human factors within risk management for medical device design and development. It also contains an introduction to both risk management and human factors and a discussion of how they are linked. The focus is on reducing risks related specifically to the use of medical devices. Human factors techniques are discussed in the context of management. The draft guidance also suggests how human factors-risk management efforts should be documented and included in premarket submissions.

This draft guidance document represents the agency's current thinking on applying human factors to new medical device design and development to help ensure that use of a device will be safe and effective. 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), which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (62 FR 8961, February 27, 1997). This draft guidance document is issued as a Level 1 guidance consistent with GGP's.

II. Electronic Access

In order to receive ''Draft Guidance on Device Use Safety: Incorporating Human Factors in Risk Management'' via your fax machine, call the CDRH Facts-On-Demand (FOD) system at 800–899–0381 or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 (1497) followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the draft guidance may also do so using the World Wide Web (WWW). 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 WWW. Updated on a regular basis, the CDRH home page includes the ''Draft Guidance on Device Use Safety: Incorporating Human Factors in Risk Management,'' device safety alerts, **Federal Register** reprints, information on premarket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://www.fda.gov/cdrh''. The ''Draft Guidance on Device Use Safety: Incorporating Human Factors in Risk Management'' will be available at ''http://www.fda.gov/cdrh/HumanFactors.html''.

III. Comments

Interested persons may submit written comments regarding this draft guidance. Two copies of any comments are to be submitted to Dockets Management Branch (address above), except that individuals may submit one copy. Comments should be identified with the docket number found in brackets in the heading of this document. A copy of the draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 20, 1999.

Linda S. Kahan,

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

[FR Doc. 99–19870 Filed 8–2–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–3021–N]

Medicare Program; August 31, 1999 Open Town Hall Meeting To Discuss the End Stage Renal Disease Network Organizations (ESRD Networks) Activities

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

ACTION: Notice of meeting.

SUMMARY: This notice announces a Town Hall meeting to provide an opportunity for health care organizations, beneficiary advocates, and other interested parties to offer comments and raise issues regarding the development of the ESRD Networks' contract activities to begin July 1, 2000. We view this new round of contracts as an opportunity to look at the current quality initiatives and how they might continue to improve the quality of care that our beneficiaries receive. The next Statement of Work will include Administration of the ESRD Program, beneficiary assistance (including grievances), quality improvement activities, and the collection of data to better understand and serve the ESRD population.

DATES: The meeting is scheduled for Tuesday, August 31, 1999 from 9 a.m. until 3 p.m., eastern daylight-saving time.

ADDRESSES: The meeting will be held in the Health Care Financing Administration Main Auditorium, 7500 Security Boulevard, Baltimore, Maryland 21244.

FOR FURTHER INFORMATION CONTACT: Condict Martak, (410) 786–1366. Linda Okimoto, (410) 786–6877.

SUPPLEMENTARY INFORMATION:

Background

We contract with the End Stage Renal Disease Network Organizations (ESRD Networks) to oversee renal dialysis services furnished by dialysis facilities to Medicare beneficiaries. The ESRD Networks are responsible for ensuring beneficiaries receive quality care. Every 3 years we develop a Statement of Work defining the ESRD Networks' contract activities.

We are announcing a Town Hall meeting to provide an opportunity for organizations representing practitioners, providers, health plans, other purchasers, beneficiaries, and other interested parties to offer comments and raise issues regarding the activities that will be conducted by the ESRD Networks in their next contract beginning in July 2000. This Town Hall meeting provides an opportunity for the renal community to provide their comments directly to the HCFA officials responsible for writing and implementing the ESRD Network contracts.

Individuals who wish to make a short statement at the meeting must contact Condict Martak via e-mail at cmartak@hcfa.gov or Linda Okimoto via e-mail at lokimoto@hcfa.gov by close of business August 15, 1999. Also, because of time constraints, only a limited number of parties may be able to make presentations. We will notify participants who have been selected to make a presentation. We will assign presentation times and notify presenters before the meeting on August 31, 1999.

While the meeting is open to the public, attendance is limited to space available. Individuals must register in advance as described below or as described on the HCFA web site: http://www.hcfa.gov/quality/qlty-2.htm.

