remuneration with the intent to induce, or in return for the referral of, Medicare or a State health care program business. State health care programs are Medicaid, the Maternal and Child Health Block Grant program, and the Social Services Block Grant program. Apart from the criminal penalties, a person or entity is also subject to exclusion from participation in the Medicare and State health care programs for a knowing and willful violation of the statute pursuant to 42 U.S.C. 1320a–7(b)(7).

The anti-kickback statute is very broad. Prohibited conduct covers not only remuneration intended to induce referrals of patients, but also includes remuneration intended to induce the purchasing, leasing, ordering, or arranging for any good, facility, service, or item paid for by Medicare or a State health care program. The statute specifically identifies kickbacks, bribes, and rebates as illegal remuneration, but also covers the transferring of anything of value in any form or manner whatsoever. This illegal remuneration may be furnished directly or indirectly, overtly or covertly, in cash or in kind and covers situations where there is no direct payment at all, but merely a discount or other reduction in price or the offering of a free good(s).

Arrangements between contractors and covered entities that could violate the anti-kickback statute would include any situation where the covered entity agrees to refer patients to the contractor in return for the contractor agreeing to undertake or furnish certain activities or services to the covered entity at no charge or at a reduced or below cost charge. These activities or services would include the provision of contracted pharmacy services, home care services, money or grants for staff or service support, or medical equipment or supplies, and the remodeling of the covered entity's premises. For example, if a contractor agreed to furnish covered outpatient drugs in return for the covered entity referring its Medicaid patients to the contractor to have their prescriptions filled, the arrangement would violate the anti-kickback statute. Similarly, if the contractor agreed to provide billing services for the covered entity at no charge in return for the covered entity referring its patients to the contractor for home or durable medical equipment, the statute would be violated.

Pursuant to the authority in 42 U.S.C. 1320a–7b(b)(3), the Secretary of HHS has published regulations setting forth certain exceptions to the anti-kickback statute, commonly referred to as ''safe harbors.'' These regulations are codified at 42 CFR 1001.952. Each of the safe harbors sets forth various requirements which may be met in order for a person or entity to be immune from prosecution or exclusion.

(D) Appendix—Suggested Contract Provisions

(1) ''The covered entity will order covered drugs directly from the manufacturer, from a designated sales representative, or a drug wholesaler and arrange to be billed directly for such drugs. The covered entity will arrange for shipment of such drugs directly to the pharmacy. The pharmacy will compare all shipments received to the orders and inform the covered entity of any discrepancy within five (5) business days of receipt. The covered entity will make timely payments for such drugs delivered to the (pharmacy) pursuant to the entity's order.''

(2) ''The covered entity will verify, using the contractor's (readily retrievable) customary business records, that a tracking system exists which will ensure that drugs purchased under the Act are not diverted to individuals who are not patients of the covered entity. Such records can include: prescription files, velocity reports, and records of ordering and receipt. These records will be maintained for the period of time required by State law and regulations.''

(3) ''Prior to the pharmacy providing pharmacy services pursuant to this agreement, the covered entity will have the opportunity, upon reasonable notice and during business hours, to examine the tracking system. For example, such a tracking system may include quarterly sample comparisons of eligible patient prescriptions to the dispensing records and a six (6) month comparison of 340B drug purchasing and dispensing records as is routinely done in other reconciliation procedures. The pharmacy will permit the covered entity or its duly authorized representatives to have reasonable access to pharmacy's facilities and records during the term of this agreement in order to make periodic checks regarding the efficacy of such tracking systems. The pharmacy agrees to make any and all adjustments to the tracking system which covered entity advises are reasonably necessary to prevent diversion of covered drugs to individuals who are not patients of the covered entity.''

(4) ''The pharmacy will dispense covered drugs only in the following circumstances: (a) Upon presentation of a prescription bearing the covered entity's name, the eligible patient's name, a designation that the patient is an eligible patient, and the signature of a legally qualified health care provider affiliated with the covered entity; or (b) receipt of a prescription ordered by telephone on behalf of an eligible patient by a legally qualified health care provider affiliated with the covered entity who states that the prescription is for an eligible patient. The covered entity will furnish a list to the pharmacy of all such qualified health care providers and will update the list of providers to reflect any changes. If a contract pharmacy is found to have violated the drug diversion prohibition, the pharmacy will pay the entity the amount of the discount in question so that the entity can reimburse the manufacturer.''

Dated: August 14, 1996.

Thomas G. Morford,

Acting Administrator, Health Resources and Services Administration.

