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]

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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.

[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.

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 the use of automated collection techniques or other forms of information technology.

Proposed Project: The National Health Service Corps (NHSC) Recruitment and Retention Assistance Application (OMB No. 0915–0230)—Revision

The National Health Service Corps (NHSC) of the Bureau of Primary Health Care (BPHC), HRSA, is committed to improving the health of the Nation's underserved by uniting communities in need with caring health professionals and by supporting communities' efforts to build better systems of care.

The Application for NHSC Recruitment and Retention Assistance submitted by sites or clinicians request information on the practice site, sponsoring agency, recruitment contact, staffing levels, service users, site's 5-year infant mortality or low birth rate averages, and next nearest site. Assistance in completing the application may be obtained through the appropriate State Primary Care Offices, State Primary Care Associations and HRSA field offices. The information on the application is used for determining eligibility of sites and to verify the need for NHSC providers. Sites must submit an application annually or when they need a provider.

Estimates of annualized reporting burden are as follows:

Type of report	Number of respondents	Response per respondents	Hours per response	Total burden hours
Application	2900	1	.25	725

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: May 24, 2001.

Jane M. Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 01–13657 Filed 5–30–01; 8:45 am]

BILLING CODE 4160–15–U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Vaccine Injury Compensation Program; List of Petitions Received

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: The Health Resources and Services Administration (HRSA) is publishing this notice of petitions received under the National Vaccine Injury Compensation Program (''the Program''), as required by section 2112(b)(2) of the Public Health Service (PHS) Act, as amended. While the Secretary of Health and Human Services is named as the respondent in all proceedings brought by the filing of petitions for compensation under the Program, the United States Court of Federal Claims is charged by statute with responsibility for considering and acting upon the petitions.

FOR FURTHER INFORMATION CONTACT: For information about requirements for filing petitions, and the Program in general, contact the Clerk, United States Court of Federal Claims, 717 Madison Place, NW., Washington, DC 20005, (202) 219–9657. For information on HRSA's role in the Program, contact the Director, National Vaccine Injury Compensation Program, 5600 Fishers Lane, Room 8A–46, Rockville, MD 20857; (301) 443–6593.

SUPPLEMENTARY INFORMATION: The Program provides a system of no-fault compensation for certain individuals who have been injured by specified childhood vaccines. Subtitle 2 of title XXI of the PHS Act, 42 U.S.C. 300aa–10 *et seq.*, provides that those seeking compensation are to file a petition with the U.S. Court of Federal Claims and to serve a copy of the petition on the Secretary of Health and Human Services, who is named as the respondent in each proceeding. The Secretary has delegated his responsibility under the Program to HRSA. The Court is directed by statute to appoint special masters who take evidence, conduct hearings as appropriate, and make initial decisions as to eligibility for, and amount of, compensation.

A petition may be filed with respect to injuries, disabilities, illnesses, conditions, and deaths resulting from vaccines described in the Vaccine Injury Table (the Table) set forth at section 2114 of the PHS Act or as set forth at 42 CFR 100.3, as applicable. This Table lists for each covered childhood vaccine the conditions which will lead to compensation and, for each condition, the time period for occurrence of the first symptom or manifestation of onset or of significant aggravation after vaccine administration. Compensation may also be awarded for conditions not listed in the Table and for conditions that are manifested after the time periods specified in the Table, but only if the petitioner shows that the condition was caused by one of the listed vaccines.

Section 2112(b)(2) of the PHS Act, 42 U.S.C. 300aa–12(b)(2), requires that the Secretary publish in the **Federal Register** a notice of each petition filed. Set forth below is a list of petitions received by HRSA on January 2, 2001, through March 30, 2001.

Section 2112(b)(2) also provides that the special master ''shall afford all interested persons an opportunity to submit relevant, written information'' relating to the following:

1. The existence of evidence ''that there is not a preponderance of the evidence that the illness, disability, injury, condition, or death described in the petition is due to factors unrelated to the administration of the vaccine described in the petition,'' and

2. Any allegation in a petition that the petitioner either:

(a) ''Sustained, or had significantly aggravated, any illness, disability, injury, or condition not set forth in the Table but which was caused by'' one of the vaccines referred to in the Table, or

(b) ''Sustained, or had significantly aggravated, any illness, disability, injury, or condition set forth in the Table the first symptom or manifestation of the onset or significant aggravation of which did not occur within the time period set forth in the Table but which was caused by a vaccine'' referred to in the Table.

This notice will also serve as the special master's invitation to all interested persons to submit written information relevant to the issues described above in the case of the