

(2) *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Medicare/Medicaid Health Insurance Common Claim Form, Instructions, and Supporting Regulations; 42 CFR 424.32, 424.44; *Form No.:* CMS-1500, CMS-1490U, CMS-1490S (OMB #0938-0008); *Use:* This form is a standardized claim form for use in the Medicare/Medicaid programs to apply for reimbursement for covered services. Many private insurers also use this form. Use of this form reduces cost and administrative burdens associated with professional claims because only one format needs to be used and maintained. CMS does not require exclusive use of this form for Medicaid.; *Frequency:* On occasion; *Affected Public:* State, Local or Tribal Government, Business or other for-profit, Not-for-profit institutions; *Number of Respondents:* 1,216,702; *Total Annual Responses:* 740,215,135; *Total Annual Hours:* 42,941,276.

(3) *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Medicare Uniform Institutional Provider Bill and Supporting Regulations; *Form No.:* CMS-1450 (OMB #0938-0279); *Use:* This standardized form is used in the Medicare/Medicaid program to apply for reimbursement of covered services by all providers that accept Medicare/Medicaid assigned claims.; *Frequency:* On occasion; *Affected Public:* Not for profit institutions and Business or other for profit; *Number of Respondents:* 46,708; *Total Annual Responses:* 158,603,290; *Total Annual Hours:* 1,666,208.

(4) *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Request for Retirement Benefit Information; *Form No.:* CMS-R-285 (OMB #0938-0769); *Use:* This information is needed to determine whether a beneficiary meets the requirements for reduction of Part A premium to zero.; *Frequency:* On occasion; *Affected Public:*, State and Local or Tribal Government; *Number of Respondents:* 1500; *Total Annual Responses:* 1500; *Total Annual Hours:* 208.

(5) *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Procedures for Making National Coverage Decisions; *Form No.:* CMS-R-0290 (OMB #0938-0776); *Use:* These information collection requirements provide the process CMS will use to make a national coverage decision for a specific item or service

under sections 1862 and 1871 of the Social Security Act. This will streamline our decision making process and will increase the opportunities for public participation in making national coverage decisions; *Frequency:* Other (as needed); *Affected Public:* Business or other for-profit, Not-for-profit institutions; *Number of Respondents:* 200; *Total Annual Responses:* 200; *Total Annual Hours:* 8,000.

(6) *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* End Stage Renal Disease Medical Information System ESRD Facility Survey; *Form No.:* CMS-2744 (OMB #0938-0447); *Use:* The ESRD Facility Survey form (CMS-2744) is completed annually by Medicare-approved providers of dialysis and transplant services. The CMS-2744 is designed to collect information concerning treatment trends, utilization of services and patterns of practice in treating ESRD patients.; *Frequency:* Annually; *Affected Public:*, Business or other for-profit and Not-for-profit institutions; *Number of Respondents:* 4,225; *Total Annual Responses:* 4,225; *Total Annual Hours:* 33,800.

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://cms.hhs.gov/regulations/prr/default.asp>, or e-mail your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.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: January 9, 2003.

John P. Burke, III,

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

Centers for Medicare and Medicaid Services

[Document Identifier: CMS-377/378/CMS-R-55]

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.

Type of Information Collection Request: Extension of a currently approved collection; *Title of Information Collection:* Comprehensive Outpatient Rehabilitation Facility (CORF) Eligibility and Survey Forms and Information Collection Requirements in 42 CFR 485.56, 485.58, 485.60, 485.64, 485.66, 410.105; *Form No.:* CMS-0359/0360/R-0055 (OMB# 0938-0267); *Use:* In order to participate in the Medicare program as a CORF, providers must meet federal conditions of participation. The certification form is needed to determine if providers meet at least preliminary requirements. The survey form is used to record provider compliance with the individual conditions and report findings to CMS; *Frequency:* Annually; *Affected Public:* State, Local, or Tribal Government; *Number of Respondents:* 556; *Total Annual Responses:* 556; *Total Annual Hours:* 264,877.

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://cms.hhs.gov/regulations/prd/default.asp>, 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: January 9, 2003.

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-0354]

Agency Information Collection Activities; Proposed Collection; Comment Request; the Evaluation of Long-Term Antibiotic Drug Therapy for Persons Involved in Anthrax Remediation Activities

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 (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 the evaluation of long-term antibiotic drug therapy for persons involved in anthrax remediation activities. In the **Federal Register** of October 8, 2002 (67 FR 62727), FDA published a notice announcing the Office of Management and Budget's (OMB's) approval of this collection of information (OMB control number 0910-0494). Because this was an emergency approval that will expire on

March 31, 2003, FDA in this notice is following the normal PRA clearance procedures by issuing this notice.

DATES: Submit written or electronic comments on the collection of information by March 18, 2003.

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 comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Karen Nelson, Officer of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1482.

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 CRF 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to the OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

The Evaluation of Long-Term Antibiotic Drug Therapy for Persons Involved in Anthrax Remediation Activities (OMB Control Number 0910-0494)—Extension

Due to a terrorist event during the fall of 2001, approximately 1,200 decontamination workers were placed on long-term antibiotic therapy to protect them from environmental anthrax spores. Through the services of a contractor, the FDA is currently administering a survey to all 1,200 decontamination workers to collect important health information pertaining to long-term use of antibiotics. This information is critical to the agency's mission in protecting the public health, and failure of the FDA to adequately follow up on these workers will reduce the agency's ability to apply lessons learned from the current situation to provide guidance during future public health emergencies should they occur. This could result, not only, in the loss of time and dollars but also in the loss of life if patients stop taking their medicines because they think the drug therapy is responsible for a health problem when in fact it is not. This type of population is likely to never be available for assessment again until a future terrorist event occurs. It would be unacceptable for the FDA not to obtain drug experience information from this group to assist in any future public health response to a terrorist attack.

FDA is requesting an extension of the OMB approval of a survey to help FDA's Center for Drug Evaluation and Research evaluate the long-term antibiotic drug therapy in persons involved in anthrax remediation activities. The reason for the extension is to allow for more time to complete the survey, which has been delayed for two reasons. The first reason relates to the delays in cleaning up some of the contaminated sites. Primarily, the cleanup of the Brentwood Post Office in Washington, DC was delayed; this post office accounts for approximately 400 of the decontamination workers. The cleanup at Brentwood is almost complete, and it is anticipated that final medical examinations of the Brentwood cleanup workers can begin in earnest in the February/March 2003 timeframe. Once the final medical examination is completed, then Market Facts, the contractor hired to conduct the survey, can begin to administer the questionnaire to these workers. The second reason is the result of having to obtain authorization from approximately 35 subcontractor firms (who employed the decontamination workers) to release contact information on the remediation workers. To date, only contact information for