Assistance, Center for Devices and Radiological Health (HFZ–220), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301–443–8818. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments on this guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Steward Crumpler, Center for Devices and Radiological Health (HFZ–340), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–4659.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a document entitled'' Guidance on the Performance Standard for Electrode Lead Wires and Patient Cables.'' This guidance document addresses the implementation of the Performance Standard for Electrode Lead Wires and Patient Cables. This standard was issued to address the electrocution hazard posed by unprotected patient electrical connectors. Since May 11, 1998, electrode lead wires or patient cables intended for use with any of the following devices have been required to comply with the standard:

1. Breathing frequency monitors,
2. Ventilatory effort monitors (Apnea detectors),
3. Electrocardiographs (ECG's),
4. Radio frequency physiological signal transmitters and receivers,
5. Cardiac monitors,
6. Electrocardiograph electrodes (including pre-wired ECG electrodes),
7. Patient transducer and electrode cables (including connectors),
8. Medical magnetic tape recorders (e.g. Holter monitors),
9. Arrhythmia detectors and alarms,
10. Telephone Electrocardiograph transmitters and receivers.

Manufacturers and users have an additional 2 years to prepare for the second phase of implementation of the standard. Beginning on May 9, 2000, any electrode lead wire or patient cable lead intended for use with any medical device must comply with the standard.

The performance standard incorporates the specific requirements of international standard, IEC–60601, clause 56.3(c), which requires leads to be constructed in such a manner as to preclude patient contact with hazardous voltages or, for certain devices, contact with electrical ground. Design changes and labeling changes need to be considered by manufacturers and importers of the devices referenced previously.

Adapters can be used to convert devices already in the marketplace so they can accept electrode wires and patient cables that comply with the new performance standard.

This guidance document represents the agency's current thinking on the performance standard for electrode lead wires and patient cables. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the applicable statute, regulations, or both. The agency has adopted good guidance practices (GGP's) (62 FR 8961, February 27, 1997), which set forth the agency's policy for the development, issuance and use of guidance documents. This is a Level 1 guidance document in accordance with the GGP's. The guidance document was made available on the World Wide Web (WWW) in March 1998 in order to provide guidance before the May 11, 1998, effective date of the first phase of implementation. Due to the risk of serious injury or death associated with the use of unprotected electrode leads and patient cables, this guidance is being implemented while the agency receives public input.

II. Comments

Interested persons may, on or before October 27, 1998, submit to the Dockets Management Branch (address above) written comments regarding this guidance document. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance document and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

In order to receive the ''Guidance on the Performance Standard for Electrode Lead Wires and Patient Cables'' via your fax machine, call the CDRH Facts-On-Demand (FOD) system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. At the first voice prompt press 1 to access DSMA Facts, at second voice prompt press 2, and then enter the document number (1197) followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so using the WWW. The Center for Devices and Radiological Health (CDRH) maintains an entry on the WWW for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the Web. Updated on a regular basis, the CDRH home page includes the ''Guidance on the Performance Standard for Electrode Lead Wires and Patient Cables,'' device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, mammography matters, and other device-oriented information. The CDRH home page may be accessed at ''http://ww.fda.gov/cdrh''.

A text-only version of the CDRH Web site is also available from a computer or VT–100 compatible terminal by dialing 800–222–0185 (terminal settings are 8/1/N). Once the modem answers, press Enter several times and then select menu choice 1: FDA BULLETIN BOARD SERVICE. From there follow instructions for logging in, and at the BBS TOPICS PAGE, arrow down to the FDA home page (do not select the first CDRH entry). Then select Medical Devices and Radiological Health. From there select CENTER FOR DEVICES AND RADIOLOGICAL HEALTH for general information, or arrow down for specific topics.

Dated: July 17, 1998.

D.B. Burlington,

Director, Center for Devices and Radiological Health.

[FR Doc. 98–20240 Filed 7–28–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–3009–N]

RIN 0938–AI99

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

AGENCY: Health Care Financing Administration, HHS.

ACTION: Notice.

SUMMARY: This notice, in accordance with section 1153(i) of the Social Security Act, gives at least 6 months' advance notice of the expiration dates of contracts with 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.

DATES: Written statements of interest must be received at the address specified no later than 5 p.m. EST, August 28, 1998. Due to staffing and resource limitations, we cannot accept statements submitted by facsimile (FAX) transmission.

ADDRESSES: Statements of interest must be submitted to the—Health Care Financing Administration, Acquisitions and Grants Groups, OICS, Attn.: Edward L. Hughes, 7500 Security Boulevard, Mail Stop C2–21–15, Baltimore, Maryland 21244–1850.

FOR FURTHER INFORMATION CONTACT: Udo Nwachukwu, (410) 786–7234.

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 Peer Review Organization (PRO) program.

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), a program which supports our mission to ensure health care security for our beneficiaries. The HCQIP rests on the belief that a plan's, provider's, or practitioner's own internal quality management system is key to good performance. The HCQIP is carried out locally by the PRO in each State. Under the HCQIP, PROs provide critical tools (for example, quality indicators and information) for plans, providers, and practitioners to improve the quality of care furnished to Medicare beneficiaries. The Congress created the PRO program in order to redirect, simplify, and enhance the cost-effectiveness and efficiency of the peer review process.

