

approximate time requested to make their presentation on or before July 15, 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 July 16, 2008.

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 Diem-Kieu Ngo 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: June 26, 2008.

Randall W. Lutter,

Deputy Commissioner for Policy.

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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 the 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, Pub. L. 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) 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 through the use of automated collection techniques or other forms of information technology.

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), is 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 the Federal HIV/AIDS Programs in the Public Health Service (PHS) Act under Title XXVI, with the flexibility to respond effectively to the changing HIV epidemic. Its emphasis is on providing life-saving and life-extending services for people living with HIV/AIDS across the country, and on 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. Agencies report data related to the service provider, clients, service visits provided/clients served, client demographics, and health insurance payments. The limitations of aggregate data are twofold: First,

because they lack client identifiers, 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. Second, 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. In addition, HAB will be able to characterize accurately the number of clients served by the Ryan White HIV/AIDS Program and the outcomes of the program services on a national scale. The ability to perform detailed analyses will be possible only if organizations submit data associated with encrypted client identifiers. These unique identifiers must be able to link data for clients across Ryan White HIV/AIDS Program-funded grantees and their subcontracted service providers.

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 and the Service Provider Form. A data file containing the client level data elements will be submitted with the two online data forms on a semi-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, 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. Through the CLDRS, these groups will 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 12 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 6-month data submission. The second table represents the estimated burden for each subsequent 6-month data submission. The estimated number of visits per 6-month reporting period ranged from 1 to 17, with an average (mean) of 4 client visits per reporting period and a median of 2 client visits per reporting period.

The number of clients is estimated two ways. The first estimate is based on providers that reported outpatient/ambulatory medical care, medical case management, and/or non-medical case management services in the 2007 Ryan

White Data Report. These providers will be required to report client level data beginning in 2009. This first estimate excludes providers of other direct client services because these providers will not be required to report client level data until 2010. The second estimate includes all providers that reported direct client services in the 2007 Ryan White Data Report.

The estimated response burden for the first 6-month reporting period CLDRS submission is as follows:

The response burden for grantees is estimated as:

Component	Source of funding	Number of respondents	Responses per grantee	Hours to complete/coordinate receipt of data reports	Total hour burden
Grantee Form	Part A	56	1	1.27	71
	Part B	57	1	6.00	342
	Part C	357	1	0.39	139
	Part D	90	1	0.67	60
	Part A MAI	56	1	1.27	71
	Part B MAI	30	1	10.00	300
Subtotal		646			983

Component	Number of respondents	Responses per grantee	Hours to develop/adjust CLD system	Total hour burden
CLD Collection System	563	1	1108.80	624254

The response burden for service providers is estimated as:

Component	Number of respondents	Responses per provider	Hours per response	Total hour burden
Provider Form	2253	1	2.35	5295

Component	Number of respondents	Responses (clients served) per provider	Total responses	Hours to collect/report data per respondent	Total hour burden
Client Data File	* 1511	493.57	745784	1.65	1230544
	** 2112	417.47	881703	1.65	1454810

* Outpatient/ambulatory medical care, medical case management, and/or non-medical case management providers only.

** All providers.

The estimated response burden for all subsequent 6-month reporting period CLDRS submissions is as follows:

The response burden for grantees is estimated as:

Component	Source of funding	Number of respondents	Responses per grantee	Hours to complete/coordinate receipt of data reports	Total hour burden
Grantee Form	Part A	56	1	1.02	57
	Part B	57	1	1.50	86
	Part C	357	1	0.32	114
	Part D	90	1	0.33	30
	Part A MAI	56	1	1.02	57

Component	Source of funding	Number of respondents	Responses per grantee	Hours to complete/coordinate receipt of data reports	Total hour burden
	Part B MAI	30	1	2.00	60
Subtotal		646			404

The response burden for service providers is estimated as:

Component	Number of respondents	Responses per provider	Hours per response	Total hour burden
Provider Form	2253	1	2.30	5182

Component	Number of respondents	Responses (clients served) per provider	Total responses	Hours to collect/report data per respondent	Total hour burden
Client Data File	* 1511 ** 2112	493.57 417.47	745784 881703	1.65 1.65	1230544 1454810

* Outpatient/ambulatory medical care, medical case management, and/or non-medical case management providers only.

** All providers.

E-mail comments to paperwork@hrsa.gov or mail comments to the HRSA Reports Clearance Officer, Room 10-33, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857. Written comments should be received within 60 days of this notice. Information can also be accessed at <http://datasupport.hab.hrsa.gov/>.

Dated: June 30, 2008.

Alexandra Huttinger,

Director, Division of Policy Review and Coordination.

[FR Doc. E8-15470 Filed 7-7-08; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Library of Medicine; Notice of Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of meetings of the Board of Regents of the National Library of Medicine.

The meetings will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Board of Regents of the National Library of Medicine; Extramural Programs Subcommittee.

Date: September 15, 2008.

Closed: 4 p.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: National Library of Medicine, Building 38, Conference Room B, 8600 Rockville Pike, Bethesda, MD 20892.

Contact Person: Donald A.B. Lindberg, MD, Director, National Library of Medicine, 8600 Rockville Pike, Bethesda, MD 20894, 301-496-6221, lindberg@mail.nih.gov.

Name of Committee: Board of Regents of the National Library of Medicine; Subcommittee on Outreach and Public Information.

Date: September 16, 2008.

Open: 7:30 a.m. to 8:45 a.m.

Agenda: Outreach Activities.

Place: National Library of Medicine, Building 38, Conference Room B, 8600 Rockville Pike, Bethesda, MD 20892.

Contact Person: Donald A.B. Lindberg, MD, Director, National Library of Medicine, 8600 Rockville Pike, Bethesda, MD 20894, 301-496-6221, lindberg@mail.nih.gov.

Name of Committee: Board of Regents of the National Library of Medicine.

Date: September 16-17, 2008.

Open: September 16, 2008, 9 a.m. to 4:30 p.m.

Agenda: Program Discussion.

Place: National Library of Medicine, Building 38, Board Room, 2nd Floor, 8600 Rockville Pike, Bethesda, MD 20892.

Closed: September 16, 2008, 4:30 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Library of Medicine, Building 38, Board Room, 2nd Floor, 8600 Rockville Pike, Bethesda, MD 20892.

Open: September 17, 2008, 9 a.m. to 12 p.m.

Agenda: Program Discussion.

Place: National Library of Medicine, Building 38, Board Room, 2nd Floor 8600 Rockville Pike, Bethesda, MD 20892.

Contact Person: Donald A.B. Lindberg, MD, Director, National Library of Medicine, 8600 Rockville Pike, Bethesda, MD 20894, 301-496-6221, lindberg@mail.nih.gov.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, drivers license, or passport) and to state the purpose of their visit.

Information is also available on the Institutes/Center's home page: <http://www.nlm.nih.gov/od/bor/bor.html>, where an agenda and any additional information for the meeting will be posted when available.