GA 30341–4146, Telephone: (770) 488–2721, Email Address: nfp6@cdc.gov.

For program technical assistance for the Congressional Glaucoma Caucus Foundation, contact: Joseph B. Smith, National Center on Birth Defects and Developmental Disabilities, 4770 Buford Highway, NE, MS F–35, Atlanta, Georgia 30341, Telephone: (770) 488–7082, Email Address: jos4@cdc.gov.

For program technical assistance for the Children's Hospital of Buffalo, contact: William A. Paradies, National Center on Birth Defects and Developmental Disabilities, 4770 Buford Highway, NE, MS F–45, Atlanta, Georgia 30341, Telephone: (770) 488–4704, Email Address: wep2@cdc.gov.

Dated: May 24, 2001.

Henry S. Cassell III

Acting Director, Procurement and Grant Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 01–13616 Filed 5–30–01; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Statement of Organization, Functions, and Delegations of Authority

Part C (Centers for Disease Control and Prevention) of the Statement of Organization, Functions, and Delegations of Authority of the Department of Health and Human Services (45 FR 67772–76, dated October 14, 1980, and corrected at 45 FR 69296, October 20, 1980, as amended most recently at 66 FR 20148–20149, dated April 12, 2001) is amended to retitle and revise the functional statement of the Division of Quarantine (DQ), National Center for Infectious Diseases (NCID).

Section C–B, Organization and Functions, is hereby amended as follows:

Delete in its entirety the title and functional statement for the Division of Quarantine (CR2) and insert the following:

Division of Global Migration and Quarantine (CR2). (1) Administers a national quarantine program to protect the United States against the introduction of diseases from foreign countries; (2) administers an overseas program for the medical examination of immigrants and others with inadmissible health conditions that would pose a threat to public health and impose a burden on public health and hospital facilities; (3) maintains liaison with and provides information on quarantine matters to other Federal agencies, State and local health departments, and interested industries; (4) provides liaison with international health organizations, such as the Pan American Health Organization and the World Health Organization, and participates in the development of international agreements affecting quarantine; (5) conducts studies to provide new information about health hazards abroad, measures for their prevention, and the potential threat of disease introduction into the United States; and (6) provides logistic support to other programs of the Centers for Disease Control and Prevention in the distribution of requested biologicals and movement of biological specimens through U.S. ports of entry.

Office of the Director (CR21). (1) Manages directs, and coordinates the activities of the Division; (2) provides leadership in development of Division policy, program planning, implementation, and evaluation; (2) identifies needs and resources for new initiatives and assigns responsibilities for their development; (4) coordinates liaison with other Federal agencies, State and local health departments, and interested industries; (5) coordinates liaison with international health organizations; (6) provides administrative services, including procurement, property and supply management, travel arrangements, space and facilities maintenance, and timekeeper coordination; (7) provides budgeting and fiscal management for the Division; (8) provides personnel support to the Division, both for Civil Service and Commissioned Corps employees, and assures that Division is in compliance with HRMO regulations for all personnel matters; (9) reviews and evaluates all administrative services for both headquarters and Quarantine Stations and provides policy procedures and guidance on such matters; (10) provides statistical and information systems consultation for study design and protocol development; (11) provides user and technical support for Local Area Network (LAN) and other designated software and hardware, and maintains LAN and other information systems in accordance with CDC guidelines; (12) designs and implements database management systems in support of Division projects; (13) provides data analysis and statistical consultation in support of Division projects; (14) assists in production of and provides graphics support for presentations and publications related to Division objectives; and (15) evaluates new software and hardware for statistical analysis, database management, graphics production, geographic information systems, and other functions related to Division objectives.

Dated: May 18, 2001.

Jeffrey P. Koplan,

Director.

[FR Doc. 01–13672 Filed 5–30–01; 8:45 am]

BILLING CODE 4160–18–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N–0063]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Medical Devices; Current Good Manufacturing Practice Quality System Regulation

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments on the collection of information by July 2, 2001.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Wendy Taylor, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Medical Devices; Current Good Manufacturing Practice (CGMP) Quality System (QS) Regulation—21 CFR Part 820 (OMB Control No. 0910–0073)—Extension

Under section 520(f) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360j(f)), the Secretary of the Department of Health and Human Services has the authority to prescribe regulations requiring that the methods used in, and the facilities and controls used for, the manufacture, preproduction design validation (including a process to assess the performance of a device but not including an evaluation of the safety and effectiveness of a device), packing, storage, and installation of a device conform to CGMP, as described in such regulations, to assure that the device

will be safe and effective and otherwise in compliance with the act.