Registration

The Office of Clinical Standards and Quality will handle registration for the meeting. Registration forms may be obtained at HCFA's web site: http://www.hcfa.gov/quality/qtly-2.htm. Individuals may register by e-mail or by sending a FAX ((410) 786–4005) to the attention of Condict Martak or Linda

Okimoto, at the Office of Clinical Standards and Quality, Quality Improvement Group, Division of Contract Policy and Performance, 7500 Security Boulevard, Baltimore, Maryland 21244–1850 until August 15, 1999. Individuals must provide their name, credentials, title, organization, address, telephone number, FAX number, and e-mail address on their registration form. They should also indicate whether or not they wish to make a short statement and whether they need directions to HCFA.

Individuals will receive an e-mail or FAX confirming their registration. The meeting materials will be provided at the time of the meeting.

If you have questions regarding registration, please contact Condict Martak at cmartak@hcfa.gov or Linda Okimoto at lokimoto@hcfa.gov.

The agency will accept written questions or other statements (not to exceed two (2) single-spaced, typed pages), preferably before the meeting, or up to 14 days after the meeting. Written submissions should be sent to: Health Care Financing Administration, Attn: Steven Jencks, M.D., Director, Quality Improvement Group, Office of Clinical Standards and Quality, S3–01–17, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Authority: Section 1881 of the Social Security Act (42 U.S.C. 1395rr).

Dated: July 27, 1999.

Michael M. Hash,

Deputy Administrator, Health Care Financing Administration.

[FR Doc. 99–19933 Filed 8–2–99; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request; Partner and Customer Satisfaction Surveys

SUMMARY: Under the provisions of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for the opportunity for public comment on the proposed data collection projects, the Center for Scientific Review (CSR), National Institutes of Health (NIH), has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection was previously published in the **Federal Register** on May 27, 1999, page 28827 and allowed 60 days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institute of Health may not conduct or sponsor, the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Proposed Collection

Title: Partner and Customer Satisfaction Surveys. *Type of Collection Request:* New request. *Need and Use of Information Collection:* The information collected in these surveys will be used by the Center for Scientific Review personnel: (1) to assess the quality of operations and processes used by CSR to review grant applications; (2) to assess the quality of service provided to our partners and customers; (3) to assist with the design of modifications of these operations, processes, and services, based on partner and customer input; (4) to develop new modes of operation based on partner and customer need; and (5) to obtain partner and customer feedback about the efficacy of implemented modifications. These surveys will almost certainly lead to quality improvement activities that will enhance and/or streamline CSR's operations. The major mechanism by which CSR will request input is through surveys. The survey for partners is generic and tailored for Scientific Review Group (SGR) past and present members and chairs. The survey for customers, i.e., grant applicants, will have slight variations determined by which category of scientific review group the researcher/investigator's grant application is reviewed. Surveys will be collected as written documents or via Internet. Information gathered from these surveys will be presented to, and used directly by, CSR management to enhance the operations, processes, and services of our organization. *Frequency of Response:* The participants will respond yearly. *Affected public:* Universities, not-for-profit institutions, business or other for-profit, small businesses and organizations, and individuals. *Type of Respondents:* Adult scientific professionals. The annual reporting burden is as follows: It is estimated that the survey form will take 20 minutes to complete. The annual hour burden is, therefore, estimated to be 1,932 hours for 5,855 respondents. Estimated costs to the respondents consists entirely of their time. Costs for time were estimated using a rate of $38.00 per hour for SGR members, SGR chairs, and principal investigators/grant applicants. The estimated annual cost for which the generic clearance is requested is $73,421. No additional costs should be incurred by respondents or recordkeepers. There are no capital, operating, or maintenance costs to report.

Requests for Comments

Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the functions of the CSR, including whether the information will have practical utility; (2) The accuracy of the agency'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 those who are to respond while maintaining their anonymity, including the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Direct Comments to OMB

Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, New Executive Office Building, Room 10235, Washington, DC 20503, Attention: Desk Officer for NIH.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans, contact: Elliot Postow, Ph.D., Director, Division of Molecular and Cellular Mechanisms, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4160 MSC 7806, Bethesda, MD 20892–7806, or call non-toll free: 301–435–0911, or e-mail your request or comments, including your address to postowe@drg.nih.gov.

Comments Due Date

Comments regarding this information collection are best assured of having their full effect if received on or before September 2, 1999.

Chris Wisdom,

Executive Officer, CSR.

[FR Doc. 99–19889 Filed 8–2–99; 8:45 am]

BILLING CODE 4140–01–M