 6:00 p.m.; February 29–March 2, 2000, 8:00 a.m. to 6:00 p.m.

Name: Public Health Training Centers Review Group.

Date and Time: March 6–9, 2000, 8:00 a.m. to 6:00 p.m.

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

Open on: March 6, 2000, 8:00 a.m. to 10:00 a.m.

Closed on: March 6, 2000, 10:00 a.m. to 6:00 p.m.; March 7–9, 2000, 8:00 a.m. to 6:00 p.m.

Name: Public Health Special Projects Review Group.

Date and Time: March 6–9, 2000, 8:00 a.m. to 6:00 p.m.

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

Open on: March 6, 2000, 8:00 a.m. to 10:00 a.m.

Closed on: March 6, 2000, 10:00 a.m. to 6:00 p.m.; March 7–9, 2000, 8:00 a.m. to 6:00 p.m.

Name: Nursing Workforce Diversity Peer Review Group.

Date and Time: March 13–16, 2000, 8:00 a.m. to 6:00 p.m.

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

Open on: March 13, 2000, 8:00 a.m. to 10:00 a.m.

Closed on: March 13, 2000, 10:00 a.m. to 6:00 p.m.; March 14–16, 2000, 8:00 a.m. to 6:00 p.m.

Name: Centers of Excellence Review Group.

Date and Time: March 20–23, 2000, 8:00 a.m. to 6:00 p.m.

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

Open on: March 20, 2000, 8:00 a.m. to 10:00 a.m.

Closed on: March 20, 2000, 10:00 a.m. to 6:00 p.m.; March 21–23, 2000, 8:00 a.m. to 6:00 p.m.

Name: Geriatric Training Regarding Physicians and Dentists Review Group.

Date and Time: March 27–30, 2000, 8:00 a.m. to 6:00 p.m.

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

Open on: March 27, 2000, 8:00 a.m. to 10:00 a.m.

Closed on: March 27, 2000, 10:00 a.m. to 6:00 p.m.; March 28–30, 2000, 8:00 a.m. to 6:00 p.m.

Name: Geriatric Education Centers Review Group.

Date and Time: March 27–30, 2000, 8:00 a.m. to 6:00 p.m.

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

Open on: March 27, 2000, 8:00 a.m. to 10:00 a.m.

Closed on: March 27, 2000, 10:00 a.m. to 6:00 p.m.; March 28–30, 2000, 8:00 a.m. to 6:00 p.m.

Name: Health Careers Opportunity Program Review Group.

Date and Time: April 3–7, 2000, 8:00 a.m. to 6:00 p.m.

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

Open on: April 3, 2000, 8:00 a.m. to 10:00 a.m.

Closed on: April 3, 2000, 10:00 a.m. to 6:00 p.m.; April 4–7, 2000, 8:00 a.m. to 6:00 p.m.

Name: Academic Administrative Units (Departments of Family Medicine) Peer Review Group.

Date and Time: April 10–13, 2000, 8:00 a.m. to 6:00 p.m.

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

Open on: April 10, 2000, 8:00 a.m. to 10:00 a.m.

Closed on: April 10, 2000, 10:00 a.m. to 6:00 p.m.; April 11–13, 2000, 8:00 a.m. to 6:00 p.m.

Name: Advanced Nursing Education Review Group (Optional Group).

Date and Time: April 25–28, 2000, 8:00 a.m. to 6:00 p.m.

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

Open on: April 25, 2000, 8:00 a.m. to 10:00 a.m.

Closed on: April 25, 2000, 10:00 a.m. to 6:00 p.m.; April 26–28, 2000, 8:00 a.m. to 6:00 p.m.

Name: Model AHEC Review Group.

Date and Time: April 25–26, 2000, 8:00 a.m. to 6:00 p.m.

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

Open on: April 25, 2000, 8:00 a.m. to 10:00 a.m.

Closed on: April 25, 2000, 10:00 a.m. to 6:00 p.m.; April 26, 2000, 8:00 a.m. to 6:00 p.m.

Name: Basic AHEC Review Group.

Date and Time: April 27–28, 2000, 8:00 a.m. to 6:00 p.m.

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

Open on: April 27, 2000, 8:00 a.m. to 10:00 a.m.

Closed on: April 27, 2000, 10:00 a.m. to 6:00 p.m.; April 28, 2000, 8:00 a.m. to 6:00 p.m.

Name: Advanced Nursing Education Review Group I.

Date and Time: May 1–4, 2000, 8:00 a.m. to 6:00 p.m.

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

Open on: May 1, 2000, 8:00 a.m. to 10:00 a.m.

Closed on: May 1, 2000, 10:00 a.m. to 6:00 p.m.; May 2–4, 2000, 8:00 a.m. to 6:00 p.m.

Name: Advanced Nursing Education Review Group II.

