SUMMARY: The Food and Drug Administration (FDA) is announcing the year 2000 meetings of its clinical hold oversight committee, which reviews the clinical hold orders that the Center for Biologics Evaluation and Research (CBER) has placed on certain investigational biological product trials. For each meeting, FDA is inviting any interested biological product company to use this confidential mechanism to submit to the committee for its review the name and number of any investigational biological product trial placed on clinical hold during the past 12 months that the company wants the committee to review

DATES: The meetings will be held on February 10, 2000; May 11, 2000; August 10, 2000; and November 9, 2000. Biological product companies may submit review requests for the February meeting by January 20, 2000; for the May meeting by March 30, 2000; for the August meeting by June 29, 2000; and for the November meeting by September 28, 2000.

ADDRESSES: Submit clinical hold review requests to Steven H. Unger, FDA Acting Ombudsman, Office of the Commissioner (HF–7), 5600 Fishers Lane, rm. 14–105, Rockville, MD 20857, 301–827–3390.

FOR FURTHER INFORMATION CONTACT: Stephen M. Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION: FDA's regulations in part 312 (21 CFR part 312) provide procedures that govern the use of investigational new drugs and biologics in human subjects. If FDA determines that a proposed or ongoing study may pose significant risks for human subjects or is otherwise seriously deficient, as discussed in the investigational new drug regulations, it may order a clinical hold on the study. The clinical hold is one of FDA's primary mechanisms for protecting subjects who are involved in investigational new drug or biologic trials. Section 312.42 describes the grounds for ordering a clinical hold.

A clinical hold is an order that FDA issues to a sponsor to delay a proposed investigation or to suspend an ongoing investigation. The clinical hold may be ordered on one or more of the investigations covered by an investigational new drug application (IND). When a proposed study is placed on clinical hold, subjects may not be given the investigational drug or biologic as part of that study. When an ongoing study is placed on clinical hold, no new subjects may be recruited to the study and placed on the investigational drug or biologic, and patients already in the study should stop receiving therapy involving the investigational drug or biologic, unless FDA specifically permits it.

When FDA concludes that there is a deficiency in a proposed or ongoing clinical trial that may be grounds for ordering a clinical hold, ordinarily FDA will attempt to resolve the matter through informal discussions with the sponsor. If that attempt is unsuccessful, a clinical hold may be ordered by or on behalf of the director of the division that is responsible for the review of the IND.

FDA regulations in § 312.48 provide dispute resolution mechanisms through which sponsors may request reconsideration of clinical hold orders. The regulations encourage the sponsor to attempt to resolve disputes directly with the review staff responsible for the review of the IND. If necessary, the sponsor may request a meeting with the review staff and management to discuss the clinical hold.

CBER began a process to evaluate the consistency and fairness of practices in ordering clinical holds by instituting an oversight committee to review clinical holds (see 61 FR 1033, January 11, 1996). CBER held its first clinical hold oversight committee meeting on May 17, 1995, and plans to conduct further quality assurance oversight of the IND process. The review procedure of the committee is designed to afford an opportunity for a sponsor who does not wish to seek formal reconsideration of a pending clinical hold to have that clinical hold considered ''anonymously.'' The committee consists of senior managers of CBER, a senior official from the Center for Drug Evaluation and Research, and the FDA Chief Mediator and Ombudsman.

Clinical holds to be reviewed will be chosen randomly. In addition, the committee will review clinical holds proposed for review by biological product sponsors. In general, a biological product sponsor should consider requesting review when it disagrees with FDA's scientific or procedural basis for the decision.

Requests for committee review of a clinical hold should be submitted to the FDA Chief Mediator and Ombudsman, who is responsible for selecting clinical holds for review. The committee and CBER staff, with the exception of the FDA Chief Mediator and Ombudsman, are never advised, either in the review process or thereafter, which of the clinical holds were randomly chosen and which were submitted by sponsors. The committee will evaluate the selected clinical holds for scientific content and consistency with FDA regulations and CBER policy.

The meetings of the oversight committee are closed to the public because committee discussions deal with confidential commercial information. Summaries of the committee deliberations, excluding confidential commercial information, may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximately 15 working days after the meeting, at a cost of 10 cents per page. If the status of a clinical hold changes following the committee's review, the appropriate division will notify the sponsor.

For each meeting, FDA invites biological product companies to submit to the FDA Chief Mediator and Ombudsman the name and IND number of any investigational biological product trial that was placed on clinical hold during the past 12 months that they want the committee to review. Submissions should be made by January 20, 2000, for the February meeting; by March 30, 2000, for the May meeting; by June 29, 2000, for the August meeting; and by September 28, 2000, for the November meeting to Steven H. Unger, FDA Acting Ombudsman (address above).

Dated: December 28, 1999.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 00–109 Filed 1–4–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–1094–N]

Medicare Graduate Medical Education Consortia Demonstration

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

ACTION: Notice.

SUMMARY: This notice announces the Medicare Graduate Medical Education (GME) Consortia demonstration, which will test how teaching hospitals and affiliated organizations respond to the incentive of shared direct GME payments. HCFA is interested in newly formed partnerships as well as already existing GME consortia. HCFA plans to conduct the demonstration with a limited number of consortia, to be chosen through a competitive

application process. An application package can be obtained from HCFA, which describes the demonstration and the criteria to be used in reviewing applications. Applications are due to HCFA 90 days after the publication of this notice.

