

person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before November 24, 2008. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by November 25, 2008.

Electronic comments should be submitted to <http://www.regulations.gov>. Select Docket No. FDA-2008-N-0578 entitled "G-CSF Stimulated Bone Marrow IRB Referral" and follow the prompts to submit your statement. Written comments should be submitted to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Please submit comments by 4:30 p.m. on December 2, 2008. Received comments may be viewed at <http://www.regulations.gov> or may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Carlos Peña at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/oc/advisory/default.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: November 5, 2008.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. E8-27118 Filed 11-13-08; 8:45 am]

BILLING CODE 4160-01-S

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 (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, e-mail paperwork@hrsa.gov or call the HRSA Reports Clearance Officer on (301) 443-1129.

Comments are invited on: (a) The proposed collection of information for the proper performance of the functions of the agency; (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: The Nursing Scholarship Program (NSP): Extension—(OMB No. 0915-0301)

The Nursing Scholarship Program (NSP) or "Nursing Scholarship" is a competitive Federal program which awards scholarships to individuals for attendance at schools of nursing. The program is administered by the Bureau of Clinician Recruitment and Service

(BCRS) in HRSA. The scholarship consists of payment of tuition, fees, other reasonable educational costs, and a monthly support stipend. In return, the students agree to provide a minimum of 2 years of full-time clinical service (or an equivalent part-time commitment, as approved by the NSP) at a health care facility with a critical shortage of nurses as defined by the program.

Nursing scholarship recipients must be willing and are required to fulfill their NSP service commitment at a health care facility with a critical shortage of nurses in the United States, the District of Columbia, the Commonwealth of Puerto Rico, the Territory of Guam, the Commonwealth of the Northern Marianas, the U.S. Virgin Islands, the Territory of American Samoa, the Republic of Palau, the Republic of the Marshall Islands, or the Federated States of Micronesia. Students who are uncertain of their commitment to provide nursing in a health care facility with a critical shortage of nurses in the United States and its Territories are advised not to participate in this program.

The NSP needs to collect data to determine an applicant's eligibility for the program, to monitor a participant's continued enrollment in a school of nursing, to monitor the participant's compliance with the NSP service obligation, and to obtain data on its program to ensure compliance with legislative mandates and prepare annual reports to Congress. The following information will be collected: (1) From the applicants and/or the schools, general applicant and nursing school data such as full name, location, tuition/fees, and enrollment status; (2) from the schools, on an annual basis, data concerning tuition/fees and student enrollment status; and (3) from the participants and their health care facilities with a critical shortage of nurses, on a biannual basis, data concerning the participant's employment status, work schedule and leave usage. The BCRS enters the cost information into its computerized data system, along with the projected amount for the monthly stipend, to determine the amount of each scholarship award.

The estimated annual burden is as follows:

Type of report	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
Application	4,000	1	4,000	2	8,000
In-school monitoring	500	1	500	2	1,000

Type of report	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
In-service monitoring	600	2	1,200	1	1,200
Total	5,100		10,200		10,200

E-mail comments to paperwork@hrsa.gov or mail the HRSA Reports Clearance Officer, Room 10-33, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: November 6, 2008.

Alexandra Huttinger,

Director, Division of Policy Review and Coordination.

[FR Doc. E8-27113 Filed 11-13-08; 8:45 am]

BILLING CODE 4165-15-P

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 (OMB), 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, e-mail paperwork@hrsa.gov or 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 HIV/AIDS Program: Client-Level Data Reporting System: New

The Client-Level Data Reporting System (CLDRS), created in 2008 by the Health Resources and Services Administration (HRSA), was designed to collect information from grantees, as well as their subcontracted service providers, funded under Parts A, B, C, D, and F of the Ryan White HIV/AIDS Treatment Modernization Act of 2006 (Ryan White HIV/AIDS Program). The Ryan White HIV/AIDS Program provides Federal HIV/AIDS Programs under Title XXVI of the Public Health Service (PHS) Act with the flexibility to

respond effectively to the changing HIV epidemic, with an emphasis on providing life-saving and life-extending services for people living with HIV/AIDS, and with targeting resources to areas that have the greatest needs.

All Program Parts of the Ryan White HIV/AIDS Program specify HRSA's responsibilities in the administration of grant funds, the allocation of funds, the evaluation of programs for the population served, and the improvement of the quality of care. Accurate records of the providers receiving Ryan White HIV/AIDS Program funding, the services provided, and the clients served continue to be critical to the implementation of the legislation and thus are necessary for HRSA to fulfill its responsibilities.

Currently, the HIV/AIDS Bureau (HAB) requires that all Ryan White HIV/AIDS Program funded grantees and their contracted service providers report aggregate data annually using the Ryan White Data Report (RDR). Agencies report data related to the service provider, clients, service visits provided/clients served, client demographics, and health insurance payments. Aggregate data by definition cannot be merged and unduplicated across service providers within a given geographic area. As a result, grantees, and ultimately HAB, cannot obtain accurate counts of the number of individuals served by the Ryan White HIV/AIDS Program. Additionally, aggregate data cannot be analyzed with the detail that is required to assess quality of care or to sufficiently account for the use of Ryan White HIV/AIDS Program funds.

A well-designed and supported client level data reporting system, using a unique identifier that will be encrypted before transfer, would provide the grantee and HRSA with the requisite information to assess quality of care and unmet needs, and the ability to more accurately and efficiently report these figures to HAB and other funding agencies. These de-identified data will be able to accurately characterize the number of clients served by the Ryan White HIV/AIDS Program and the outcomes of the program services on a national scale.

The CLDRS provides data on the characteristics of Ryan White HIV/AIDS

Program-funded grantees, their contracted service providers, and the clients being served with program funds. It is intended to support clinical quality management, performance measurement, service delivery, and client monitoring at both the system and client levels. The reporting system consists of two online data forms, the Grantee Information Form, the Service Provider Form and a data file containing the client-level data elements. Data will be submitted twice in the first year. The first submission will contain data for January through June, and the second submission will contain data for the entire calendar year. In subsequent years data will be collected on an annual basis.

The new legislation specifies increased grantee accountability and linking performance to budget. The CLDRS will be used to ensure compliance with the requirements of the reauthorized legislation, evaluate the progress of programs, to monitor grantee and provider performance, measure the Government Performance and Result Act (GPRA) and the Performance Assessment Rating Tool (PART) goals, and meet reporting responsibilities to the Department, Congress, and OMB.

In addition to meeting the goal of accountability to Congress, clients, advocacy groups, and the general public, information collected through the CLDRS is critical for HRSA, State and local grantees, and individual providers to assess the status of existing HIV-related service delivery systems to investigate trends in service utilization, and to identify areas of greatest need.

Discussions were conducted with volunteer grantee agencies representing Parts A, B, C, D, and Minority AIDS Initiatives, Parts A and B, as a basis for the burden estimates for the CLDRS components that follow. These burden estimates are broken out by burden to grantee respondents and burden to provider respondents, and are presented in two tables. The first table represents the estimated burden for the first year data submission. The second table represents the estimated burden for years two and three.

The number of total burden hours for the CLD Collection System is estimated differently in year 1 than in years 2 and 3. The estimate for the first year