Commissioner's consideration are comprehensive, accurate, fully discussed and encompass the issues involved.

Provides correspondence control for the Commissioner and controls and processes all agency public correspondence directed to the Commissioner. Develops and operates tracking systems designed to identify and resolve early warnings and bottleneck problems with executive correspondence.

Provides direct support to the Commissioner and Deputy Commissioners including briefing materials, background information for meetings, responses to outside inquiries, and maintenance and control of the Commissioner's working files.

Performs agencywide assignments involving complex problems and issues related to agency programs, strategies and activities, including preparation of special reports for the Department.

Coordinates the agency's communications with the Public Health Service, DHHS, and the White House including correspondence for the Assistant Secretary for Health and Secretarial signatures.

2. Delete the subparagraph *Executive Secretariat (DAB–1),* under the Office of Executive Operations (DAB) in its entirety.

3. Delete the subparagraph *Program Management Staff (DAB–2),* under the Office of Executive Operations (DAB) in its entirety.

4. **Prior Delegations of Authority**. Pending further delegations, directives, or orders by the Commissioner of Food and Drugs, all delegations of authority to positions of the affected organizations in effect prior to this date shall continue in effect in them or their successors.

Dated: March 14, 1997.

Michael A. Friedman,

Lead Deputy Commissioner for the Food and Drug Administration.

[FR Doc. 97–10981 Filed 4–28–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HSQ–232–N]

Medicare Program: Initiative Involving Facilities That Furnish Hemodialysis Treatments

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

ACTION: Notice.

SUMMARY: This notice announces our planned initiative to demonstrate the feasibility of collecting, collating, and analyzing data about the treatment of hemodialysis patients. The collected data will be distributed to participating facilities in a timely manner so that it may be used for quality improvement. This effort is intended to lead to the development of a quality assessment system for hemodialysis facilities that will permit facilities to track, on a routine basis, facility specific health and clinical outcome measures. The system is intended ultimately to permit facilities to use this information to design and implement specific interventions to improve care at these facilities and to test the ability of regulatory agencies to use this information to recognize best performers and to focus their survey resources. If feasible, facility performance indicators results can disseminated to patients and facilities in the future. This initiative will have several phases. The first phase is described in this notice.

FOR FURTHER INFORMATION CONTACT: Judith J. Kari, (410) 786–6829 or Jacquelyn A. Polder, (206) 615–2317.

SUPPLEMENTARY INFORMATION:

I. Overview

In July 1995, the President and Vice President of the United States announced the Administration's ''Reinventing Health Care Regulations'' initiative. This initiative is part of a larger strategy to reduce regulatory burden on the American public. HCFA also is committed to reducing regulatory burden while meeting our responsibility for ensuring quality health care services for Medicare beneficiaries.

We have several initiatives underway involving facility conditions of coverage or participation that are directed toward improving outcomes of care and satisfaction for patients, while at the same time reducing the burden on providers, and increasing flexibility and expectations for continuous improvement. This notice concerns one phase of an initiative involving facilities that furnish hemodialysis treatments to patients with end stage renal disease (ESRD). We believe that by establishing information exchange systems between ESRD facilities and HCFA we can collect identified clinical indicators of care; analyze the data collected; and use it to design interventions to improve care. Moreover, by using electronic systems effectively such information can be collected and used in a timely fashion.

If we determine that this is a good monitoring system, ultimately it could decrease regulatory burden. In the future, routine surveys of these facilities might be conducted with less frequency than they are now, or in ways that allow us to assess facility compliance without being onsite. Surveys would still be conducted in response to complaints about the quality of care or if the data indicate a potential serious problem. This notice announces our initiative to test such an infrastructure in a limited area.

The project will test a new mechanism that will permit hemodialysis facilities to provide patient specific clinical information to us on a regular basis for the purpose of evaluating the quality of care being provided to patients with ESRD. They will evaluate care by comparing clinical information within their own facility over time as well as comparing their clinical data against national and network data. The primary goal of this project is to improve the quality of care to Medicare beneficiaries with ESRD by tracking specific clinical indicators. A secondary goal is to collaborate with hemodialysis providers in the designing of a measurement system that will assist facilities in their efforts to improve care, and ultimately reduce the regulatory burden on these facilities. In the future, HCFA will explore the possibilities of awarding a certificate of achievement to facilities that document sustained achievement in the outcome indicators over a period of time.

II. Background

In 1993, as part of our effort to ensure quality care for Medicare ESRD beneficiaries, we began a descriptive epidemiological evaluation project called the End Stage Renal Disease Core Indicators Project. The core indicators project was designed to assist us and health professionals who provide care to dialysis patients by regularly collecting and analyzing certain clinical data about ESRD hemodialysis patients that are indicators of the quality of care being provided. The ''core'' indicators initially selected for evaluation included adequacy of dialysis (as measured by pre- and post-dialysis blood urea nitrogen levels to calculate an urea reduction ratio), anemia (as measured by hematocrit levels), blood pressure control, and nutritional status (as measured by serum albumin levels). They were developed by a workgroup with representation from facilities and the professional community, including the National Kidney Foundation, Forum of ESRD Networks, American Nephrology Nurses Association, National Renal Administrators Association, and Renal Physicians

Association. Data on these core indicators have been collected on a national random sample (3 percent) of patients with ESRD who were dialyzed during the last calendar quarters of 1993, 1994, and 1995. The preliminary analysis of data collected and analysis for patients dialyzed during the last quarter of 1995 indicates a measurable national improvement in the adequacy of dialysis and reduction of anemia.

