means to address problems associated with the categories, including possible alternatives to the categories for communicating information on reproductive and developmental toxicity. The agency is specifically seeking comment and data on the following:

(1) The extent to which the category designations are relied upon in making decisions about drug therapy in pregnant women and women of childbearing potential and decisions about inadvertent fetal exposure, the extent to which such reliance may be misplaced, and the extent to which such reliance may have untoward public health consequences;

(2) The extent to which current pregnancy labeling (category designation and accompanying narrative text) is effective in communicating risk of reproductive and developmental toxicity;

(3) The extent to which current pregnancy labeling may not adequately address the range of issues that may bear on decisions about drug therapy in pregnant women and women of childbearing potential and decisions about inadvertent fetal exposure (e.g., indication-specific concerns, pregnancy status, magnitude of exposure, incidental exposure, chronic exposure, timing of exposure);

(4) Additional information (data or interpretation of data) that could be included in pregnancy labeling to better address the range of issues that bear on decisions about drug therapy in pregnant women and women of childbearing potential and decisions about inadvertent fetal exposure; and

(5) Options to improve communication of reproductive and developmental risk in labeling, which could include alternatives to the categories (both content and format options) or efforts to make the current category scheme and accompanying narrative text more consistent and informative.

The agency encourages individuals, industry, consumer groups, health care professionals, and researchers with particular expertise in this area, as well as other interested persons, to respond to this notice. The agency strongly encourages persons who cannot attend the hearing to send information relevant to the topics and questions listed above to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm 1–23, Rockville, MD 20857. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with Docket No. 97N–0289. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

## IV. Notice Of Hearing Under Part 15

The Commissioner of Food and Drugs (the Commissioner) is announcing that the public hearing will be held in accordance with part 15. The presiding officer will be the Commissioner or his designee. The presiding officer will be accompanied by a panel of Public Health Service employees with relevant expertise.

Persons who wish to participate in the part 15 hearing must file a written or facsimile notice of participation with the Advisors and Consultants Staff by August 28, 1997. To ensure timely handling, the outer envelope or facsimile cover sheet should be clearly marked with Docket No. 97N–0289 and the statement ''Pregnancy Labeling Hearing.'' Groups should submit two copies. The notice of participation should contain the speaker's name, address, telephone number, FAX number, title, business affiliation, if any, a brief summary of the presentation, and approximate amount of time requested for the presentation.

The agency requests that persons or groups having similar interests consolidate their presentations and present them through a single representative. FDA will allocate the time available for the hearing among the persons who properly file notices of participation. If time permits, FDA may allow participation at the conclusion of the hearing from interested persons attending the hearing who did not submit a written notice of participation.

After reviewing the notices of participation and accompanying information, FDA will schedule each appearance and notify each participant by mail, telephone, or FAX, of the time allotted to the person and the approximate time the person's presentation is scheduled to begin. The hearing schedule will be available at the hearing. After the hearing the schedule will be placed on file in the Dockets Management Branch (address above) under Docket Number 97N–0289.

Under § 15.30(f), the hearing is informal and the rules of evidence do not apply. The presiding officer and any panel members may question any person during or at the conclusion of their presentation. No other person attending the hearing may question a person making a presentation or interrupt the presentation of a participant.

Public hearings under part 15 are subject to FDA's guideline (part 10, subpart C (21 CFR part 10, subpart C)) concerning the policy and procedures for electronic media coverage of FDA's public administrative proceedings. Under § 10.205, representatives of the electronic media may be permitted, subject, to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants. Representatives of the electronic media are urged to provide advance notice of their planned attendance, to the identified contact person for the hearing, so that their needs for space and technical assistance can be anticipated and accommodated. The hearing will be transcribed as required in § 15.30(b). Orders for copies of the transcript can be placed through the Dockets Management Branch (address above).

Any disabled persons requiring special accommodations in order to attend the hearing should direct those needs to the contact person listed above.

To the extent that the conditions for the hearing, as described in this notice, conflict with any provisions set out in part 15, this notice acts as a waiver of those provisions as specified in § 15.30(h).

To permit time for all interested persons to submit data, information, or views on this subject, the administrative record will remain open following the hearing until November 12, 1997.

Dated: July 23, 1997.

**William K. Hubbard,**

*Associate Commissioner for Policy Coordination.*

[FR Doc. 97–20247 Filed 7-30-97; 8:45 am]

BILLING CODE 4160–01–F

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Care Financing Administration

**[Form #HCFA–R–200]**

### Emergency Clearance: Public Information Collection Requirements Submitted to the Office of Management and Budget (OMB)

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 (DHHS), has submitted to the Office of Management and Budget (OMB) the following request for Emergency review. We are requesting an emergency review because the collection of this information is needed prior to the expiration of the normal time limits under OMB's regulations at

5 CFR Part 1320. The collection of HEDIS 3.0 performance measures, including the Health of Seniors and Consumer Assessment of Health Plans Study surveys is necessary for HCFA to obtain the information necessary for the proper oversight and administration of the Medicare Managed Care Program. The Agency cannot reasonably comply with the normal clearance procedures because public harm is likely to result due to the delay in reporting of health care quality measures. If emergency clearance is not provided HCFA will be forced to postpone the collection of this data due to the timing of contracts and their respective cycles.