DATES: Closing date for submission of applications will be April 4, 2000, 5 p.m. E.S.T.

APPLICATIONS: To receive an application package, and for further information, contact Sid Mazumdar, (410) 786–6673.

ADDRESSES: Mail correspondence to the following: Health Care Financing Administration, Room C4–14–15, 7500 Security Boulevard, Baltimore, Maryland 21244–1850, Attention: Sid Mazumdar.

I. Background

Section 4628 of the Balanced Budget Act of 1997 requires a demonstration which will permit direct Graduate Medical Education payments ordinarily paid to a teaching hospital to be paid to a consortium. According to the legislation, a qualifying consortium is to consist of a teaching hospital (with one or more residency programs) and at least one of the following: a school of allopathic or osteopathic medicine, another teaching hospital (which can be a children's hospital), a Federally Qualified Health Center, a medical group practice, a managed care entity, or an entity furnishing outpatient services. The legislation gives authority to the Secretary of Health and Human Services to expand the definition of an organization qualified to participate in a consortium.

Organizations that are already established will be able to begin the demonstration in July 2000. Other consortia will begin with the demonstration payment in July 2001. No consortium projects will begin after the summer of 2001. Applying consortia must provide letters of commitment demonstrating that all participating organizations agree to the proposed system of governance and methodology for distributing funds. HCFA will evaluate applications on how the proposed project will help achieve stated goals; the system of administration and decision making; plans for quality improvement and evaluation; and staff and capability for education and training. Applicants will be evaluated according to a numerical scoring system corresponding to the specific criteria that are described in the application.

II. Payment Methodology

HCFA will pay to the consortium the fraction (or entirety) of the direct Graduate Medical Education (GME) payment of the teaching hospital(s) that the consortium agrees upon, subject to HCFA's approval. This amount will be subtracted from HCFA's payment to the teaching hospitals. The demonstration will be budget neutral, that is, it will allow no more money to be paid to the consortium than what the direct GME payment would otherwise have been to its participating entities. The application package contains a more detailed explanation of the payment methodology.

Authority: Section 4628 of the Balanced Budget Act of 1997, Public Law 105–33.

(Catalog of Federal Domestic Assistance Program No. 93.779, Health Financing, Demonstrations, and Experiments)

Dated: December 15, 1999.

Nancy-Ann Min DeParle,

Administrator, Health Care Financing Administration.

[FR Doc. 00–121 Filed 1–4–00; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–3028–N]

Medicare Program; Notice of the Solicitation for Proposals To Expand the Medicare Lifestyle Modification Program Demonstration

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

ACTION: Notice.

SUMMARY: This notice announces our solicitation for proposals to expand the Medicare Lifestyle Modification Program Demonstration to one additional, national multi-site cardiovascular lifestyle modification program. The purpose of this demonstration is to test the feasibility and cost-effectiveness of providing payment for cardiovascular lifestyle modification program services to Medicare beneficiaries. This demonstration will test proven and intensive programs designed to reduce or reverse the progression of cardiovascular disease of patients at risk for invasive treatment procedures. The expansion will allow for a comparison between two different lifestyle modification models across several factors, including price. The demonstration began October 1, 1999 and will be conducted over a 4-year period. Currently, the demonstration is being implemented at several sites subscribing to one multi-site lifestyle modification program model. Enrollment for each multi-site program is limited to 1,800 Part B eligible Medicare beneficiaries who satisfy specific clinical admission criteria.

DATES: *Letters of Intent:* Letters of Intent must be received by the HCFA project officer by February 4, 2000.

Proposals: Proposals (an original and 5 copies), each with a copy of the timely letter of intent, must be received by the HCFA project officer by April 4, 2000.

ADDRESSES: *Letters of Intent and Proposals:* Department of Health and Human Services, Health Care Financing Administration, Attention: Armen Thoumaian, Ph.D., Project Officer, Medicare Lifestyle Modification Program Demonstration, Office of Clinical Standards and Quality, Mail Stop: S3–02–01, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Demonstration Website: www.hcfa.gov/quality/qlty-3.htm.

FOR FURTHER INFORMATION CONTACT: Armen Thoumaian, Ph.D., (410) 786–6672, or e-mail Athoumaian@hcfa.gov.

SUPPLEMENTARY INFORMATION:

I. Background

A. Problem

Research has provided evidence that specific lifestyle changes can lead to a decrease in the levels of cardiovascular risk factors, resulting in lower morbidity and mortality associated with coronary artery disease (CAD). Lifestyle modification programs are increasingly becoming an approach to the secondary prevention of coronary disease morbidity. The programs may reduce the incidence of hospitalizations and invasive procedures among patients with substantial coronary occlusion.

Studies have shown that controlling single risk factors such as a low-fat diet, smoking cessation, exercise, or stress management are beneficial in the treatment of cardiovascular disease. Other psycho-social risk factors, including depression and social isolation, have already been shown to be important. Multi-factorial risk reduction programs that include reduction of some or all of these risk factors in a comprehensive cardiovascular lifestyle management program, however, have yet to be evaluated for their effectiveness or long-term cost savings in the Medicare population.

We currently pay for 12 weeks of cardiac rehabilitation services for Medicare patients who have a prior