The CGMP/QS regulation implementing the authority provided by this statutory provision is found in part 820 (21 CFR part 820) of the Code of Federal Regulations and sets forth basic CGMP requirements governing the design, manufacture, packing, labeling, storage, installation, and servicing of all finished medical devices intended for human use. Section 820.20(a) through (e) requires management with executive responsibility to establish, maintain, and/or review: The quality policy; the organizational structure; the quality plan; and the quality system procedures of the organization. Section 820.22 requires the conduct and documentation of quality system audits and reaudits. Section 820.25(b) requires the establishment of procedures to identify training needs and documentation of such training.

Section 820.30(a)(1) and (b) through (j) requires, in the following respective order, the establishment, maintenance, and/or documentation of: Procedures to control design of class III and class II devices, and certain class I devices as listed therein; plans for design and development activities and updates; procedures identifying, documenting, and approving design input requirements; procedures defining design output, including acceptance criteria, and documentation of approved records; procedures for formal review of design results and documentation of results in the design history file (DHF); procedures for verifying device design and documentation of results and approvals in the DHF; procedures for validating device design, including documentation of results in the DHF; procedures for translating device design into production specifications; procedures for documenting, verifying and validating approved design changes before implementation of changes; and the records and references constituting the DHF for each type of device.

Section 820.40 requires the establishment and maintenance of procedures for the review, approval, issuance, and documentation of required records (documents) and changes to those records.

Section 820.50 requires the establishment and maintenance of procedures and requirements to ensure service and product quality, records of acceptable suppliers and purchasing data describing specified requirements for products and services.

Sections 820.60 and 820.65 require, respectively, the establishment and maintenance of procedures for identifying all products from receipt to distribution and for using control numbers to track surgical implants and life-sustaining or supporting devices and their components.

Section 820.70(a) through (e), and (g) through (i) requires the establishment, maintenance, and/or documentation of: Process control procedures; procedures for verifying or validating changes to specification, method, process, or procedure; procedures to control environmental conditions and inspection result records; requirements for personnel hygiene; procedures for preventing contamination of equipment and products; equipment adjustment, cleaning and maintenance schedules; equipment inspection records; equipment tolerance postings; procedures for utilizing manufacturing materials expected to have an adverse effect on product quality; and validation protocols and validation records for computer software and software changes.

Sections 820.72 and 820.75(a), (b) introductory text, (b)(2), and (c) require, respectively, the establishment, maintenance, and/or documentation of: Equipment calibration and inspection procedures; national, international or in-house calibration standards; records that identify calibrated equipment and next calibration dates; validation procedures and validation results for processes not verifiable by inspections and tests; procedures for keeping validated processes within specified limits; records for monitoring and controlling validated processes; and records of the results of revalidation where necessitated by process changes or deviations.

Sections 820.80 and 820.86, respectively, require the establishment, maintenance, and/or documentation of: Procedures for incoming acceptance by inspection, test or other verification; procedures for ensuring that in-process products meet specified requirements and the control of product until inspection and tests are completed; procedures for, and records that show, incoming acceptance or rejection is conducted by inspections, tests or other verifications; procedures for, and records that show, finished devices meet acceptance criteria and are not distributed until device master (DMR) activities are completed; records in the device history record (DHR) showing acceptance dates, results and equipment used; and the acceptance/rejection identification of products from receipt to installation and servicing.

Sections 820.90 and 820.100 require, respectively, the establishment, maintenance and/or documentation of: Procedures for identifying, recording, evaluating, and disposing of nonconforming product; procedures for reviewing and recording concessions made for, and disposition of, nonconforming product; procedures for reworking products, evaluating possible adverse rework effect and recording results in the DHR; procedures and requirements for corrective and preventive actions, including analysis, investigation, identification and review of data, records, causes and results; and records for all corrective and preventive action activities.

Sections 820.120(b) and (d), 820.130, 820.140, 820.150, 820.160, and 820.170, respectively, require the establishment, maintenance, and/or documentation of: Procedures for controlling and recording the storage, examination, release and use of labeling; the filing of labels/labeling used in the DHR; procedures for controlling product storage areas and receipt/dispatch authorizations; procedures for controlling the release of products for distribution; distribution records that identify consignee, product, date and control numbers; and instructions, inspection and test procedures that are made available, and the recording of results for devices requiring installation.

