

are never advised, either in the review process or thereafter, which of the clinical holds were randomly chosen and which were submitted by sponsors. The committee will evaluate the selected clinical holds for scientific content and consistency with FDA regulations and CBER policy.

The meetings of the oversight committee are closed to the public because committee discussions deal with confidential commercial information. Summaries of the committee deliberations, excluding confidential commercial information, may be requested in writing from the Freedom of Information Office (HFI-35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A-16, Rockville, MD 20857, approximately 15 working days after the meeting, at a cost of 10 cents per page. If the status of a clinical hold changes following the committee's review, the appropriate division will notify the sponsor.

FDA invites biological product companies to submit to the FDA Chief Mediator and Ombudsman the name and IND number of any investigational biological product trial that was placed on clinical hold during the past 12 months that they want the committee to review at its May 13, 1997, meeting. Submissions should be made by April 4, 1997, to Amanda Bryce Norton, FDA Chief Mediator and Ombudsman (address above).

Dated: March 5, 1997.

William K. Hubbard,
Associate Commissioner for Policy
Coordination.

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Health Care Financing Administration, HHS

Submitted for Collection of Public Comment: Submission for OMB Review (HCFA-R-4)

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, has submitted to the Office of Management and Budget (OMB) the following proposals for the collection of information. 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 Request:* Extension of a currently approved collection; *Title of Information Collection:* Information Collection Requirements contained in 42 CFR 447.253; *Form No.:* HCFA-R-4; *Use:* The Medicaid Management Information System (MMIS) is a State-operated, Federally mandated computer system used for automated Medicaid claims processing and information retrieval for program management. Data elements represent the Federally imposed recordkeeping requirements of MMIS; *Frequency:* Annually; *Affected Public:* Business or other for profit; State, local, or tribal government; *Number of Respondents:* 50; *Total Annual Responses:* 50; *Total Annual Hours:* 2,298,250.

To request copies of the proposed paperwork collection referenced above, E-mail your request, including your address, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786-1326. Written comments and recommendations for the proposed information collections should be sent within 30 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: OMB Human Resources and Housing Branch, Attention: Allison Eydt, New Executive Office Building, Room 10235, Washington, D.C. 20503.

Dated: March 5, 1997.

Edwin J. Glatzel,

Director, Management Analysis and Planning
Staff, Office of Financial and Human
Resources, Health Care Financing
Administration.

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[Document Identifier: HCFA-R-201]

Correction Notice: Agency Information Collection Activities: Submission for Emergency OMB Review; Comment Request

AGENCY: Health Care Financing
Administration, HHS.

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.), the Health Care Financing Administration (HCFA), Department of Health and Human Services, has submitted to the Office of Management and Budget (OMB) the following proposals for the collection of information. Interested persons are

invited to send comments regarding the 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:* New collection; *Title of Information Collection:* Managed Care Organization, Incentive Arrangement Disclosure Form and Supporting Regulations 42 CFR 417.479, 417.500, 434.44, 434.67, 434.70, 1003.100, 1003.101, 1003.103, 1003.106; *Form No.:* HCFA-R-201; *Use:* Final rule OMC-10, published in the Federal Register on 12/31/96, disclosed to the public that the information collection requirements referenced in OMC-10-F, would be submitted to OMB for emergency review upon publication of the rule. However, Section V of final rule OMC-10 neglected to denote that the forms used to capture the information collection requirements referenced in OMC-10 would also be submitted to OMB as part of the emergency review. These forms which will be used to demonstrate and monitor compliance with statute governing physician incentives under Medicare and Medicaid managed care organizations, were created in an extensive cooperative effort with the American Association of Health Plans, State Medicaid Agency representatives, and the Medicaid Managed Care Technical Advisory group. Therefore, we are correcting this oversight and are requesting comment on the forms and supporting regulations. These forms are available for inspection on the HCFA website, on the Internet, at <http://www.hcfa.gov>; *Frequency:* Annually; *Affected Public:* Business or other for profit, not for profit institutions, state, local or tribal government, and federal government; *Number of Respondents:* 450; *Total Annual Responses:* 450; *Total Annual Hours:* 45,000.

To obtain copies of the supporting statement and any related forms, E-mail your request, including your address and phone number, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786-1326. Written comments and recommendations for the proposed information collection should be sent within 5 days of this notice directly to