The 3 percent random national sample consists of approximately 7,000 patients of the over 228,000 end stage renal disease patients in the United States. With approximately 2,747 hemodialysis facilities in the United States, the average number of patients per facility included in the core indicators project is between 2 and 4.

The core indicators project has been very useful because it provides timely information about the quality of care being provided to patients throughout the national system. Perhaps the most important message from the first 3 years of the Core Indicators Project is that there is a significant opportunity to improve ESRD care throughout the country. The Core Indicators Project has enhanced the expertise of HCFA and the ESRD provider community in using clinical indicators to improve quality of hemodialysis care.

While the study is a statistically valid measure of national performance and network level performance, it was not designed to measure care provided at the facility level. An essential next step is to develop the capacity to measure care at the facility level in order to assist us and ESRD providers to design and implement quality improvement interventions to address each facility's opportunities to improve care.

III. Hemodialysis Facilities of Achievement Project

A. Scope of Initiative

The ultimate goal of the Hemodialysis Facilities of Achievement project is to foster continuous quality improvement efforts in ESRD facilities. This will be accomplished through an electronic data collection system that can provide the information needed to design interventions to improve care at such facilities.

We currently use periodic on-site surveys to measure whether facilities approved to participate in Medicare meet the quality standards contained in Federal law and regulations. The surveys are carried out by State survey agency personnel operating under Federal guidelines; however, because of budget limitations these surveys are conducted infrequently. Moreover, the standards do not emphasize outcome measures that can be used for continuous quality improvement. On a separate track, these standards, called conditions for coverage, are also under revision. It is anticipated that information learned from this project will be useful in determining how outcome measures can best be used under revised conditions for coverage.

The project we are announcing in this notice focuses on quality of care through establishing a systematic collection of clinical data on all of the patients within a limited number of participating volunteer facilities. It builds on the knowledge and experience that we have gained through the Core Indicators Project.

It will feature: A system to collect uniform clinical information on each patient; a method to transmit these data to us; and a technique to analyze these data that facilities will use to improve quality of care. We will assist participating facilities to:

- Establish baseline measures of identified clinical indicators,
- Use national and regional data from the Core Indicators Project to set facility specific quality improvement goals, and
- Provide a mechanism by which facilities can periodically measure and monitor their progress over time.

This project will permit ESRD networks and us to help facilities implement and evaluate intervention strategies responsive to the needs of specific facilities, types of patients, or geographic areas.

It is our belief that an outcome-oriented approach to quality can reduce the cost and improve the quality of the ESRD program and ultimately reduce regulatory burden. This project will take advantage of electronic communication technology through a system to track identified quality indicators.

B. Selection of Participants

Our regional offices have the primary responsibility for oversight of quality of care provided to Medicare beneficiaries. In the case of ESRD facilities, the regional office works with the State survey agencies and with ESRD networks to carry out this oversight responsibility. The Seattle regional office will coordinate this project; the Seattle office was responsible for the Core Indicators Project and thus has both experienced staff and data support capacity.

The Seattle regional office staff will be responsible for the operation of the project from initial assessment of capacity of facilities through evaluation. Based on their evaluation of the computer capacity and capabilities of facilities in selected geographic areas they will: select participating sites; establish a mechanism for electronic communication; develop software for the project; train participating facilities in the use of equipment and data; collect and analyze data on all patients in participating facilities on a regular basis; profile and share these data with facilities and networks; participate in planning quality improvement initiatives at the facility and network level; and determine which facilities are to be recognized for their successful participation in the project.

To begin the project, we will contact all hemodialysis facilities in a defined geographic area to elicit interest in participation and to assess the computer capacity and capability of the facility. Unless the response overwhelms available resources, we intend to include any facility in the geographic area that wants to participate and has the computer capability to participate.

C. Establishing Communication and Information Sharing

Software and electronic access will be developed and field tested by the Seattle regional office. The software used will be similar to data input forms that are used in the Core Data Indicators project and we anticipate that facilities will submit similar information. Once these mechanisms are secure, regional office staff will begin the training phase of the project. The regional office will provide assistance to assure that all project participants understand how to use the equipment and software programs that will be at the center of this project. When each facility is trained and ready, it will be asked to transmit to the Seattle regional office identified clinical information similar to data collected as part of the Core Indicators Project. Throughout the duration of the project, the facilities will periodically submit clinical data to us and will work with us on evaluation of the data.