Sections 820.180(b) and (c), 820.181, 820.184, and 820.186 require, respectively, the maintenance of records: That are retained at prescribed site(s), made readily available and accessible to FDA and retained for the device's life expectancy or for 2 years; that are contained or referenced in a DMR consisting of device, process, quality assurance, packaging and labeling, and installation, maintenance, and servicing specifications and procedures; that are contained in DHRs, demonstrate the manufacture of each unit, lot or batch of product in conformance with DMR and regulatory requirements, and include manufacturing and distribution dates and quantities, acceptance documents, labels and labeling, and control numbers; and that are contained in a quality system record (QSR) consisting of references, documents, procedures, and activities not specific to particular devices.

Sections 820.198(a) through (c) and 820.200(a) and (d), respectively, require the establishment, maintenance and/or documentation of: Complaint files and procedures for receiving, reviewing, and evaluating complaints; complaint investigation records identifying the device, complainant, and relationship of the device to the incident; complaint records that are reasonably accessible to the manufacturing site or at prescribed sites; procedures for performing and

verifying that device servicing requirements are met and that service reports involving complaints are processed as complaints; and service reports that record the device, service activity, and test and inspection data.

Section 820.250 requires the establishment and maintenance of procedures to identify valid statistical techniques necessary to verify process and product acceptability; and sampling plans, when used, that are written and based on a valid statistical rationale, and procedures for ensuring adequate sampling methods.

The CGMP/QS regulation amends and revises the CGMP requirements for medical devices set out at part 820. It adds design and purchasing controls; modifies previous critical device requirements; revises previous validation and other requirements; and harmonizes device CGMP requirements with quality system specifications in the international standard, ISO (International Organization for Standardization) 9001:1994 ''Quality Systems—Model for Quality Assurance in Design, Development Production, Installation and Servicing.'' The rule does not apply to manufacturers of components or parts of finished devices, nor to manufacturers of human blood and blood components subject to 21 CFR part 606. With respect to devices classified in class I, design control requirements apply only to class I devices listed in § 820.30(a)(2) of the regulation.

The rule imposes burdens upon finished device manufacturer firms, which are subject to all recordkeeping requirements, and upon finished device contract manufacturer, specification developer, repacker and relabeler, and contract sterilizer firms, which are subject only to requirements applicable to their activities. Due to modifications to the guidance given for remanufacturers of hospital single use devices, reusers of hospital single-use devices will now be considered to have the same requirements as manufacturers in regard to this regulation. The establishment, maintenance, and/or documentation of procedures, records and data required by this final regulation will assist FDA in determining whether firms are in compliance with CGMP requirements, which are intended to ensure that devices meet their design, production, labeling, installation, and servicing specifications and, thus are safe, effective, and suitable for their intended purpose. In particular, compliance with CGMP design control requirements should decrease the number of design-related device failures that have resulted in deaths and serious injuries.

If FDA did not impose these recordkeeping requirements, it anticipates that design-related device failures would continue to occur in the same numbers as before and continue to result in a significant number of device recalls and preventable deaths and serious injuries. Moreover, manufacturers would be unable to take advantage of substantial savings attributable to reduced recall costs, improved manufacturing efficiency, and improved access to international markets through compliance with CGMP requirements that are harmonized with international quality system standards.

The CGMP/QS regulation applies to some 9,229 respondents. These recordkeepers consist of 7,229 original respondents and an estimated 2,000 hospitals that remanufacture or reuse single use medical devices. They include manufacturers, subject to all requirements and contract manufacturers, specification developers, repackers/relabelers and contract sterilizers, subject only to requirements applicable to their activities. Hospital remanufacturers of single use medical devices (SUDs) are now defined to be manufacturers under guidelines issued by the Center for Devices and Radiological Health's (CDRHs) Office of Surveillance and Biometrics. Respondents to this collection have no reporting activities, but must make required records available for review or copying during FDA inspection. The regulation contains additional recordkeeping requirements in such areas as design control, purchasing, installation, and information relating to the remanufacture of single use medical devices. The estimates for burden are derived from those incremental tasks that were determined when the new CGMP/QS regulation became final (October 7, 1996, 61 FR 52602) as well as those carry-over requirements. The carry-over requirements are based on decisions made by the agency on July 16, 1992, under OMB Paperwork Reduction Act submission No. 0910–0073. This still provides valid baseline data.