Date and Time: May 8–11, 2000, 8:00 a.m. to 6:00 p.m.

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

Open on: May 8, 2000, 8:00 a.m. to 10:00 a.m.

Closed on: May 8, 2000, 10:00 a.m. to 6:00 p.m.; May 9–11, 2000, 8:00 a.m. to 6:00 p.m.

Name: Basic Nurse Education and Practice Review Group.

Date and Time: May 16–19, 2000, 8:00 a.m. to 6:00 p.m.

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

Open on: May 16, 2000, 8:00 a.m. to 10:00 a.m.

Closed on: May 16, 2000, 10:00 a.m. to 6:00 p.m.; May 17–19, 2000, 8:00 a.m. to 6:00 p.m.

Name: Allied Health Project Grants Review Group.

Date and Time: May 22–25, 2000, 8:00 a.m. to 6:00 p.m.

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

Open on: May 22, 2000, 8:00 a.m. to 10:00 a.m.

Closed on: May 22, 2000, 10:00 a.m. to 6:00 p.m.; May 23–25, 2000, 8:00 a.m. to 6:00 p.m.

Name: Chiropractic/Demonstration Review Group.

Date and Time: May 22–25, 2000, 8:00 a.m. to 6:00 p.m.

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

Open on: May 22, 2000, 8:00 a.m. to 10:00 a.m.

Closed on: May 22, 2000, 10:00 a.m. to 6:00 p.m.; May 23–25, 2000, 8:00 a.m. to 6:00 p.m.

Purpose: The Health Professions and Nurse Education Special Emphasis Panel shall advise the Director of the Bureau of Health Professions on the technical merit of grants to improve the training, distribution, utilization, and quality of personnel required to staff the Nation's health care delivery system.

Agenda: The open portion of each meeting will cover welcome and opening remarks, financial management and legislative implementation updates, and overview of the review process. The meetings will be closed at approximately 10:00 a.m. on the first day of each meeting until adjournment for the review of grant applications. The closing is in accordance with the provision set forth in section 552b(c)(6), Title 5 U.S. Code, and the Determination by the Associate Administrator for Management and Program Support, Health Resources and Services Administration, pursuant to Public Law 92–463.

Anyone wishing to obtain a roster of members or other relevant information should write or contact Mrs. Sherry Whipple, Program Analyst, Peer Review Branch, Parklawn Building, Room 8C–23, 5600 Fishers Lane, Rockville, Maryland 20857, telephone 301–443–5926.

Dated: September 2, 1999.

Jane M. Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 99–23335 Filed 9–7–99; 8:45 am]

BILLING CODE 4160–15 P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

Solicitation of Information and Recommendations for Developing OIG Compliance Program Guidance for Individual Physicians and Small Group Practices

AGENCY: Office of Inspector General (OIG), HHS.

ACTION: Notice.

SUMMARY: This **Federal Register** notice seeks the input and recommendations of interested parties as the OIG considers developing a compliance program guidance for individual and small group physician practices, especially those serving Medicare and other Federal

health care program beneficiaries. Many physicians have expressed an interest in better protecting their practices from the potential for fraud and abuse. While the OIG believes that the great majority of physicians are honest and share our goal of protecting the integrity of Medicare and other Federal health care programs, all health care providers have a duty to reasonably ensure that the claims submitted to Medicare and other Federal health care programs are true and accurate. The development of a comprehensive, effective compliance program by individual physicians and small group practices will go a long way toward achieving this goal. Over the past two years, the OIG has developed guidances for hospitals, clinical laboratories, home health agencies, third-party medical billing companies and durable medical equipment companies. While the OIG has previously referred physicians and physician groups to the OIG's compliance guidance for third-party medical billing companies for guidance regarding the risk areas that are most directly relevant to physicians, we have received continued interest from physicians for a specific guidance directed at their individual practices. In order to provide such meaningful guidance to individual and small group physician practices, the OIG is soliciting comments, recommendations and other suggestions from concerned parties and organizations on how best to develop a compliance program guidance to reduce the potential for fraud and abuse in the individual or small group physician practice, as well as feedback as to whether such a guidance would be beneficial to physician practices.

DATES: To assure consideration, comments must be delivered to the address provided below by no later than 5 p.m. on November 8, 1999.

ADDRESSES: Please mail or deliver your written comments, recommendations and suggestions to the following address: Department of Health and Human Services, Office of Inspector General, Attention: OIG–7–CPG, Room 5246, Cohen Building, 330 Independence Avenue, S.W., Washington, D.C. 20201.

We do not accept comments by facsimile (FAX) transmission. In commenting, please refer to the file code OIG–7–CPG. Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, in Room 5541 of the Office of Inspector General at 330 Independence Avenue, S.W., Washington, D.C. 20201 on Monday