[FR Doc. 96–21485 Filed 8–22–96; 8:45 am]

BILLING CODE 4160–15–P

National Institutes of Health

National Heart, Lung, and Blood Institute; Proposed Collection; Comment Request the Framingham Study

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on the proposed data collection projects, the National Heart, Lung, and Blood Institute (NHLBI), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

PROPOSED COLLECTION: Title: The Framingham Study. Type of Information Collection Request: Extension of a currently approved collection (OMB No. 0925–0216). Need and Use of Information Collection: This project involves physical examination and testing of the surviving members of the original Framingham Study cohort and the surviving members of the offspring cohort. Investigators will contact doctors, hospitals, and nursing homes to ascertain participants' cardiovascular events occurring outside the study clinic. Information gathered will be used to further describe the risk factors, occurrence rates, and consequences of cardiovascular disease in middle aged and older men and women. Frequency of Response: The cohort participants respond every two years; the offspring participants respond every four years. Affected Public: Individuals or households; Businesses or other for profit; Small businesses or

organizations. Type of Respondents: Middle aged and elderly adults; doctors and staff of hospitals and nursing homes. The annual reporting burden is as follows:

Type of respondents	Estimated number of respondents	Estimated number of responses per respondent	Average burden hours per response	Estimated total annual burden hours requested
Original cohort examined in clinic	192	1.0	1.9	365
Original cohort examined in residence	121	1.0	1.2	145
Offspring examined in clinic	1,157	1.0	3.9	4,512
Offspring examined in residence	20	1.0	1.5	30
[1] Event information	1,887	1.0	0.75	1,415
Total				6,467

[1] Annual burden is placed on doctors, hospitals, nursing homes, and respondent relatives/informants through requests for information which will help in the compilation of the number and nature of new fatal and nonfatal events occurring outside the Framingham examining clinic.

The cost to the respondents consists of their time and travel; time is estimated using a rate of $10.00 per hour and travel is estimated using a cost of $0.35 per mile. The annualized cost to respondents is estimated at: $19,622. The Capital Costs are $5,698. The Operating and Maintenance Costs are $2,914,926.

REQUEST FOR COMMENTS: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used: (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

FOR FURTHER INFORMATION: To request more information on the proposed project, to obtain a copy of the data collection plans and instruments, or to submit comments, contact Ms. Mishyelle Croom, Project Clearance Liaison, National Heart, Lung, and Blood Institute, NIH, Building 31, Room 4A28, MSC 2490, 31 Center Dr., Bethesda, MD 20892–2490 or call non-toll free number (310) 496–1763, or E-mail your request or comments, including your address, to: CroomM@nih.gov.

Comments due Date: Comments regarding this information collect are best assured of having their full effect if received on or before October 22, 1996.

Dated: August 14, 1996.

Sheila Merritt,

Executive Officer, NHLBI.

[FR Doc. 96–21535 Filed 8–22–96; 8:45 am]

BILLING CODE 4140–01–M

National Institute on Aging; Notice of Closed Meeting

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting:

Name of Panel: National Institute on Aging Special Emphasis Panel (Teleconference Call).

Date of Meeting: September 10, 1996.

Times of Meeting: 1:00 to 3:30 p.m.

Place of Meeting: Gateway Building, 7201 Wisconsin Avenue, Bethesda, MD 20814.

Purpose/Agenda: To review three institutional training grants.

Contact Person: Arthur D. Schaerdel, DVM. Scientific Review Administrator, Gateway Building, Room 2C212, National Institutes of Health, Bethesda, Maryland 20892–9205, (301) 496–9666.

This notice is being published less than 15 days prior to the above meeting due to the urgent need to meet timing limitation imposed by the review and funding cycle.

The meeting will be closed in accordance with the provisions set forth in § 552b(c)(4) and 552b(c)(6), title 5, U.S.C. Applications and/or proposals and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications and/or proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

(Catalog of Federal Domestic Assistance Program No. 93.866, Aging Research, National Institutes of Health)

Dated: August 13, 1996.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 96–21534 Filed 8–22–96; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4120–N–02]

Office of Administration; Notice of Submission of Proposed Information Collection to OMB

AGENCY: Office of Administration—HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below has been submitted to the Office of Management and Budget (OMB) for emergency review and approval, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: The due date for comments is: August 30, 1996.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments must be received within seven (7) days from the date of this Notice. Comments should refer to the proposal by name and should be sent to: Joseph F. Lackey, Jr., HUD Desk Officer, Office of Management and Budget, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Kay F. Weaver, Reports Management Officer, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410, telephone (202) 708–0050. This is not a toll-free number. Copies of available documents submitted to OMB may be obtained from Ms. Weaver.