

such approach satisfies the requirements of the applicable statutes and regulations.

## II. Comments

Interested persons may, at any time, submit written comments on the guidance to the Dockets Management Branch (address above). 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 and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

## III. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/cder/guidance/index.htm>, <http://www.fda.gov/ohrms/dockets/default.htm>, or <http://www.fda.gov/cber/guidelines.htm>.

Dated: May 17, 2001.

**Margaret M. Dotzel,**

*Associate Commissioner for Policy.*

[FR Doc. 01-13249 Filed 5-24-01; 8:45 am]

BILLING CODE 4160-01-S

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Care Financing Administration

[Document Identifier: HCFA-R-216]

#### Agency Information Collection Activities: Proposed Collection; Comment Request

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

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.

*Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Procedures for Advisory Opinions Concerning Physician Referrals and Supporting Regulations in 42 CFR 411.370 through 411.389; *Form No.:* HCFA-R-216 (OMB# 0938-0714); *Use:* Section 4314 of Public Law 105-33, in establishing section 1877(g)(6) of the Act, requires the Department to provide advisory opinions to the public regarding whether a physician's referrals for certain designated health services are prohibited under the other provisions in section 1877 of the Act. These regulations provide the procedures under which members of the public may request advisory opinions from HCFA. Because all requests for advisory opinions are purely voluntary, respondents will only be required to provide information to us that is relevant to their individual requests.; *Frequency:* On occasion; *Affected Public:* Not-for-profit institutions, Business or other for-profit, and Individuals and Households; *Number of Respondents:* 200; *Total Annual Responses:* 200; *Total Annual Hours:* 2,000.

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](mailto: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, HCFA-R-216, Room N2-14-26, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: May 17, 2001.

**John P. Burke III,**

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

[FR Doc. 01-13207 Filed 5-24-01; 8:45 am]

BILLING CODE 4120-03-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Care Financing Administration

[Document Identifier: HCFA-R-224]

#### Agency Information Collection Activities: Proposed Collection; Comment Request

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

*Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Collection of Managed Care Data Using the Uniform Institutional Providers Form (HCFA-1450/UB-92) and Supporting Statute section 1853(a)(3) of the Balanced budget Act of 1997; *Form No.:* HCFA-R-224 (OMB No. 0938-0711); *Use:* Section 1853(a)(3) of the Balanced Budget Act (BBA) requires Medicare+Choice organizations, as well as eligible organizations with risk-sharing contracts under section 1876, to submit encounter data. Data regarding inpatient hospital services are required for periods beginning on or after July 1, 1997. These data may be collected starting January 1, 1998. Other data (as the Secretary deems necessary) may be required beginning July 1, 1998.

The BBA also requires the Secretary to implement a risk adjustment methodology that accounts for variation in per capita costs based on health status. This payment method must be implemented no later than January 1, 2000. The encounter data are necessary to implement a risk adjustment methodology.

HCFA continues to require hospital inpatient encounter data from Medicare+Choice organizations to

develop and implement a risk adjustment payment methodology as required by the Balanced Budget Act of 1997.

*Frequency:* Monthly; *Affected Public:* Business or other for-profit, Not-for-profit institutions, and Federal government; *Number of Respondents:* 211; *Total Annual Responses:* 1,353,500; *Total Annual Hours:* 6,533.

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](mailto: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, HCFA-R-224, Room N2-14-26, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: May 17, 2001.

**John P. Burke III,**

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

[FR Doc. 01-13208 Filed 5-24-01; 8:45 am]

**BILLING CODE 4120-03-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Advisory Committee; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92-463), announcement is made of the following National Advisory body scheduled to meet during the month of June 2001.

The National Advisory Committee on Rural Health will convene its thirty-eight meeting at the time and place specified below:

*Name:* National Advisory Committee on Rural Health.

*Date and Time:* June 3, 2001; 2 p.m.-5:15 p.m., June 4, 2001; 8:30 a.m.-7 p.m., June 5, 2001; 8:30 a.m.-12:30 p.m..

*Place:* Squaw Valley Lodge, 201 Squaw Peak Road, Olympic Valley, CA 96146, Phone: 1-800-922-9970.

The meeting is open to the public.

*Purpose:* The National Advisory Committee on Rural Health provides advice and recommendations to the Secretary with respect to the delivery, research, development, and administration of health care services in rural areas.

*Agenda:* Sunday afternoon, June 3, at 2 p.m. the acting chairperson, Tom Nesbitt will open the meeting and welcome the Committee members. The first plenary session will be a presentation on a public health proposal by two of the members. This will be followed by a discussion on the Committee's 2001 project, "A Targeted Look at the Rural Safety Net." At 3:45 p.m. the presentations will include discussions on "Maintaining the Rural Health Care Delivery System Safety Net."

Monday morning at 8:30 a.m., the Committee will prepare for site visits. From 9 a.m. to 7 p.m. the Committee will make site visits to the Placer County Medical and Public Health Clinic, the Eastern Plumas District Hospital and the Plumas District Hospital. Transportation to the sites will not be provided to the general public.

The final plenary session will be convened on Tuesday, June 5. Beginning at 8:30 a.m. there will be a brief review of the site visits, a review of the public health proposal presented on Sunday and state presentations from California and Nevada on "Federal Safety Issues in Rural Areas." The meeting will conclude with a discussion on the Committee's Report, future activities and the next meeting. The meeting will be adjourned at 12:30 p.m.

Anyone requiring information regarding the subject Committee should contact Marcia K. Brand, Ph.D., Executive Secretary, National Advisory Committee on Rural Health, Health Resources and Services Administration, Room 9A-55, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857, telephone (301) 443-0835, Fax (301) 443-2803.

Persons interested in attending any portion of the meeting should contact Michele Pray, Office of Rural Health Policy (ORHP), (301) 443-0835. The National Advisory Committee meeting agenda will be posted on ORHP's Web site, <http://www.ruralhealth.hrsa.gov>.

Dated: May 21, 2001.

**Jane M. Harrison,**

*Director, Division of Policy Review and Coordination.*

[FR Doc. 01-13250 Filed 5-24-01; 8:45 am]

**BILLING CODE 4160-15-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of Child Health and Human Development; 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.

The meeting 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 of Child Health and Human Development Special Emphasis Panel.

*Date:* July 19, 2001.

*Time:* 4 pm to 5 pm.

*Agenda:* To review and evaluate grant applications.

*Place:* 6100 Executive Blvd., Room 5E01, Rockville, MD 20852 (Telephone Conference Call).

*Contact Person:* Robert H. Stretch, Scientific Review Administrator, Division of Scientific Review, National Institute of Child Health, and Human Development, NIH, 6100 Executive Blvd., Room 5E01, MSC 7510, Bethesda, MD 20892, (301) 435-6912.

(Catalogue of Federal Domestic Assistance Program Nos. 93.209, Contraception and Infertility Loan Repayment Program; 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research, National Institutes of Health, HHS)

Dated: May 18, 2001.

**LaVerne Y. Stringfield,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 01-13192 Filed 5-24-01; 8:45 am]

**BILLING CODE 4140-01-M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of Child Health and Human Development; 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.

The meeting 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.