1999. Oral presentations from the public will be scheduled between approximately 10:15 a.m. and 10:45 a.m. and between approximately 3 p.m. and 3:30 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before June 9, 1999, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Closed Committee Deliberations: On June 16, 1999, from 1:30 p.m. to 2 p.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential commercial information (5 U.S.C. 552b(c)(4)). This portion of the meeting will be closed to permit discussion of this information.

FDA regrets that it was unable to publish this notice 15 days prior to the June 16, 1999, General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee meeting. Because the agency believes there is some urgency to bring this issue to public discussion and qualified members of the General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee were available at this time, the Commissioner concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: June 2, 1999.

Jane E. Henney,

Commissioner of Food and Drugs.

[FR Doc. 99–14297 Filed 6–3–99; 11:59 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–R–65]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, has submitted to the Office of Management and Budget (OMB) the following proposal for the collection of information. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: Extension of a currently approved collection;

Title of Information Collection: Information Collection Requirements in Final Peer Review Organization Sanction Regulations 42 CFR 1004.40, 1004.50, 1004.60, and 1004.70;

Form No.: HCFA–R–65 (OMB# 0938–0444);

Use: The Peer Review Improvement Act of 1982 amended Title XI of the Social Security Act to create the Utilization and Quality Control Peer Review Organization (PRO) program. The PRO program replaced the existing Professional Standards Review Organization (PSRO) program and streamlined peer review activities. PROs will ensure that care provided to Medicare patients is reasonable, medically necessary, appropriate, of a quality that meets professionally recognized standards of care, and that inpatient services could not be more appropriately provided on an outpatient basis or in a different type facility;

Frequency: On occasion;

Affected Public: Not-for-profit institutions, and Business or other for-profit;

Number of Respondents: 53;

Total Annual Responses: 1,060;

Total Annual Hours: 22,684.

To obtain copies of the supporting statement for the proposed paperwork collections referenced above, access HCFA's WEB SITE ADDRESS at http://www.hcfa.gov/regs/prdact95.htm, or E-mail your request, including your address and phone number, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 30 days of this notice directly to the OMB Desk Officer designated at the following address: OMB Human Resources and Housing Branch, Attention: Allison Eydt, New Executive Office Building, Room 10235, Washington, D.C. 20503.

Dated: May 6, 1999.

John P. Burke III,

HCFA Reports Clearance Officer, HCFA, Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards.

[FR Doc. 99–14318 Filed 6–4–99; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–1771]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, has submitted to the Office of Management and Budget (OMB) the following proposal for the collection of information. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: Extension of a currently approved collection;

Title of Information Collection: Attending Physicians Statement and Documentation of Medicare Emergency and Supporting Regulations in 42 CFR Sections 424.101 and 424.103;

Form No.: HCFA–1771 (OMB# 0938–0023);

Use: Payment, by Medicare, may be made for certain Part A inpatient hospital services and Part B outpatient services provided in a nonparticipating U.S. or foreign hospital, when services are necessary to prevent the death or serious impairment to the health of an individual. This form is used to document the attending physician's statement that the hospitalization was required due to an emergency and give clinical support for the claim;

Frequency: On occasion;

Affected Public: Business or other for profit;

Number of Respondents: 2,000;
Total Annual Responses: 2,000;
Total Annual Hours: 500.

To obtain copies of the supporting statement for the proposed paperwork collections referenced above, access HCFA's WEB SITE ADDRESS at http://www.hcfa.gov/regs/prdact95.htm, or E-mail your request, including your address and phone number, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 30 days of this notice directly to the OMB Desk Officer designated at the following address: OMB Human Resources and Housing Branch, Attention: Allison Eydt, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: May 19, 1999.

John P. Burke III,

HCFA Reports Clearance Officer, HCFA, Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards.

[FR Doc. 99–14319 Filed 6–4–99; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases: Opportunity for Cooperative Research and Development Agreements (CRADAs) in Conjunction With a Major Multicenter Clinical Trial—the Study of Health Outcomes of Weight Loss (SHOW)

AGENCY: National Institutes of Health, Public Health Service, DHHS.

ACTION: Notice.

SUMMARY: The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) seeks capability statements from parties interested in entering into a potential Cooperative Research and Development Agreement (CRADA) to provide anti-obesity agents for treating subjects in the Study of Health Outcomes of Weight Loss (SHOW).