In June 1984, we began awarding contracts to PROs. We currently maintain 53 PRO contracts with organizations that provide medical review activities for the 50 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 ensure 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 new paragraph (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 the contract expires 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 submit a proposal within the specified period of time, we 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 13 PRO contracts with entities that do not meet the statutory definition of an in-State organization. The areas affected for purposes of this notice and their respective expiration dates are as follows:

Delaware—March 31, 1999
Illinois—March 31, 1999
Kentucky—March 31, 1999
Nevada—March 31, 1999
Vermont—March 31, 1999
Wyoming—March 31, 1999
Alaska—June 30, 1999
District of Columbia—June 30, 1999
Idaho—June 30, 1999
Maine—June 30, 1999
Hawaii—September 30, 1999
Nebraska—September 30, 1999
South Carolina—September 30, 1999

II. Provisions of the Notice

This notice announces the scheduled expiration dates of the current contracts between us and the out-of-State PROs responsible for review in the areas mentioned above.

Interested in-State organizations may submit statements of interest to be the PRO for these States. We must receive the statements no later than August 28, 1998, and, in its statement of interest, the organization must furnish materials that demonstrate that it meets the definition of an in-State organization. Specifically, the organization must have its primary place of business in the State in which review will be conducted or be a subsidiary of a parent corporation, whose headquarters is located in that State. In its statement, each interested organization must further demonstrate that it meets the following requirements:

A. Be Either a Physician-Sponsored or a Physician-Access Organization

1. Physician-Sponsored Organization

a. The organization must be composed of a substantial number of the licensed doctors of medicine and osteopathy practicing medicine or surgery in the review area, and be representative of the physicians practicing in the review area.

b. The organization must not be a health care facility, health care facility association, or health care facility affiliate.

c. In order to meet the substantial number requirement of A.1.a., an organization must be composed of at least 10 percent of the licensed doctors of medicine and osteopathy practicing medicine or surgery in the review area. In order to meet the representation requirement of A.1.a., an organization must state and have documentation in its files demonstrating that it is composed of at least 20 percent of the licensed doctors of medicine and osteopathy practicing medicine or surgery in the review area. Alternately, if the organization does not demonstrate that it is composed of at least 20 percent of the licensed doctors of medicine and osteopathy practicing medicine or

surgery in the review area, the organization must demonstrate in its statement of interest through letters of support from physicians or physician organizations, or through other means, that it is representative of the area physicians.

2. Physician-Access Organization

a. The organization must have 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 ensure adequate peer review of the services provided by the various medical specialties and subspecialties.

b. The organization must not be a health facility, health care facility association, or health care facility affiliate.

c. An organization meets the requirements of A.2.a. if it demonstrates that it has available to it at least one physician in every generally recognized specialty; and has an arrangement or arrangements with physicians under which the physicians would conduct review for the organization.

B. Have at Least one Individual who is a Representative of Consumers on its Governing Board

If one or more organizations meet the above requirements in a PRO area and submit statements of interest in accordance with this notice, we will consider those organizations to be potential sources for the 13 contracts upon their expiration. These organizations will be entitled to participate in a full and open competition for the PRO contract to provide medical review services.

III. Information Collection Requirements

This notice contains information collection requirements that have been approved by the Office of Management and Budget (OMB) under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35) and assigned OMB Control Number 0938–0526.

Authority: Section 1153 of the Social Security Act (42 U.S.C. 1320c–2).

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance Program; and No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: June 1, 1998.

Nancy-Ann Min Deparle,

Administrator, Health Care Financing Administration.

[FR Doc. 98–20253 Filed 7–28–98; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Child Health and Human Development; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Child Health and Human Development, Special Emphasis Panel Health Services Research and Intervention in Safe Motherhood in Rural Balochistan, Pakistan.

Date: August 11, 1998.

Time: 12:00 PM to 5:30 PM.

Agenda: To review and evaluate grant applications.

Place: 6100 Executive Blvd., Room 5E01, Rockville, MD 20852.

Contact Person: Hameed Khan, PHD, Scientific Review Administrator, Division of Scientific Review, National Institute of Child Health and Human Development, National Institutes of Health, 6100 Executive Blvd., Room 5E01, Bethesda, MD 20892, (301) 496–1485.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.865, Research for Mothers and Children; 93.864, Population Research; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS).

Dated: July 22, 1998.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 98–20273 Filed 7–28–98; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Child Health and Human Development; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Child Health and Human Development, Special Emphasis Panel, The Effects of Swimming Lessons on the Risk of Drowning Among Children Ages 1–5 Years.

Date: August 24, 1998.

Time: 1:00 PM to 5:30 PM.

Agenda: To review and evaluate grant applications.

Place: 6100 Executive Blvd., Room 5E01 Rockville, MD 20852.

Contact Person: Hameed Khan, PHD, Scientific Review Administrator, Division of Scientific Review, National Institute of Child Health and Human Development, National Institutes of Health, 6100 Executive Blvd., Room 5E01, Bethesda, MD 20892, (301) 496–1485.

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929. Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: July 22, 1998.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 98–20274 Filed 7–28–98; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice