

information on postmarketing safety reporting regulations (21 CFR 314.80 and 600.80) submitted to the Office of Management and Budget (OMB) for review and clearance. This notice merely provides applicants with an alternative mechanism for submitting postmarketing periodic adverse drug experience reports to the agency.

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520), OMB approved the information collection for MedWatch—The FDA Medical Products Reporting Program (Forms FDA 3500 and FDA 3500A) and assigned it OMB control number 0910–0291. The approval for 0910–0291 expires on June 30, 2003; an extension of the approval is pending at OMB. OMB also approved the information collection for adverse experience reporting for marketed drugs and licensed biological products and assigned them OMB control numbers 0910–0230 and 0910–0308, respectively. The approval for 0910–0230 expires on September 30, 2005, and the approval for 0910–0308 expires on May 31, 2005.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/cder/guidance/index.htm> or <http://www.fda.gov/cber/guidelines.htm>.

Dated: June 17, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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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: HRSA Competing Training Grant Application, Instructions and Relating Regulations (OMB No. 0915–0060)—Revision—The Bureau of Health Professions (BHPr), Health Resources and Services Administration (HRSA) operates and administers training grant programs authorized under Titles VII and VIII of the Public Health Service (PHS) Act. HRSA uses the information in the application to determine the eligibility of applicants for awards, to calculate the amount of each award and to judge the relative merit of applications. The application contains a basic set of general instructions as well as program-specific instructions which includes the detailed description of the project. The budget is negotiated for all years of the project period based on this application.

The burden estimate is as follows:

Form	Number of respondents	Response per respondent	Total responses	Hours per response	Total burden hours
Progress Report	1,805	1	1,805	56.25	101,531

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to: Allison Eyte, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503, Fax Number 202–395–4650.

Dated: June 17, 2003.

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: The National Sample Survey of Registered Nurses 2004 (OMB No. 0915–0192)—Revision

The National Sample Survey of Registered Nurses (NSSRN) is carried out to assist in fulfilling two Congressional mandates. Section 792 of the Public Health Service Act (42 U.S.C. 295k), calls for the collection and analysis of data on health professions. Section 806 (f) of the Public Health Service Act (42 U.S.C. 296e) requires that discipline specific workforce information and analytical activities are carried out as part of the advanced nursing education, workforce diversity, and basic nursing education and practice programs.

Government agencies, legislative bodies and health professionals used data from previous national sample

surveys of registered nurses to inform workforce policies. The information from this survey will continue to serve policy makers, and other consumers. Furthermore data collected in this survey will assist in determining the impact that changes in the health care system are having on employment status of registered nurses (RNs), the setting in which they are employed and the proportion of RNs who are employed full time and part time in nursing. The data will also indicate the number of RNs who are employed in jobs unrelated to nursing.

The proposed survey design for the 2004 NSSRN follows that of the previous seven surveys. A probability sample is selected from a sampling frame compiled from files provided by the State Boards of Nursing in the 50 States and the District of Columbia. These files constitute a multiple sampling frame of all RNs licensed in the 50 States and the District of Columbia. Sampling rates are set for each State based on considerations of statistical precision of the estimates and the costs involved in obtaining reliable national and State level estimates.

Each sampled nurse will be asked to complete a self-administered questionnaire, which includes items on

educational background, duties, employment status and setting, geographic mobility, and income.

Estimated burden is as follows:

	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hour
Questionnaires	39,584	1	39,584	.33	13,063

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to: Allison Eyte, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503, Fax Number (202) 395-4650.

Dated: June 17, 2003.

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: Ryan White CARE Act: Title III Client-level Demonstration Project (CDP)—New

The CDP was originally established in 1994 to collect information from grantees and their subcontracted service providers funded under Titles I and II of the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act of 1990, as amended by the Ryan White CARE Act Amendments of 1996 (codified under Title XXVI of the Public Health Service (PHS) Act). This new effort will collect client level data from a sample of Ryan White CARE Act Title III Grantees. The HRSA's HIV/AIDS Bureau administers funds for all titles of the CARE Act. The Title III program is authorized by section 2651 of the PHS Act.

The PHS Act specifies that HRSA is responsible for the administration of grant funds, the allocation of funds, the evaluation of programs for the population served, and the improvement of the quantity and quality of care. Accurate records on the grantees receiving CARE Act funding, the services provided, and the clients served are critical to the implementation of the legislation and thus are necessary for HRSA to fulfill its responsibilities. The information requested is the

minimum necessary to perform the evaluation and oversight function.

Client level information will be collected from a sample of Title III CARE Act funded grantees regarding the number of clients served, services provided, demographic information about clients served, and health status of clients served. In addition, client level information will be collected that measures mortality status and additional indicators of health status and whether standards of care are being followed by providers.

The primary purposes of the CDP are to examine client level demographic and service data on HIV/AIDS infected/affected clients being served by the Ryan White CARE Act and demonstrate the usefulness of these data for planning and evaluation purposes at both the local and national levels. Through this system, HRSA seeks to supplement the information collected in the CARE Act Data Report (CADR). Because there is no nationwide acceptance of client level reporting for HIV/AIDS services, the CADR collects data aggregated at the grantee level and contains duplicated counts of clients who have received services from more than one provider during a given reporting period.

Based on data from eligible grantees, the number of clients that a grantee serves would average about 250. About 2 hours is required annually to respond to these questions.

The burden estimate for this project is as follows:

Grantee	Number of respondents	Responses per respondent	Total responses	Burden hour per respondent	Total burden hour
<500 Clients	15	250	3,750	2	7,500
500+ Clients	10	1,232	12,320	2	24,640
Total	25	16,070	32,140