trials for RA products and on special considerations for juvenile RA.

This draft guidance has been under development since 1995. The first version of the draft guidance was completed in March 1996. An additional section on juvenile RA was added in May of that year. A second version was completed in January 1997. Two public workshops have been held on the topic: One was held on March 27, 1996 (61 FR 8961, March 6, 1996), and the other was held on July 23, 1996 (61 FR 32447, June 24, 1996). On February 5, 1997 (62 FR 4535, January 30, 1997), the draft guidance was discussed at a meeting of the Arthritis Advisory Committee. This draft guidance is the result of those efforts.

The draft guidance represents the agency's current thinking on rheumatoid arthritis. 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 requirements of the applicable statute, regulations, or both.

Written requests for single copies of the draft guidance for industry should be submitted to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Interested persons may submit written comments on the draft guidance to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments and requests are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 8, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–6908 Filed 3–17–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–3000–N]

Medicare Program; Solicitation of Proposals for a Demonstration Project for the Use of Informatics, Telemedicine, and Education in the Treatment of Diabetes Mellitus in the Rural and Inner-City Medicare Populations

AGENCY: Health Care Financing Administration (HCFA).

ACTION: Notice.

SUMMARY: This notice announces our intent to solicit proposals from eligible health care telemedicine networks for a demonstration project to use high capacity computing and advanced networks for the improvement of primary care and prevention of health care complications for Medicare beneficiaries with diabetes mellitus, who are residents of medically underserved rural areas or medically underserved inner city areas. We are soliciting these proposals under the authority of section 4207 of the Balanced Budget Act of 1997, section 1875 of the Social Security Act, and sections 402(a)(1)(B) and (a)(2) of the Social Security Amendments of 1967.

This notice also describes the requirements for submitting proposals and applications for this demonstration project.

DATES: For consideration, letters of intent must be received by April 17, 1998 and mailed to the following address: Lawrence E. Kucken, Health Care Financing Administration, Office of Health Standards and Quality, Mailstop C3–24–07, 7500 Security Boulevard, Baltimore, MD 21244–1850.

Copies: To order copies of the **Federal Register** containing this document, send your request to: New Orders, Superintendent of Documents, P.O. Box 371954, Pittsburgh, PA 15250–7954. Specify the date of the issue requested and enclose a check or money order payable to the Superintendent of Documents, or enclose your Visa or Master Card number and expiration date. Credit card orders can also be placed by calling the order desk at (202) 512–1800 or by faxing to (202) 512–2250. The cost for each copy is $8.00. As an alternative, you can view and photocopy the **Federal Register** document at most libraries designated as Federal Depository Libraries and at many other public and academic libraries throughout the country that receive the **Federal Register**.

This **Federal Register** document is also available from the **Federal Register** online data base through GPO Access, a service of the U.S. Government Printing Office. Free public access is available on a Wide Area Information Server (WAIS) through the Internet and via asynchronous dial-in. Internet users can access the data base by using the World Wide Web (the Superintendent of Document's home page address is http://www.access.gpo.gov/su_docs/), by using local WAIS client software, or by telnet to swais.access.gpo.gov, then log in as guest (no password required). Dial-in users should use communications software and modem to call (202) 512–1661; type swais, then log in as guest (no password required).

FOR FURTHER INFORMATION CONTACT: Lawrence E. Kucken, (410) 786–6694

SUPPLEMENTARY INFORMATION:

I. Background

A. Diabetes Mellitus in the Medicare Population

Diabetes is one of the most prevalent and costly diseases in the Medicare population. The National Health Interview Survey reported a prevalence of 10.4 percent in individuals aged 65 and older, based on the American Diabetes Association (ADA) diagnostic criteria of fasting blood glucose greater than 140. Medical costs for patients with diabetes are two to five times higher than costs for patients without diabetes. Cardiovascular disease, stroke, renal disease, and amputation occur more frequently in the elderly patient with diabetes than in those without diabetes.

A significant percentage of the morbidity associated with diabetes can be reduced or delayed in the Medicare population by appropriate diagnosis, preventive strategies, and management. Appropriate foot care, eye examinations and treatment of retinopathy, and other interventions on the part of the health care team, and involvement of the patient in his or her own self-care, such as intense blood glucose monitoring for patients on insulin have been shown to significantly reduce poor outcomes associated with diabetes.

B. Current HCFA Initiatives in Medicare Diabetes Treatment

We have undertaken several major initiatives aimed at improving quality of life, decreasing morbidity and mortality, and providing the most appropriate, cost-effective care for Medicare beneficiaries with diabetes. Peer Review Organizations in each State have been charged with identification of quality of care issues in their State and

development of partnerships with hospitals and physicians to improve care for persons with diabetes. Projects are underway in all 50 states and the District of Columbia. In addition, we have coordinated and financed a partnership among key users and developers of performance measurement techniques to identify components of quality care for persons with diabetes and to develop a set of performance measures to assess and improve the care provided to these individuals across all health care settings.

