

Boulevard, Baltimore, Maryland 21244–1850.

Dated: September 26, 2002.

John P. Burke, III,

Paperwork Reduction Act Team Leader, CMS Reports Clearance Officer, Office of Strategic Operations and Strategic Affairs, Division of Regulations Development and Issuances.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare and Medicaid Services

[Document Identifier: CMS–10064, CMS–416]

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

AGENCY: Centers for Medicare and Medicaid Services.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare and Medicaid Services (CMS) (formerly known as 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:* Extension of a currently approved collection; *Title of Information Collection:* Minimum Data Set (MDS) for Swing Bed Hospitals and Supporting Regulations in 42 CFR, Sections 413.337 and 483.20; *Form No.:* CMS–10064 (OMB# 0938–0872); *Use:* We are requesting re-approval of resident assessment information that swing bed hospitals are required to submit as described at 42 CFR 483.20 in the manner necessary to administer the payment rate methodology described in 42 CFR 413.337; *Frequency:* Other: Days 5, 14, 30, 60 & 90 of stay; *Affected Public:* Not-for-profit institutions, and

State, Local or Tribal Government; *Number of Respondents:* 1,250; *Total Annual Responses:* 156,480; *Total Annual Hours:* 132,360.

(2.) *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Annual Early and Periodic Screening, Diagnostic, and Treatment Services (EPSDT) Participation Report and Supporting Regulations in 42 CFR 441.60; *Form No.:* CMS–416 (OMB# 0938–0354); *Use:* States are required to submit an annual report on the provision of EPSDT services to CMS pursuant to section 1902(a)(43) of the Social Security Act. These reports provide CMS with data necessary to assess the effectiveness of State EPSDT programs. It is also helpful in developing trend patterns, national projections, responding to inquiries, and determining a State's results in achieving its participation goal; *Frequency:* Annually; *Affected Public:* State, Local or Tribal Government; *Number of Respondents:* 56; *Total Annual Responses:* 56; *Total Annual Hours:* 1,568.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS Web site address at <http://www.hcfa.gov/regs/prdact95.htm>, or e-mail your request, including your address, phone number, OMB number, and CMS 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 30 days of this notice directly to the OMB desk officer: OMB Human Resources and Housing Branch, Attention: Brenda Aguilar, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: September 26, 2002.

John P. Burke, III,

Paperwork Reduction Act Team Leader, CMS Reports Clearance Officer, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development and Issuances.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02N–0418]

Agency Information Collection Activities; Proposed Collection; Comment Request; Adverse Experience Reporting for Licensed Biological Products; and General Records

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection requirements relating to FDA's adverse experience reporting (AER) for licensed biological products, and general records associated with the manufacture and distribution of biological products.

DATES: Submit written or electronic comments on the collection of information by December 3, 2002.

ADDRESSES: Submit electronic comments on the collection of information to <http://www.accessdata.fda.gov/scripts/oc/dockets/edockethome.cfm>. Submit written comments on the collection of information to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All documents should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JennaLynn P. Capezzuto, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency request