brief description of the objective of the studies, the experimental design, how the data were collected and analyzed, and a brief description of the results of the studies, whether positive, negative, or inconclusive. The summary of the clinical study(ies) should also include a discussion of the subject inclusion and exclusion criteria, the study population, reasons for patient discontinuations, and results of statistical analyses.

7. *Bibliography*. A copy of the key references, a brief summary of the salient features of each key reference, and a brief discussion of why the reference is relevant to an evaluation of the safety and effectiveness evaluation of the device.

Manufacturers who are aware of information that would support the reclassification of their device into class I or class II may either submit information using the format described below or may submit a formal reclassification petition, which should include the information described below in addition to the information required under 21 CFR 860.123:

1. *Identification*. A brief narrative identification of the device. This identification should be specific enough to distinguish a particular device from a generic type of device. Where appropriate, this identification should include a listing of the materials, and the component parts, and a description of the intended use of the device.

2. *Risks to health*. An identification of the risks to health should be provided. This section should summarize all adverse safety and effectiveness information that has not been submitted under section 519 of the act, particularly the most significant. The mechanisms or procedures which will control the risk should be described. A list of the general hazards associated with the device and a bibliography with copies of the referenced material should be provided.

3. *Recommendation*. A statement whether the manufacturer believes the device should be reclassified into class I or class II.

4. *Summary of reasons for recommendation*. Each manufacturer should include a summary of the reasons for requesting reclassification of its device and an explanation of why it believes the device meets the statutory criteria for reclassification into class I or class II. Each manufacturer should also identify the special controls that it believes would be sufficient to provide reasonable assurance of the safety and effectiveness of its device if it believes the device should be reclassified into class II.

5. *Summary of valid scientific evidence on which the recommendation is based*. Manufacturers are advised that, when considering a formal reclassification petition, FDA will rely only upon valid scientific evidence to determine that there is reasonable assurance of the safety and effectiveness of the device, if regulated by general controls alone (class I) or by general controls and special controls (class II). Valid scientific evidence consists of evidence from well-controlled investigations, partially controlled studies, studies and objective trials without matched controls, well-documented case histories conducted by qualified experts, and reports of significant human experience with a marketed device, from which it can fairly and responsibly be concluded by qualified experts that there is reasonable assurance of the safety and effectiveness of a device under its conditions of use. The evidence required may vary according to the characteristics of the device, its conditions of use, the existence and adequacy of warnings and other restrictions, and the extent of experience with its use. Isolated case reports, random experience, reports lacking sufficient details to permit scientific evaluation, and unsubstantiated opinions are not regarded as valid scientific evidence to show safety or effectiveness (see § 860.7(c)(2)).

According to § 860.7(d)(1), there is reasonable assurance that a device is safe when it can be determined, based upon valid scientific evidence, that the probable benefits to health from use of the device for its intended uses and conditions of use, when accompanied by adequate directions and warnings against unsafe use, outweigh any probable risks. The valid scientific evidence used to determine the safety of a device shall adequately demonstrate the absence of unreasonable risk of illness or injury associated with the use of the device for its intended uses and conditions for use. Moreover, under § 860.7(e)(1), there is reasonable assurance that a device is effective when it can be determined, based upon valid scientific evidence, that in a significant portion of the target population, the use of the device for its intended uses and conditions of use, when accompanied by adequate directions for use and warnings against unsafe use, will provide clinically significant results.

Manufacturers submitting a formal reclassification petition may wish to request two petitions as examples of successful reclassification petitions. Magnetic resonance imaging devices, Docket Nos. 87P–0214/CP–1 through CP–13, and Nd:YAG Laser for posterior capsulotomy devices, Docket No. 86P–0083, were both reclassified from class III to class II subsequent to the submission of reclassification petitions. Both petitions are available upon submission of a Freedom of Information request to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20850.

IV. Submission of Required Information

The summary of, and citation to, any information required by the act must be submitted by the dates listed above to the Document Mail Center (address above).

Dated: June 4, 1997.

Joseph A. Levitt,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 97–15450 Filed 6–12–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–255]

Agency Information Collection Activities: Proposed Collection; 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, is publishing the following summary of proposed collection for public comment. 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:* Municipal Health Services Cost Report Form, and supporting regulations 42 CFR 405.427; *Form No.:* HCFA–255; *Use:* The Municipal Health Services Program (MHSP) Cost Report (HCFA–255) is

used by the participating MHSP clinics to report costs for health care services rendered to Medicare beneficiaries. It is also used to gather data to properly evaluate the MHSP demonstration. This form has been used since 1979. *Frequency:* Annually; *Affected Public:* Not-for-profit institutions, and State, Local or Tribal Government; *Number of Respondents:* 14; *Total Annual Responses:* 14; *Total Annual Hours:* 476.