C. Development of the Telemedicine Network Demonstration

In October 1996, we initiated a 3-year, rural outreach demonstration of Medicare payment for telemedicine services. The demonstration focuses primarily on medical consultations between a primary care physician with a patient located at a remote rural site (spoke) and a medical specialist (consultant) located at a medical center facility (hub). Through this demonstration, we are addressing concerns that certain populations, primarily persons in rural or inner-city areas, have limited access to health care specialists, and that recent advances in telecommunications technology can provide low cost access to medical specialists.

The demonstration is designed to examine alternative payment methods, including separate payments to providers at each end of the telecommunication network, as well as a single ''bundled payment'' to cover services of both providers. Provider payments are based on predetermined amounts associated with CPT–4 evaluation and management codes contained in the Medicare physician fee schedule. In the case of the bundled payment option scheduled to begin during the third year of the demonstration, sites will determine the relative payment amounts received by the consulting specialists and the referring primary care physicians. Coincident with the implementation of the bundled payment approach, we will negotiate with demonstration participants to develop a telemedicine facility fee structure based on telemedicine cost centers and billing data accumulated during the demonstration. These negotiations will recognize the principle of efficient provider pricing, reflecting the optimal use of telemedicine resources and prudent buying.

Through this demonstration, we will obtain information about the utilization and costs of telemedicine services, as well as the general characteristics and practice patterns of individual telemedicine programs. Ultimately, the demonstration should provide insight and information to help us determine whether telemedicine coverage is warranted and, if so, how to implement cost-effective Medicare coverage.

II. Provisions of This Notice

A. Purpose

The purpose of this demonstration is to determine and evaluate the advantage of informatics and telemedicine for improving access to needed services, reducing the cost of such services, and improving the quality of life for affected Medicare beneficiaries. In this notice, ''medical informatics'' means the storage, retrieval, and use of biomedical and related information for problemsolving and decisionmaking through computing and communications technologies, and ''telemedicine'' means the use of telecommunications technologies for diagnostic, monitoring and medical education purposes.

We are soliciting innovative proposals that will use medical informatics, including telemedicine, to improve primary care for Medicare beneficiaries who live in medically underserved rural and inner-city areas and who suffer from diabetes. Proposals should describe existing protocols for the application or demonstration of telecommunications or informatics, that, at a minimum, have been pilot-tested by the applicant, thus precluding the need for long developmental timeframes.

Those protocols that have been developed for the general population must be modified, as necessary, to meet the special needs of the Medicare elderly, disabled, and end-stage renal disease populations, and should be replicable for the general Medicare underserved population. They should address developmental issues through descriptions of end products, for example, a curriculum to train health care professionals, and related strategies and workplans. They should also contain available cost effectiveness data related to the described protocols and developmental components.

Proposals must specifically address the following issues:

- The application of telecommunications for the purpose of providing Medicare beneficiaries diagnosed with diabetes, access to, and compliance with, appropriate care guidelines;
- The development of a curriculum to train health care professionals in the use of medical informatics and telecommunications;
- The demonstration of the application of advanced technologies, such as video-conferencing from a patient's home, remote monitoring of a patient's medical condition, interventional informatics, and the application of individualized, automated care guidelines, to assist primary care providers in assisting patients with diabetes in a home setting;
- The application of medical informatics to residents with limited English language skills;
- The development of standards in the application of telemedicine and medical informatics; and
- The development of a model for the cost effective delivery of primary and related care both in a managed care and fee-for-service environment.

B. Minimal Qualifications of Health Care Providers

We are interested in proposals from eligible health care provider telemedicine networks. An eligible health care provider network must be a consortium that is comprised of:

- At least one tertiary care hospital, but no more than 2 such hospitals;
- At least one medical school;
- No more than four facilities in rural or urban areas; and
- At least one regional telecommunications provider.

The consortium must be located in an area with a high concentration of medical schools and tertiary care facilities in the United States and have appropriate arrangements (within or outside the consortium) with such schools and facilities, universities, and telecommunications providers, in order to conduct the project. We interpret ''minimal concentration'' as an area with at least three medical schools and three tertiary care facilities, physically located within a recognized area, such as a Standard Metropolitan Statistical Area, county or city. Additionally, eligible applicants must guarantee that they will be responsible for payment of all costs of the project that are not paid by Federal funds and that the maximum amount of Federal funds to be made to the consortium shall not exceed the limitation specified below under ''payment provisions.''

C. Payment Provisions

Under this demonstration, services related to the treatment or management of (including prevention of complications from) diabetes for Medicare beneficiaries furnished under the project shall be considered to be services covered under Part B of Title XVIII of the Social Security Act. Subject to the limitations described below,

payment for these services will be made at a rate of 50 percent of the costs that are reasonable and necessary and related to the provision of such services.

