

| Item Number | Title of Standard | Reference Number and Date |
|-------------|--|-----------------------------|
| 53 | Sterilization of Health Care Products—Chemical Indicators—Part 2: Class 2 Indicators for Air Removal Test Sheets and Packs | ANSI/AAMI ST66: 1999 |
| 54 | Sterilization of Medical Devices—Microbiological Methods—Part 2: Tests of Sterility Performed in the Validation of a Sterilization Process | ANSI/AAMI/ISO 11737-2: 1998 |
| 55 | Sterilization of Single-Use Medical Devices Incorporating Materials of Animal Origin—Validation and Routine Control of Sterilization by Liquid Chemical Sterilants | ANSI/AAMI/ISO 14160: 1998 |
| 56 | Standard Test Method for Determination of Leaks in Flexible Packaging by Bubble Emission | ASTM D3078: 1994 |
| 57 | Standard Practice for Performance Testing of Shipping Containers and Systems | ASTM D4169: 1999 |
| 58 | Standard Test Method for Seal Strength of Flexible Barrier Materials | ASTM F88: 1999 |
| 59 | Standard Test Methods for Failure Resistance of Unrestrained and Nonrigid Packages for Medical Applications | ASTM F1140: 1996 |
| 60 | Standard Terminology Relating to Barrier Materials for Medical Packaging | ASTM F1327: 1998 |
| 61 | Standard Guide for Integrity Testing of Porous Barrier Medical Packages | ASTM F1585: 1995 |
| 62 | Standard Test Method for Microbial Ranking of Porous Packaging Materials (Exposure Chamber Method) | ASTM F1608: 1995 |
| 63 | Standard Test Method for Determining Integrity of Seals for Medical Packaging by Visual Inspection | ASTM F1886: 1998 |
| 64 | Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration | ASTM F1929: 1998 |
| 65 | Standard Guide for Accelerated Aging of Sterile Medical Device Packages | ASTM F1980: 1999 |
| 66 | Transfusion and Infusion Assemblies and Similar Medical Devices <161> | USP 24: 2000 |

Dated: October 31, 2000.

Linda S. Kahan,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Public Law 104-13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to OMB under the Paperwork Reduction Act of 1995. To

request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, call the HRSA Reports Clearance Officer on (301) 443-1129.

Comments are invited on: (a) 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; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Scholarship Program for Students of Exceptional Financial Need (EFN) and Program of Financial Assistance for Disadvantaged Health Professions Students (FADHPS): Regulatory Requirements (OMB No. 0915-0028)—Reinstatement, with change.

The EFN Scholarship Program, authorized by section 736 of the Public Health Service (PHS) Act, and the FADHPS Program, authorized by section 740(a)(2)(F) of the PHS Act, provides financial assistance to schools of allopathic and osteopathic medicine and dentistry for awarding tuition scholarships to health professions students who are of exceptional financial need. To be eligible for support under the FADHPS Program, a student must also be from a disadvantaged background. In return for this support, students of allopathic and osteopathic medicine must agree to complete residency training in primary care in 4 years, and practice in primary care for 5 years after completing residency training.

The program regulations contain recordkeeping requirements designed to ensure that schools maintain adequate records for the Government to monitor program activity and that funds are spent as intended.

The estimate of burden for the regulatory requirements of this clearance are as follows:

| Form | Number of respondents | Responses per respondents | Total responses | Minutes per response | Total burden (in hours) |
|------------------|-----------------------|---------------------------|-----------------|----------------------|-------------------------|
| EFN/FADHPS | 80 | 1 | 80 | 10 | 13 |

Send comments to Susan G. Queen, Ph.D., HRSA Reports Clearance Officer, Room 14-33, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: November 7, 2000.

Jane M. Harrison,

Director, Division of Policy Review and Coordination.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

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

Periodically, the Health Resources and Services Administration (HRSA)

publishes abstracts of information collection requests under review by the Office of Management and Budget, in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301)-443-1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

Proposed Project: Social Support for Homeless Mothers: Implications for Best Practices and Program Design—New

The Health Care for the Homeless Clinicians' Network (HCHCN) of the National Health Care for the Homeless Council, Inc., through a cooperative agreement with the Bureau of Primary Health Care, Health Resources and Services Administration, proposes to

conduct a study on the social support available to homeless mothers, most of whom are parenting children alone. The study will be of adult homeless women and will be conducted by convening focus groups and administering a questionnaire to focus group members. The study is designed to look at clients' life events, histories of violence, medical and physical illness, social support, children's needs, and services use. The results will help to define best practices as they relate to social support processes and enable HCH programs to offer the appropriate mix of supports necessary to help mothers transition into permanent housing. The participants will be recruited from ten sites of the national Health Care for the Homeless program.

The estimated response burden is as follows:

| Type of respondent | Number of respondents | Responses per respondent | Hours per response | Total hour burden |
|--------------------------------------|-----------------------|--------------------------|--------------------|-------------------|
| Focus Group (including survey) | 100 | 1 | 1.5 | 150 |

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to: John Morrall, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: November 7, 2000.

Jane M. Harrison,

Director, Division of Policy Review and Coordination.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Proposed Collection; Comment Request, The Jackson Heart Study, Annual Follow-Up Component—Phase III

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 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 Jackson Heart Study, Annual Follow-Up Component—Phase III. *Type of Information Collection Request:* Revision (OMB 0925-0464; expiration 04/30/2002). *Need and use of*

Information Collection: The Jackson Heart Study (JHS) Clinical Component will involve 6,500 African-American men and women aged 35-84, representative of African-American residents of Jackson, Mississippi. Family members are to be included in order to permit future studies of familial and genetic contributions to cardiovascular disease (CVD). The examination includes a series of questionnaires, physical assessments and laboratory measurements. Data collected in this study includes both conventional risk factors and new or emerging factors that may be related to CVD. Some of the newer areas of focus include early indicators of disease, genetics, sociocultural influences such as socioeconomic status and discrimination, and physiological relations between common disorders such as high blood pressure, obesity and diabetes and their influence on CVD and will take three years to complete. The JHS Clinical Component has received Clinical Exemption (CE-99-11-09) from the NIH Clinical Exemption Review