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 to obtain the supporting statement and any related forms, 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 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Financial and Human Resources, Management Analysis and Planning Staff, Attention: John Rudolph, Room C2–26–17, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: June 5, 1997.

Edwin J. Glatzel,

Director, Management Analysis and Planning Staff, Office of Financial and Human Resources.

[FR Doc. 97–15506 Filed 6–12–97; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Special Projects of National Significance Program; HIV Service Delivery Models

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice of limited competition.

SUMMARY: The Health Resources and Services Administration (HRSA) announces a limited competition to support the completion and dissemination of innovative programs to advance knowledge and skills in the delivery of health and support services. The objectives of the Special Projects of National Significance (SPNS) Program are to: assess the effectiveness of particular models of care; support innovative program design; and to promote replication of effective models. Awards will be made under the program authority of Section 2691 of the Public Health Service Act, as amended by the Ryan White CARE Act Amendments of 1996, Public Law 104–146, dated May 20, 1996.

HRSA is limiting competition among eight (8) currently funded SPNS Program cooperative agreement projects that were initially funded in fiscal year (FY) 1994 for three years, including: The Center for Community Health, Education, and Research, Dorchester, MA; Emory University, Atlanta, GA; the Interamerican College of Physicians and Surgeons, New York, NY; Missouri Department of Health, Jefferson City, MO; University of Colorado Health Science Center, Denver, CO; University of Texas Health Science Center, San Antonio, TX; University of Washington, Seattle, WA; and, the Visiting Nurse Association, Los Angeles, CA.

An additional two-year project period will allow these projects the opportunity to fully and comprehensively evaluate, and disseminate the models of HIV care developed during the initial project.

GRANTS/AMOUNTS: The total amount of funds available in FY 97 is $2,200,000. Up to eight projects will be funded for an additional two-year project period. Funding beyond FY 97 is subject to the appropriation of FY 98 funds for the Ryan White CARE Act and satisfactory progress in meeting the project's objectives.

FOR FURTHER INFORMATION CONTACT: Additional information may be obtained from Ms. Mirtha Beadle, Deputy Director, SPNS Program, Office of Science and Epidemiology, Bureau of Health Resources Development, Health Resources and Services Administration, 5600 Fishers Lane, Room 7A–08, Rockville, MD 20857. The telephone number is (301) 443–6439 and the FAX number is (301) 443–4965.

OTHER GRANT INFORMATION:

Certification Regarding Environmental Tobacco Smoke:

The Public Health Service strongly encourages all grant and contract recipients to provide a smoke-free workplace and to promote the non-use of all tobacco products. In addition, Public Law 103–227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care or early childhood development services are provided to children.

OMB Catalog of Federal Domestic Assistance:

The number for the Special Projects of National Significance Program is 93.928.

Dated: June 5, 1997.

Claude Earl Fox,

Acting Administrator.

[FR Doc. 97–15448 Filed 6–12–97; 8:45 am]

BILLING CODE 4160–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National institute of Mental Health Notice of Closed Meetings

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 meetings of the National Institute of Mental Health Special Emphasis Panel:

Agenda/Purpose: To review and evaluate grant applications.

Committee Name: National Institute of Mental Health Special Emphasis Panel.

Date: June 19, 1997.

Time: 11 a.m.

Place: One Washington Circle, One Washington Circle, N.W., Washington, DC 20037.

Contact Person: Maureen L. Eister, Parklawn, Room 9–101, 5600 Fishers Lane, Rockville, MD 20857, Telephone: 301, 443–3936.

Committee Name: National Institute of Mental Health Special Emphasis Panel.

Date: June 25, 1997.

Time: 6 p.m.

Place: Holiday Inn Chevy Chase, 5520 Wisconsin Ave, Chevy Chase, MD 20815.

Contact Person: Michael D. Hirsch, Parklawn, Room 9–101, 5600 Fishers Lane, Rockville, MD 20857 Telephone: 301, 443–3936.

Committee Name: National Institute of Mental Health Special Emphasis panel.

Date: June 27, 1997.

Time: 10 a.m.

Place: Chevy Chase Holiday Inn, 5520 Wisconsin Avenue, Chevy Chase, MD 20815.

Contact Person: Michael D. Hirsch, Parklawn, Room 9–101, 5600 Fishers Lane, Rockville, MD 20857; Telephone: 301, 443–3936.

Committee Name: National Institute of Mental Health Special Emphasis Panel.

Date: July 2, 1997.

Time: 3 p.m.

Place: Parklawn, Room 9–101, 5600 Fishers Lane, Rockville, MD 20857.

Contact Person: Donna Ricketts, Parklawn, Room 9–101, 5600 Fishers Lane, Rockville, MD 20857; Telephone: 301, 443–3936.

The meetings will be closed in accordance with the provisions set forth in secs. 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. Applications and/or proposals and the discussions could reveal confidential trade