

with physical disabilities or mobility limitations. Prior to receiving an award, the applicant organization must assure compliance with the ADAAG.

### Submission Requirements and Deadlines

#### A. Letter of Intent (LOI)

1. *One Original and Two Copies* of the LOI must be postmarked by the following deadline dates in order to be considered in the application cycles. (FACSIMILES ARE NOT ACCEPTABLE.)

#### 2. Letter of Intent Due Dates:

October 6, 1997  
April 6, 1998

#### B. Application

1. *One Original and Two Copies* of the invited application must be submitted on PHS Form 5161-1 (OMB Number 0937-0189) and must be postmarked by the following deadline dates in order to be considered in the application cycles.

#### 2. Application Due Dates:

##### Earliest Possible Award Date:

January 12, 1998  
June 8, 1998  
March 1, 1998  
July 30, 1998

Applications may be accepted by CDC and ATSDR ONLY after the LOI has been reviewed by CDC and ATSDR and *written invitation* from CDC and ATSDR has been received by prospective applicant. An invitation to submit an application does not constitute a commitment to fund. Availability of funds may limit the number of Letters of Intent, regardless of merit, that receive an invitation to submit an application.

#### C. Addresses for Submission of Letters of Intent and Invited Applications

One original and two copies of the Letters of Intent and invited applications must be postmarked on or before the deadline date and mailed to: Henry S. Cassell, III, Grants Management Officer, Attention: Karen Reeves, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Mailstop E-09, Atlanta, GA 30305.

#### D. Deadline

Letters of Intent and Applications shall be considered as meeting the deadline if they are either:

- Received on or before the deadline date, or
- Postmarked on or before the deadline date and received in time for submission to the independent review group. (Applicants must request a

legibly dated U.S. Postal Service postmark or obtain a legibly dated receipt from a commercial carrier or the U.S. Postal Service. Private metered postmarks will not be acceptable as proof of timely mailing.)

#### E. Late Applications

Applications that do not meet the criteria in D.1. or D.2. above are considered late applications and will be returned to the applicant without review.

### Where To Obtain Additional Information

To receive additional written information, call (404) 332-4561. You will be asked to leave your name, address, telephone number and refer to Announcement Number 803. You will receive a complete program description, application form, and information on application procedures. CDC/ATSDR will not send applications by facsimile or express mail.

This and other CDC/ATSDR announcements are also available through the CDC homepage on the Internet. The address for the CDC homepage is <http://www.cdc.gov>.

If you have any questions after reviewing the contents of all documents, you may contact: Karen Reeves, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Mailstop E-09, Atlanta, GA 30305. Telephone (404) 842-6596, E-Mail Address: [ker1@cdc.gov](mailto:ker1@cdc.gov).

Please refer to Announcement Number 803 when requesting information, submitting your Letter of Intent and submitting the invited application in response to the announcement.

Potential applicants may obtain a copy of "Healthy People 2000" (Full Report, Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report, Stock No. 017-001-00473-1) referenced in the "Introduction" through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325, telephone (202) 512-1800.

Dated: April 23, 1997.

#### Claire Broome,

*Deputy Director, Centers for Disease Control and Prevention (CDC), and Deputy Administrator, Agency for Toxic Substances and Disease Registry (ATSDR).*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### Statement of Organization, Functions, and Delegations of Authority

Part D (Food and Drug Administration), Chapter DA, Office of the Commissioner, of the Statement of Organization, Functions, and Delegations of Authority for the Department of Health and Human Services (DHHS) (35 FR 3685, February 25, 1970, and 60 FR 56605, November 9, 1995, as amended most recently in pertinent part at 54 FR 50536, December 7, 1989) is amended to reflect revised functions and title change for the former Executive Secretariat to the newly established Office of Executive Secretariat (OES), Office of the Commissioner, Food and Drug Administration (FDA).

The newly established OES will continue to serve as the focal point for the coordination, identification, development, and implementation of the agency's highest program priorities for the Commissioner. The OES staff will advise the Commissioner, Deputy Commissioners, Senior Staff members and other key agency officials on all activities that affect agencywide programs, projects and initiatives. This reorganization will simplify the organizational structure within the Office of the Commissioner. This action will further enhance and streamline the management and coordination of the agency's Executive Secretariat functions.

The proposed revisions are as follows:

1. Delete the *Office of Executive Operations (DAB)* under the Office of the Commissioner (DA), in its entirety and replace with the following:

*Office of Executive Secretariat (DAB).* Coordinates identification of and expedites development and implementation of the agency's highest program priorities and initiatives for the Commissioner.

Develops and maintains management information necessary for monitoring the Commissioner's and agency's goals and priorities.

Advises the Commissioner, Deputy Commissioners, Senior Staff members and other key agency officials on all activities that affect agencywide programs, projects, and initiatives. Informs appropriate agency staff of the decisions and assignments made by the Commissioner and Deputy Commissioners.

Assures that materials in support of recommendations presented for the

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.*

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## 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