Costs that may be included under these payments are as follows:

- Acquisition of telemedicine equipment for use in patients' homes (but only for patients located in medically undeserved areas);
- Curriculum development and training of health professionals in medical informatics and telemedicine;
- Payment of telecommunications costs (including salaries and maintenance of equipment), including telecommunications between patients' homes and the eligible network and between the network and other entities in the consortium; and
- Payments to practitioners and providers under the Medicare programs.

The following costs are not covered or payable under this demonstration:

- The purchase or installation of transmission equipment (other than such used by health professionals to deliver medical informatics services under the project);
- The establishment or operation of a telecommunications common carrier network; or
- The establishment, acquisition, or building of real property, except for minor renovations related to the installation of reimbursable equipment costs.

D. Limitation

The total amount of payments that may be made for this project will not exceed $30,000,000 for the 4-year period of the demonstration.

E. Limitation on Cost Sharing

The project may not impose cost sharing on a Medicare beneficiary for the receipt of services under the project in excess of 20 percent of the costs that are reasonable and related to the provision of such services.

F. Evaluation

Proposals submitted for this demonstration must contain provisions for an independent evaluation of the cost effectiveness of the services provided. The evaluation must be performed by an independent contractor competitively chosen according to bidding procedures approved by the our project officer. Proposals should address the elements to be incorporated into a request for proposal (RFP) to be used in the procurement of an evaluation contractor.

G. Length of Demonstration

This demonstration project will cover a period of 4 years.

III. Application Procedures

The application procedure is two-step process involving submission of letters of intent and formal proposals.

A. Step 1—Letters of Intent

A potential applicant is required to submit letters of intent containing brief descriptions of the applicant's ability to meet each of the provisions of this notice, including the following specific items:

- Protocols and plans related to the purpose of the project (Section II);
- Work plans describing the methods to be used in completing the project within the prescribed period of performance; minimal organizational characteristics and location requirements (Section II. B); and cost and payment guarantees (Section II. C);
- Descriptions of the use of Federal funds received under the project and the source and amount of non-Federal funds used in the project (Sections II. D and E);
- An evaluation strategy and design (Section II. F); and
- Length of the demonstration (Section II. G).

In addition, letters of intent should indicate acceptance of the payment provisions set forth in this notice, should not exceed six single spaced pages in length (including attachments), and must be signed by an appropriate official of the proposing entity.

For consideration, letters of intent must be received within 30 days from the publication of this notice and mailed to the following address: Lawrence E. Kucken, Mailstop C3–24–07, Health Care Financing Administration, Office of Health Standards and Quality, 7500 Security Boulevard, Baltimore, Maryland 21244–1850

Letters of intent will be screened against criteria based on provisions of this notice and period of performance requirements. Application kits, in turn, will be sent promptly to applicants whose letters of intent meet each these criteria.

B. Step 2—Formal Proposals

Detailed instructions for the preparation of formal proposals will be contained in application kits and will address criteria for screening proposals, evaluation criteria and associated weights, and procedural considerations. We may consider verbal presentations in lieu of written proposals. In addition, application kits will contain guidelines to be used by the applicant for preparation of the demonstration proposal cost estimate. This cost estimate will be used by the OMB in the final approval of Medicare waiver status for the project.

In accordance with the provisions of Executive Order 12866, this notice was not reviewed by the Office of Management and Budget.

AUTHORITY: Sec. 1875 of the Social Security Act (42 U.S.C. 139511); sections 402(a)(1)(B) and (a)(2) of the Social Security Amendments of 1967, as amended (42 U.S.C. 1395b–1(a)(1)(B) and (a)(2)); and Section 4207(a), (b), (c), and (d) of the Balanced Budget Act of 1997 (P.L. 105–33) (Catalog of Federal Domestic Assistance Program No 93.779 Health Financing Demonstrations, and Experiments)

Dated: February 25, 1998.

Nancy Ann-Min DeParle,

Administrator, Health Care Financing Administration.

Dated: March 10, 1998.

Donna E. Shalala,

Secretary.

[FR Doc. 98–6940 Filed 3–17–98; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Warren Grant Magnuson Clinical Center; Submission for OMB review; Comment Request; Customer and Other Partners Satisfaction Surveys

SUMMARY: In compliance with the requirement 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 Warren Grant Magnuson Clinical Center (CC), the 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 (Volume 62, Number 79, page 20012) and allowed 60 days for public comments. No public comments were received. The purpose of this notice is to provide an additional 30 days for public comment.

5 CFR 1320.5

Respondents to this request for information collection should not respond unless the request displays a currently valid OMB control number.

Proposed Collection

Title: Customer and Other Partners Satisfaction Surveys. *Type of Information Collection Request:* New request. *Need and Use of Information Collection:* The information collected in