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.

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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.

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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.