FDA estimates respondents will have a total annual recordkeeping burden of approximately 3,167,670 hours (shown as 3,167,670 in table 1, of this document, of this justification statement due to rounding). This figure also consists of approximately 114,882 hours spent on a startup basis by 650 new firms. Table 1 of this document identifies burden estimates per sections of the regulation.

In the **Federal Register** of February 28, 2001 (66 FR 12798), the agency requested comments on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours	Total Operating and Maintenance Costs
820.20(a)	9,229	1	9,229	6.58	60,727	
820.20(b)	9,229	1	9,229	4.43	40,884	
820.20(c)	9,229	1	9,229	6.17	56,943	
820.20(d)	9,229	1	9,229	9.89	91,275	
820.20(e)	9,229	1	9,229	9.89	91,275	
820.22	9,229	1	9,229	32.72	301,973	
820.25(b)	9,229	1	9,229	12.68	117,024	
820.30(a)(1)	9,229	1	9,229	1.75	16,151	
820.30(b)	9,229	1	9,229	5.95	54,913	
820.30(c)	9,229	1	9,229	1.75	16,151	
820.30(d)	9,229	1	9,229	1.75	16,151	
820.30(e)	9,229	1	9,229	23.39	215,866	
820.30(f)	9,229	1	9,229	37.42	345,349	
820.30(g)	9,229	1	9,229	37.42	345,349	
820.30(h)	9,229	1	9,229	3.34	30,825	

TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]—Continued

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours	Total Operating and Maintenance Costs
820.30(i)	9,229	1	9,229	17.26	159,293	
820.30(j)	9,229	1	9,229	2.64	24,365	
820.40[2]	9,229	1	9,229	8.91	82,230	
820.40(a) and (b)	9,229	1	9,229	2.04	18,827	
820.50(a)(1) through (a)(3)	9,229	1	9,229	21.9	202,115	$1,181,925
820.50(b)	9,229	1	9,229	6.02	55,559	
821.60	9,229	1	9,229	0.32	2,953	
821.65	9,229	1	9,229	0.67	6,183	
820.70(a)(1) through (a)(5)	9,229	1	9,229	1.85	17,074	
820.70(b) and (c)	9,229	1	9,229	1.85	17,074	
820.70(d)	9,229	1	9,229	2.87	26,487	
820.70(e)	9,229	1	9,229	1.85	17,074	
820.70(g)(1) through (g)(3)	9,229	1	9,229	1.43	13,197	
820.70(h)	9,229	1	9,229	1.85	17,074	
820.70(i)	9,229	1	9,229	7.5	69,218	
820.72(a)	9,229	1	9,229	4.92	45,407	
820.72(b)(1) and (b)(2)	9,229	1	9,229	1.43	13,197	
820.75(a)	9,229	1	9,229	2.69	24,826	
820.75(b)	9,229	1	9,229	1.02	9,414	
820.75(c)	9,229	1	9,229	1.11	10,244	
820.80(a) through (e)	9,229	1	9,229	4.8	44,299	
820.86	9,229	1	9,229	0.79	7,291	
820.90(a)	9,229	1	9,229	4.95	45,684	
820.90(b)(1) and (b)(2)	9,229	1	9,229	4.95	45,684	
820.100(a)(1) through (a)(7)	9,229	1	9,229	12.48	115,178	
820.100(b)	9,229	1	9,229	1.28	11,813	
820	9,229	1	9,229	0.45	4,153	
820.120(b)	9,229	1	9,229	0.45	4,153	
820.120(d)	9,229	1	9,229	0.45	4,153	
820.130[2]	9,229	1	9,229	0.45	4,153	
820.140[2]	9,229	1	9,229	6.34	58,512	
820.150(a) and (b)	9,229	1	9,229	5.67	52,328	
820.160(a) and (b)	9,229	1	9,229	0.67	6,183	
820.170(a) and (b)	9,229	1	9,229	1.5	13,844	
820.180(b) and (c)	9,229	1	9,229	1.5	13,844	
820.181(a) through (e)	9,229	1	9,229	1.21	11,167	
820.184(a) through (f)	9,229	1	9,229	1.41	13,013	
820.186	9,229	1	9,229	0.4	3,692	
820.198(a) through (c)	9,229	1	9,229	4.94	45,591	
820.200(a) and (d)	9,229	1	9,229	2.61	24,088	
820.250	9,229	1	9,229	0.67	6,183	
Total					3,167,673	$1,181,925

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The typographical errors that appeared in tabel 1 of a notice published in the **Federal Register** of February 28, 2001 (66 FR 12798 at 12801), are corrected in this document as follows: ''820.4'' is corrected to read ''820.40''; and part ''821'', which appeared twice, is corrected to read ''820.60'' and ''820.65'', respectively.