D. Clinical Indicators

The clinical indicators that will be collected for the first phase of the project will be similar to that of the Core Indicators Project which were determined in consultation with renal care organizations and patient groups. We have a data base with several years of data from the Core Indicators Project, so we expect that the historical data base will have an influence on suggestions for data collection.

E. Recognizing Facilities That Successfully Participate in the Project

The long term objective of this project is to assist hemodialysis facilities in

developing the capacity and ability to engage in continuous quality improvement. This will contribute to improved care for patients and reduced regulatory burden for providers. This is not a simple endeavor nor one that will be put in place quickly. It will be important to recognize achievement by the facilities as they progress towards the long term objective.

We place a high level of emphasis on helping providers develop and maintain programs of quality improvement. In the case of hemodialysis facilities we are demonstrating this commitment to work in collaboration with providers to achieve that goal.

It is important to note that this is just the first phase of the project. The real test of success will be when facilities have gained the experience to have ongoing systems in place to assess the quality of care they are providing to patients by evaluating quality indicators of outcomes of care. With measurement systems in place, hemodialysis facilities will be able to provide important information to patients and to us about the quality of care being provided.

F. Evaluation of the Project

Information about project results will be packaged in brochures and newsletters so that ESRD patients and non-participating ESRD facilities will be aware of the results. We will continuously evaluate this project as it progresses and perform a separate analysis upon completion. We believe that all of the participants in this project will learn a great deal, and we will remain open to the need to make accommodations to unique situations that may arise. We are convinced that this project has enormous potential to improve patient care, lessen regulatory burden, and use scarce resources more wisely. The definitive measure of success of this project will be that systems for collecting patient specific clinical data are in place, that transmission of data to us is done at regular intervals, and that hemodialysis facilities are skilled in using the data to design interventions to continuously improve care to their patients.

IV. Collection of Information Requirements

This notice contains information collection requirements, which are currently exempt from the Paperwork Reduction Act of 1995, as outlined in 5 CFR 1320.3(h)(5). The project described in this notice is an extension of the National Core Indicators Project, which has been reviewed and approved by the National Institutes of Health (NIH) Clinical Exemption Review Committee; NIH Case # CE95–02–02, February 1995. As a condition of this approval, PHS/HCFA will submit a copy of this updated data collection protocol, which will gather customary medical information from patient records, captured during the course of a medical examination, to the United States Renal Data System (NIH) before the study is initiated.

Both the Core Indicators Project and the extension pilot project described in this notice support a current REGO II effort to improve the quality of care provided to Medicare beneficiaries. The Core Indicators Project systematically, annually, collects clinical information associated with the quality of care provided to a sample of End Stage Renal Disease (ESRD) patients. This notice describes a pilot extension of that project which expands the effort by collecting information from patient records more frequently and communicating the information more efficiently to HCFA in an electronic fashion for HCFA/PHS evaluation.

It is envisioned that core information regarding outcomes of care on all ESRD Medicare beneficiaries will eventually be shared with HCFA electronically on a regular basis, to provide HCFA/PHS the data to initiate and monitor quality improvement efforts. If this pilot is successful, and HCFA decides to implement the REGO II project based on the currently approved Core Indicators Project, HCFA will seek full OMB approval for the data collection requirements that fall under the purview of the Paperwork Reduction Act.

In accordance with the provisions of Executive Order 12866, this notice was reviewed by the Office of Management and Budget.

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

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

Dated: June 14, 1996.

Bruce C. Vladeck,

Administrator, Health Care Financing Administration.

Dated: August 1, 1996.

Donna E. Shalala,

Secretary.

Note: This document was received in the Office of the Federal Register on April 24, 1997.

[FR Doc. 97–11025 Filed 4–28–97; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Notice of Meeting of the National Advisory Council for Human Genome Research

Pursuant to Pub. L. 92–463, notice is hereby given of the meeting of the National Advisory Council for Human Genome Research, National Human Genome Research Institute, May 19 and 20, 1997, National Institutes of Health, Building 31, C wing, 6th Floor, Conference Room 10, Bethesda, MD.

This meeting will be open to the public on Monday, May 19, 8:30 a.m. to approximately 3:00 p.m. to discuss administrative details or other issues relating to committee activities. Attendance by the public will be limited to space available.

In accordance with the provisions set forth in secs. 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. and sec. 10(d) of Pub. L. 92–463, the meeting will be closed to the public on May 19, from 3:00 p.m. to recess and on May 20 from 8:30 a.m. to adjournment, for the review, discussion and evaluation of individual grant applications. The applications and the discussions could reveal confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with application, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Dr. Elke Jordan, Deputy Director, National Human Genome Research Institute, National Institutes of Health, Building 31, Room 4B09, Bethesda, Maryland 20892, (301) 496–0844, will furnish the meeting agenda, rosters of Committee members and consultants, and substantive program information upon request.

Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should contact Ms. Jane Ades, (301) 594–0654, two weeks in advance of the meeting.

(Catalogue of Federal Domestic Assistance Program No. 93.172, Human Genome Research.)

Dated: April 23, 1997.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 97–10964 Filed 4–28–97; 8:45 am]

BILLING CODE 4140–01–M