

Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

The agency encourages any person who submits relevant information on the application to do so by May 15, 1995, and to provide an additional copy of the submission directly to the contact person identified above, to facilitate consideration of the information during the 30-day review period.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (sec. 802 (21 U.S.C. 382)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Center for Biologics Evaluation and Research (21 CFR 5.44).

Dated: April 12, 1995.

James C. Simmons,

Acting Director, Office of Compliance, Center for Biologics Evaluation and Research.

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Health Care Financing Administration

[HSQ-227-N]

Medicare Program; Peer Review Organization Contracts: Solicitation of Statements of Interest From In-State Organizations—Alaska, Delaware, the District of Columbia, Idaho, Kentucky, Maine, Nebraska, Nevada, South Carolina, Vermont, and Wyoming

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

ACTION: General notice.

SUMMARY: This notice, in accordance with section 1153(i) of the Social Security Act, announces the scheduled expiration dates of the current contracts between HCFA and several out-of-State Utilization and Quality Control Peer Review Organizations. It also specifies the period of time in which in-State organizations may submit a statement of interest so that they may be eligible to compete for these contracts. The States currently affected and their respective expiration dates are as follows:

Delaware	March 31, 1996.
Nevada	March 31, 1996.
Wyoming	March 31, 1996.
Alaska	June 30, 1996.
District of Columbia	June 30, 1996.
Idaho	June 30, 1996.
Maine	June 30, 1996.
Vermont	June 30, 1996.
Nebraska	September 30, 1996.
Kentucky	September 30, 1996.
South Carolina	September 30, 1996.

DATES: Written statements of interest must be received at the address

specified no later than 5 p.m. EST, June 2, 1995. Due to staffing and resource limitations, we cannot accept statements submitted by facsimile (FAX) transmission.

ADDRESSES: Statements of interest must be submitted to—Health Care Financing Administration, OFHR, OAG, Attn.: Brian Hebbel, Room G-M-1, East Low Rise Building, 6325 Security Boulevard, Baltimore, Maryland 21207.

FOR FURTHER INFORMATION CONTACT: Kathleen Kelso, (410) 966-7214.

SUPPLEMENTARY INFORMATION:

I. Background

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) by establishing the Utilization and Quality Control Peer Review Organization (PRO) program. Congress created the PRO program in order to redirect, simplify, and enhance the cost-effectiveness and efficiency of the peer review process.

PROs currently review certain health care services furnished under Title XVIII of the Act (Medicare) and under certain other Federal programs to determine whether those services are reasonable, medically necessary, furnished in the appropriate setting, and are of a quality that meets professionally recognized standards. PRO activities are a part of the Health Care Quality Improvement Program (HCQIP) that supports HCFA's mission of assuring health care security for its eligible beneficiaries. The HCQIP is carried out locally by the PRO in each State. Under the HCQIP, PROs provide information for health care plans, providers, and practitioners to improve the quality of care furnished to Medicare beneficiaries.

In June 1984, HCFA began awarding contracts to PROs. We currently maintain 53 PRO contracts with organizations that provide medical review activities for 49 of the United States, the District of Columbia, Puerto Rico, and the Virgin Islands. The organizations that are eligible to contract as PROs have satisfactorily demonstrated that they are either physician-sponsored or physician-access organizations in accordance with sections 1152 and 1153 of the Act and our regulations at 42 CFR 462.102 and 462.103. A physician-sponsored organization is one that is both composed of a substantial number of the licensed doctors of medicine or osteopathy practicing medicine or surgery in the respective review area

and is representative of the physicians practicing in the review area. A physician-access organization is one that has available to it, by arrangement or otherwise, the services of a sufficient number of licensed doctors of medicine or osteopathy practicing medicine or surgery in the review area to assure adequate peer review of the services furnished by the various medical specialties and subspecialties. In addition, the organization must not be a health care facility, health care facility association, or a health care facility affiliate, and must have a consumer representative on its governing board.

The Omnibus Budget Reconciliation Act of 1987 (Pub. L. 100-203) amended section 1153 of the Act by adding a new subsection (i) that prohibits the Secretary from renewing the contract of any PRO that is not an in-State organization without first publishing in the **Federal Register** a notice announcing when the contract will expire. This notice must be published no later than 6 months before the date of expiration, and must specify the period of time during which an in-State organization may submit a proposal for the contract. If one or more qualified in-State organizations submits a proposal within the specified period of time, HCFA may not automatically renew the contract on a noncompetitive basis but must instead provide for competition for the contract in the same manner used for a new contract. An in-State organization is defined as an organization that has its primary place of business in the State in which review will be conducted or that is owned by a parent corporation, the headquarters of which is located in that State.

There are currently 11 PRO contracts with entities that do not meet the statutory definition of an in-State organization. The areas affected for purposes of this notice are Alaska, Delaware, the District of Columbia, Idaho, Kentucky, Maine, Nebraska, Nevada, South Carolina, Vermont, and Wyoming.

II. Provisions of the Notice

This notice announces the scheduled expiration dates of the current contracts between HCFA and the out-of-State PROs responsible for review in Alaska, Delaware, the District of Columbia, Idaho, Kentucky, Maine, Nebraska, Nevada, South Carolina, Vermont, and Wyoming. Interested in-State organizations may submit statements of interest to be the PRO for the aforementioned States. The statements must be received by HCFA no later than June 2, 1995. In its statement of interest, the organization must furnish materials