HCFA is requesting OMB review and approval of this collection by 08/15/97, with a 180-day approval period. During this 180-day period HCFA will publish a separate **Federal Register** notice announcing the initiation of an extensive 60-day agency review and public comment period on these requirements. Then HCFA will submit the requirements for OMB review and an extension of this emergency approval.

*Type of Information Request:* Revision of a currently approved collection; *Title of Information Collection:* HEDIS 3.0 (Health Plan Data and Information Set), including the Health of Seniors and Consumer Assessment of Health Plans Study (CAHPS) surveys and supporting regulations 42 CFR 417.470, and 42 CFR 417.126; *Form Number:* HCFA-R–200 (OMB #0938–0701); Use: HEDIS and CAHPS will be used for 3 purposes: (1) to provide summary comparative data to the Medicare beneficiary to assist them in choosing among health plans; (2) to provide information to health plans for internal quality improvement activity; and (3) to provide HCFA, as purchaser, information useful for monitoring quality of and access to care provided by the plans; *Frequency:* Annually; *Affected Public:* Individuals or Households, non-profit and for profit HMOs which contract with HCFA to provide managed health care to Medicare beneficiaries; *Number of Respondents:* 293,834; *Total Annual Responses:* 293,834, *Total Annual Hours Requested:* 181,520. To request copies of the proposed paperwork collections referenced above, call the Reports Clearance Office on (410) 786–1324. Written comments and recommendations for the proposed information collections should be sent by 08/11/97 directly to the OMB Desk Officer designated at the following address: OMB Human Resources and Housing Branch, Attention: Allison Eydt, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: July 23, 1997.

**John P. Burke III,**

*HCFA Reports Clearance Officer, HCFA Office of Information Services, Information Technology Investment Management Group, Division of HCFA Enterprise Standards.*

[FR Doc. 97–20089 Filed 7–30–97; 8:45 am]

**BILLING CODE 4120–03–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Office of Inspector General

### Program Exclusions: June 1997

**AGENCY:** Office of Inspector General, HHS.

**ACTION:** Notice of program exclusions.

During the month of June 1997, the HHS Office of Inspector General imposed exclusions in the cases set forth below. When an exclusion is imposed, no program payment is made to anyone for any items or services (other than an emergency item or service not provided in a hospital emergency room) furnished, ordered or prescribed by an excluded party under the Medicare, Medicaid, Maternal and Child Health Services Block Grant and Block Grants to States for Social Services programs. In addition, no program payment is made to any business or facility, e.g., a hospital, that submits bills for payment for items or services provided by an excluded party. Program beneficiaries remain free to decide for themselves whether they will continue to use the services of an excluded party even though no program payments will be made for items and services provided by that excluded party. The exclusions have national effect and also apply to all Executive Branch procurement and non-procurement programs and activities.

| Subject, city, state | Effective date |
|---|---|
| **Program-Related Convictions** | |
| ABRAMS, GARY, LA MIRADA, CA | 07/07/97 |
| ALCARE RESPIRATORY SERVICES, TAPPAN, NY | 07/08/97 |
| AMICO, MICHAEL A, STATEN ISLAND, NY | 07/08/97 |
| ARNDT, SOU KWEI, GREENSBURG, PA | 07/10/97 |
| BAILEY, ROBYN KAMILYAH, MAGNOLIA, AR | 07/06/97 |
| BATES, ROBERT E, SILVER SPRING, MD | 07/07/97 |
| BIXBY, ANGELA M, DOUGLASVILLE, GA | 07/10/97 |
| BIXBY, HOWARD A, DOUGLASVILLE, GA | 07/10/97 |
| CAMPBELL, JAMES A, VALLEY, AL | 07/03/97 |
| CARTER, STEPHEN, DALLAS, TX | 07/06/97 |
| CHATMAN, SABRINA D, LITHONIA, GA | 07/07/97 |
| CHERRY-HAMMOND, CAPPRECCIA Y, ATLANTA, GA | 07/02/97 |
| COLLINS, STACEY BERNARD, TEXARKANA, TX | 07/02/97 |
| DAHDAH, CHARLES J, MIAMI, FL | 07/02/97 |
| DECIUTIIS, CHARLES E, BRONX, NY | 07/10/97 |
| DIAZ, GEORGE, MIAMI, FL | 07/01/97 |
| DISMOND, MICHAEL L, ALBUQUERQUE, NM | 06/25/97 |
| DODD, JUDY L, DAINGERFIELD, TX | 07/03/97 |
| DOMINY, HERBERT K, JESUP, GA | 07/10/97 |
| DUHON, LESHIA A, LAFAYETTE, LA | 07/07/97 |
| ELIKWU, PATRICK NGOZI, AUSTELL, GA | 07/01/97 |
| ETIENNE, JEAN JOSEPH, RIVIERA BEACH, FL | 07/10/97 |
| FALEK, ALEXIS BROWN, PITTSBURGH, PA | 07/10/97 |
| FRANKEL, STUART M, N MIAMI BEACH, FL | 07/10/97 |
| GALES, BERNARD, ATLANTA, GA | 07/10/97 |
| GELIN, GUERRIER, LANTANA, FL | 07/08/97 |
| GENE KUTSCH, D.M.D., P.C., ALBANY, OR | 06/26/97 |