Burden (labor) hour and cost estimates were developed under FDA contract by the Eastern Research Group, Inc. (ERG), in 1996 when the CGMP/QS regulation became final. These figures are still accurate. Additional factors considered in deriving estimates included:

- Establishment type: Query has been made of CDRHs registration/listing

data bank and has counted 7,229 domestic firms subject to CGMPs. They were then grouped as: Manufacturers (5,463), contract manufacturers (204), specification developers (960), repackers/relabelers (574), remanufacturer (21) and contract sterilizers (7). In addition, hospitals that reuse or remanufacture devices are now considered manufacturers under new FDA guidance. It is estimated that out of the 6,000 hospitals in the United States, one-third of them (or 2,000 hospitals) will reuse or remanufacture single use medical devices. Thus, the number of manufacturers will increase from 5,463 to 7,463 making the total number of firms subject to CGMPs 9,229.

- Potentially affected establishments: Except for manufacturers, not every type of firm is subject to every CGMP/QS requirement. For example, all are subject to quality policy (§ 820.20(a)), document control (§ 820.40), and other requirements, whereas only manufacturers and specification developers are subject to part 820 Subpart C—Design Controls. The type of firm subject to each requirement was identified by ERG.

FDA estimated the burden hours (and costs) for the previous CGMP regulation in 1992. That estimate was submitted to OMB on May 4, 1992, under OMB Paperwork Reduction Act submission No. 0910–0073. It was approved by OMB on July 16, 1992, and it expired on June 30, 1995. The methodology used is different than that used by ERG in estimating incremental tasks when the new CGMP/QS became a final rule. Nevertheless, the agency believes its 1992 estimate adequately represents labor hours (and costs) needed to comply with previous CGMP requirements carried over into the new CGMP/QS regulation. The 1992 estimate used 9,289 respondents (rather than 9,229 respondents), which compensates for differences in methodology.

FDA estimates that some 650 ''new'' establishments (marketing devices for the first time) will expend some 114,882 ''development'' hours on a one-time startup basis to develop records and procedures for the CGMP/QS regulation.

FDA estimates that annual labor hours are apportioned as follows: 40 percent—to requirements dealing with manufacturing specifications, process controls and the DHR; 20 percent—to requirements dealing with components and acceptance activities; 25 percent—to requirements dealing with equipment, records (the DMR and QSR), complaint investigations, labeling/packaging and reprocessing/investigating product nonconformance; and 15 percent—to quality audit, traceability, handling, distribution, statistical, and other requirements.

Dated: May 23, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–13655 Filed 5–30–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–10030]

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

AGENCY: Health Care Financing Administration, HHS.

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 collections for public comment. Interested persons are invited to send comments regarding this 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: New Collection; *Title of Information Collection:* National Medicare Practitioner and Provider Survey; *Form No.:* HCFA–10030 (OMB# 0938–NEW); *Use:* Under the Medicare Integrity Program, established by the Health Insurance Portability and Accountability Act of 1996, HCFA was instructed to promote the integrity of the Medicare program by, among other things, education providers of services about payment integrity and benefit quality assurance issues. HCFA needs this information to design a national education plan aimed at reducing inadvertent errors caused by a lack of understanding of Medicare Rules and Regulations. The information will assist HCFA in creating high quality, accessible educational opportunities to help Medicare providers, practitioners, office staff and billing agents decrease unintentional errors on Medicare claims.; *Frequency:* Other: One-time only; *Affected Public:* Business or other for-profit; *Number of Respondents:* 9,000; *Total Annual Responses:* 9,000; *Total Annual Hours:* 3,600.

To obtain copies of the supporting statement and any related forms 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, phone number, OMB number, and HCFA document identifier, 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: OMB Human Resources and Housing Branch, Attention: Wendy Taylor, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: May 9, 2001.

John P. Burke III,

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

[FR Doc. 01–13651 Filed 5–30–01; 8:45 am]

BILLING CODE 4120–03–P

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 the Office of Management and Budget 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.