

Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-2570, or

Robert A. Yetter, Center for Biologics Evaluation and Research (HFM-10), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-0373.

#### SUPPLEMENTARY INFORMATION:

#### I. Background

FDA is announcing the availability of a draft guidance for industry entitled "INDs for Phase 2 and 3 Studies of Drugs, Including Specified Therapeutic Biotechnology-Derived Products; Chemistry, Manufacturing, and Controls Content and Format." This draft guidance is intended to: (1) Facilitate drug discovery and development, (2) ensure that sufficient data will be submitted for the agency to assess the safety as well as the quality of the proposed clinical studies from the CMC and microbiology perspectives, and (3) expedite the entry of new drugs into the marketplace.

This level 1 draft guidance is being issued consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). This draft guidance represents the agency's current thinking on CMC content and format of IND's for phase 2 and 3 studies of drugs, including specified therapeutic biotechnology-derived products. 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 requirements of the applicable statute, regulations, or both.

#### II. Comments

Interested persons may submit written comments on the draft guidance to the Dockets Management Branch (address above).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 The draft guidance and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

#### III. Electronic Access

Copies of this draft guidance are available on the Internet at "http://www.fda.gov/cder/guidance/index.htm" or "http://www.fda.gov/cber/guidelines.htm".

Dated: April 13, 1999.

**William K. Hubbard,**

Acting Deputy Commissioner for Policy.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Care Financing Administration

[Document Identifier: HCFA-1728 and HCFA-R-0266]

#### 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:* Revision of a currently approved collection; *Title of Information Collection:* Home Health Agency Cost Report and Supporting Regulations in 42 CFR 413.20, 413.24 and 413.106; *Form No.:* HCFA-1728 (OMB No. 0938-0022); *Use:* Participating providers are required to submit annual information to HCFA in order to achieve settlement of costs for health care services rendered to Medicare beneficiaries. The HCFA-1728 is the form used by Home Health Agencies to report their health care costs to determine the amount reimbursable for services furnished to Medicare beneficiaries. *Frequency:* Annually; *Affected Public:* Business or other for profit, Not for profit institutions, and State, Local or Tribal Gov.; *Number of Respondents:* 8,950; *Total Annual Responses:* 8,950; *Total Annual Hours Requested:* 1,575,200.

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Medicaid Disproportionate Share Hospital Payments—Institutions for Mental Disease; *Form No.:* HCFA-R-0266 (OMB# 0938-0746); *Use:* This PRA

package announces the Federal share of disproportionate share hospital (DSH) allotments for Federal fiscal years (FFYs) 1998 through 2002. It also describes the methodology for calculating the Federal share DSH allotments for FFY 2003 and thereafter, and announces the FFY 1998 and FFY 1999 limitations on aggregate DSH payments States may make to institutions for mental disease (IMD) and other mental health facilities.; *Frequency:* Annually; *Affected Public:* State, Local, or Tribal Government; *Number of Respondents:* 54; *Total Annual Responses:* 54; *Total Annual Hours:* 2,160.

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 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: April 13, 1999.

**John P. Burke III,**

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

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Care Financing Administration

[Document Identifier: HCFA-R-0268, R-0271, and R-0274]

#### 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