the applicant from the Director of the Office of Device Evaluation, CDRH.

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

Opportunity for Administrative Review

Section 515(d)(3) of the act authorizes any interested person to petition, under section 515(g) of the act, for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under 21 CFR part 12 of FDA's administrative practices and procedures regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under 21 CFR 10.33(b). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the **Federal Register**. If FDA grants the petition, the notice will state the issue to be reviewed, the form of the review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before August 1, 1997 file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h) (21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated: June 10, 1997.

Joseph A. Levitt,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 97–17289 Filed 7–1–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–482]

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

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 proposal 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.

Type of Information Collection Request: Extension of a currently approved collection; *Title of Information Collection:* Methodology for Estimating Waiver Costs of HCFA Demonstration Projects; *Form No.:* HCFA–482; *Use:* The information collected is intended to provide guidance to individuals responsible for the preparation of waiver cost estimates for HCFA demonstrations. These estimates are used in analysis of potential costs and benefits associated with implementing a proposed policy. *Frequency:* On occasion; *Affected Public:* State, Local or Tribal Government, Business or other for profit, Not for profit institutions and, Individuals or Households; *Number of Respondents:* 50; *Total Annual Responses:* 50; *Total Annual Hours:* 4,000.

To obtain copies of the supporting statement for the proposed paperwork collections referenced above, access HCFA's WEB SITE ADDRESS at http://www.hcfa.gov/regs/prdact95.htm, or to obtain 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 collections must be mailed 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: May 29, 1997.

Edwin J. Glatzel,

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

[FR Doc. 97–17241 Filed 7–1–97; 8:45 am]

BILLING CODE 4120–03–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–R–88 and HCFA–2552]

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

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 proposal 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:* Reinstatement, without change, of a previously approved collection for which approval has expired; *Title of Information Collection:* Information Collection Requirements in HCFA Pub 14–3 Section 2120.1–2125 and Section 4115 of the Carriers Manual (HCFA–R–88); *Use:* Verification of ambulance compliance with State and Local

requirements is necessary to determine whether the ambulance qualifies for reimbursement under Medicare. Carriers require ambulances providing service to Medicare beneficiaries to submit documentation showing that they have the required equipment. *Frequency:* On occasion; *Affected Public:* Business or other for-profit; *Number of Respondents:* 100; *Total Annual Hours:* 25.

2. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Cost Report for Electronic Filing for Hospital and Hospital Health Care Complex Cost Report and Supporting Regulations in 42 CFR 413.20 and 413.24; *Form No.:* HCFA–2552–96; *Use:* This form is required by statute and regulation for participation in the Medicare program. The information is used to determine final payment for Medicare. Hospitals and related complexes are the main users. *Frequency:* Annually; *Affected Public:* Business or other for-profit, Not-for profit institutions, and State, Local or Tribal Government; *Number of Respondents:* 7,000; *Total Annual Responses:* 7,000; *Total Annual Hours Requested:* 4,599,000.

To obtain copies of the supporting statement for the proposed paperwork collections referenced above, access HCFA's Web Site Address at http://www.hcfa.gov/regs/prdact95.htm, or to obtain 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 collections must be mailed 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: June 24, 1997.

Edwin J. Glatzel,

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

[FR Doc. 97–17243 Filed 7–1–97; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HSQ–207–NC]

RIN 0938–AG32

Medicare Program; Description of the Health Care Financing Administration's Evaluation Methodology for the Peer Review Organization 5th Scope of Work Contracts

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: General notice with comment period.

SUMMARY: This notice describes how HCFA intends to evaluate the Peer Review Organizations (PROs) for quality improvement activities, under their 5th Scope of Work (SOW) contracts, for efficiency and effectiveness in accordance with the Social Security Act. In accordance with the provisions of the Government Performance and Results Act of 1993, the 5th SOW contracts with the PROs are performance-based contracts.

DATES: This notice is effective on July 2, 1997. Written comments will be considered if we receive them at the appropriate address, as provided below, no later than 5 p.m. on September 2, 1997.

ADDRESSES: Mail written comments (an original and 3 copies) to the following address: Health Care Financing Administration, Department of Health and Human Services, Attention: HSQ–207–NC, P.O. Box 26676, Baltimore, MD 21207–0476.

If you prefer, you may deliver your written comments (an original and 3 copies) to one of the following addresses:

Room 309–G, Hubert H. Humphrey Building, 200 Independence Avenue, S.W., Washington, DC 20201–0001.
or
Room C5–09–26, 7500 Security Boulevard, Baltimore, MD 21244–1850.

Because of staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code HSQ–207–NC. Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, in Room 309–G of the Department's offices at 200 Independence Avenue, S.W., Washington DC 20201–0001, on Monday through Friday of each week from 8:30 a.m. to 5 p.m. (phone: (202) 690–7890).

Comments may also be submitted electronically to the following e-mail address: HSQ207NC@hcfa.gov. E-mail comments must include the full name and address of the sender and must be submitted to the referenced address in order to be considered. All comments must be incorporated in the e-mail message because we may not be able to access attachments. Electronically submitted comments will also be available for public inspection at the Independence Avenue address shown above.

FOR FURTHER INFORMATION CONTACT: Henry Koehler, (410) 786–6850.

SUPPLEMENTARY INFORMATION:

I. Background

A. Program Description

The Peer Review Improvement Act of 1982 (title I, subtitle C of the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA), Pub. L. 97–248) amended part B of title XI of the Social Security Act (the Act), establishing the PRO program. The PRO program was established in order to redirect, simplify, and enhance the cost-effectiveness and efficiency of the medical peer review process. Sections 1153 (b) and (c) of the Act define the types of organizations eligible to become PROs and establish certain limitations and priorities regarding PRO contracting. In 42 CFR part 462, subpart C, of our regulations, we describe the types of organizations eligible to become PROs. In § 462.101, we require they: (a) Be either a physician-sponsored organization as described in § 462.102, or a physician-access organization as described in § 462.103; and (b) demonstrate their ability to perform the review requirements set forth in § 462.104.

Under section 1153(h)(2) of the Act, the Secretary is required to publish in the **Federal Register** the general criteria and standards that will be used to evaluate the efficient and effective performance of contract obligations by PROs, and provide the opportunity for public comment. This notice sets forth the criteria that will be used to monitor PRO performance of quality improvement activities.

Section 1154 of the Act requires that PROs review those services furnished by physicians, other health care practitioners, and institutional and non-institutional providers of health care services, including health maintenance organizations and competitive medical plans, as specified in their contract with the Secretary. The Secretary enters into