Collaborator applicants developing capability statements may also include proposals to provide funding for assessment of outcomes of interest to the Collaborator. The availability of provide sector support may increase the feasibility of particular aspects of the final SHOW design, but the primary criterion for selecting potential collaborator(s) is the scientific merit of proposals for use of anti-obesity agents.

The control of the SHOW clinical trial shall reside entirely with the Institute and the scientific participants of the trial. In the event that any adverse effects are encountered which, for legal or ethical reasons, may require communications with the FDA, the relevant collaborating institutions will be notified. Neither the conduct of the trial nor the results should be represented as an NIDDK endorsement of the drug under study.

DATES: Only written CRADA capability statements received by the NIDDK on or before September 1, 1999 will be considered during the initial design phase, confidential information must be clearly labeled. Potential collaborators may be invited to meet with the Selection Committee at the Collaborator's expense to provide additional information. The Institute may issue an additional notice of CRADA opportunity during the design of the trial if circumstances change or if the trial design alters substantially.

FOR FURTHER INFORMATION AND QUESTIONS: Capability statements should be submitted to Dr. Michael W. Edwards, Office of Technology Development, National Institute of Diabetes and Digestive and Kidney Diseases, National Institutes of Health, BSA Building, Suite 350 MSC 2690, 9190 Rockville Pike, Bethesda, MD 20814–3800; Tel: 301/496–7778, Fax: 301/402–0535; Email: mels@nih.gov.

SUPPLEMENTARY INFORMATION: SHOW will be conducted as a cooperative agreement among the SHOW Clinical Centers (approximately fifteen centers), a Data Coordinating Center, and the NIH. SHOW will address two primary research questions: (1) Do interventions designed to produce sustained weight loss in obese individuals with type 2 diabetes improve health? (2) How do the benefits and risks of interventions designed to produce weight loss compare with the benefits and risks related to treatment of obesity-related comorbid conditions in the absence of weight loss intervention?

SHOW is expected to recruit approximately 6000 obese diabetic patients over a three-year period with four additional years of treatment and follow-up (average treatment duration 5.5 years). It is anticipated that two-thirds of the patients recruited to the study will be randomly assigned to enrollment in weight loss interventions and one-third to community care. The SHOW trial is likely to have three arms, as follows:

(1) Community Care—Patients will receive medical care for their obesity and obesity-related comorbid conditions (e.g., diabetes, hypertension, dyslipidemia) from their primary care physician. The primary care physician will be given standard of care recommendations for treatment of obesity and comorbid conditions (e.g., guidelines from the American Diabetes Association) and will be provided with results of diagnostic tests carried out at study sites.

(2) Intensive Lifestyle Intevention—Patients will under go a long-term behavioral treatment program that includes dietary modification, increased physical activity, and behavioral therapies designed to enhance weight loss and weight maintenance. This intervention is anticipated to be conducted in groups. Obesity-related comorbid conditions will be treated by the primary care physician as in Group 1.

(3) Intensive Lifestyle Intervention plus Weight-Loss Medication—Medication will be added to the intensive lifestyle intervention in an attempt to enhance long-term weight maintenance. Comorbid conditions will be treated by the primary care physician as in Group 1.

The SHOW RFAs may be accessed at:
http://www.nih.gov/grants/guide/rfa–files/RFA–DK–98–019.html for Clinical Centers RFA
http://www.nih.gov/grants/guide/rfa–files/RFA–DK–98–020.html for the Data Coordinating Center RFA

Capability Statements

The design concept described above is not final. The final design will be developed over the course of the first year of the trial by the SHOW Steering Committee (which will include the Principal Investigators of the Clinical Centers, the Principal Investigator of the Data Coordinating Center, and the NIDDK Project Coordinator). It is possible that the final design for SHOW may include no anti-obesity agents, or may include more than one anti-obesity agent.

A Selection Committee will utilize the information provided in the ''Collaborator Capability Statements'' received in response to this announcement to help in its deliberations. The Selection Committee will interact with the Steering Committee to develop the most appropriate design, based on a thorough understanding of the efficacy and side effects associated with all agents proposed.

It is the intention of the NIDDK that all qualified collaborators have the