

satisfies the requirements of the applicable statutes and regulations.

II. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014; the collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001; and the collections of information referred to in the guidance entitled “Establishment and Operation of Clinical Trial Data Monitoring Committees” have been approved under OMB control number 0910–0581.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

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/ohrms/dockets/default.htm>.

Dated: October 24, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–21332 Filed 10–29–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Privacy Act of 1974: New System of Records

AGENCY: Health Resources and Services Administration (HRSA), HHS.

ACTION: Notification of new system of records.

SUMMARY: In accordance with the requirements of the Privacy Act, the

Health Resources and Services Administration (HRSA) is publishing a notice of a proposal to add a new system of records. The Campus Based Branch (CBB) of the Division of Health Careers Diversity and Development in the Bureau of Health Professions is currently utilizing a document management system (DMS) that dynamically manages its flow of documents produced and received. The DMS is an intra-office system in which documents contained within the system are only shared among CBB staff. The DMS contains names and other personally identifiable information of borrowers.

DATES: HRSA invites interested parties to submit comments on the proposed New System of Records on or before December 10, 2007. HRSA has sent a report of a New System of Records to Congress and to the Office of Management and Budget (OMB) on October 18, 2007. The New System of Records will be effective 40 days from the date submitted to OMB unless HRSA comments which would result in a contrary determination.

ADDRESSES: Please address comments to Donn Taylor, Health Resources and Services Administration, Privacy Act Coordinator, 5600 Fishers Lane, Room 14A–20, Rockville, Maryland 20857; Telephone (301) 443–0204. Comments received will be available for inspection at this same address from 9 a.m. to 3 p.m., Monday through Friday. This is not a toll-free number.

FOR FURTHER INFORMATION CONTACT:

Henry Lopez, Director, division of Health Careers diversity and Development, Bureau of Health Professions, 5600 Fisher Lane, Room 8–42, Rockville, Maryland 20857; Telephone 301–443–1173. This is not a toll-free number.

SUPPLEMENTARY INFORMATION: The Health Resources and Services Administration proposes to establish a New System of Records: “Campus Based Branch Programs Document Management System, HHS/HRSA/BHPr.” The CBB programs which use the DMS are authorized by the following sections of the Public Health Service Act: Section 721 of the Public Health Service Act (42 U.S.C. 292q) the Health Professions Student Loan Program; Section 724 of the Public Health Service Act (42 U.S.C. 292s) the Primary Care Loan Program; Section 724 of the Public Health Service Act (42 U.S.C. 292t) the Loans for Disadvantaged Students Program; Section 835 of the Public Health Service Act (42 U.S.C. 297a) the Nursing Student Loan Program; and Section 737 of the Public Health Service

Act (42 U.S.C. 293a) the Scholarships for Disadvantaged Students Program. In accordance with their applicable regulations, the funds appropriated or distributed from these CBB programs are monitored by the CBB. The DMS is an automated system that enables CBB to fulfill its duty in monitoring these programs. The DMS contains annual operating and performance data from educational institutions participating in CBB programs, as well as personally identifiable information of borrowers.

Dated: October 12, 2007.

Elizabeth M. Duke,
Administrator.

Report of a New System of Records 09–15–0069

SYSTEM NAME:

Campus Based Branch (CBB) Program Document Management System (DMS), HHS/HRSA/BHPr.

SECURITY CLASSIFICATION:

None

SYSTEM LOCATION:

The Division of Health Careers Diversity and Development (DHCDD) of the Bureau of Health Professions (BHPr), Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS). Records are located at 5600 Fishers Lane, Room 8–42, Rockville, MD 20857.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Student and faculty borrowers who participate/participated in CBB loan and scholarship programs.

CATEGORIES OF RECORDS IN THE SYSTEM:

The systems include materials such as:

1. Names, addresses, phone numbers, medical records, financial information, and social security numbers of borrowers.

2. Annual Operating Reports that contain financial information from institutions, including aggregate amounts of loans disbursed, collected and retired.

3. Performance reports on the aggregate number of borrowers, their classification in race/ethnicity categories, and whether they are practicing in primary care.

4. Contact information of financial aid officers that include name, title, school address and direct phone number.

5. Correspondence from the financial aid officers regarding issues with specific borrowers. The majority of these correspondence only indicate the borrower's name and/or amount borrowed.

6. Correspondence from borrowers on specific issues on CBB programs or the school that administers the programs. These correspondences may include the borrower's name, address and phone number.

7. Case reports from educational institutions on borrowers whom the school is claiming an uncollectible debt or a total disability write-off. The documents contained in these case reports may include name, address, financial income information, medical records and social security numbers.

8. Any other correspondence or documentation related to general or specific issues regarding CBB programs at institutions or borrowers who participate in CBB programs.

AUTHORITY FOR MAINTENANCE OF SYSTEM:

Section 721 of the Public Health Service Act (42 U.S.C. 292q), Health Professions Student Loan; Section 835 of the Public Health Service Act (42 U.S.C. 297a), Nursing Student Loan; Section 723 of the Public Health Service Act (42 U.S.C. 292s), Primary Care Loan; Section 724 of the Public Health Service Act (42 U.S.C. 292t), Loans for Disadvantaged Students; Section 737 of the Public Health Service Act (42 U.S.C. 293a), Scholarships for Disadvantaged Students.

PURPOSE(S):

The purpose of the DMS system is to support the CBB in monitoring its programs, in order to ensure the efficiency of the factual information in reports and documents, and to archive the documents for efficient access and verification.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

Records maintained in the system above, disclosure of which is governed by the System of Records Notice for the "Campus Based Branch Program Document Management System, HHS/HRSA/BHPr" may be disclosed to others:

1. HRSA may disclose records to Department contractors and subcontractors for the purpose of assisting CBB in reviewing cases and maintaining systems, including conducting data analysis for program evaluations, compiling managerial and statistical reports, and record systems processing and refinement. Contractors will maintain, and are also required to ensure that subcontractors maintain, Privacy Act safeguards with respect to such records.

2. Disclosure may be made to a Congressional office from the record of

an individual or institutional participant, in response to any inquiry from the Congressional office made at the request of that individual.

3. Disclosure may be made to the Department of Justice, or to a court or other tribunal, from this system of records, when (a) HHS, or any component thereof; or (b) any HHS employee in his or her official capacity; or (c) any HHS employee in his or her individual capacity where the Department of Justice (or HHS, where it is authorized to do so) has agreed to represent the employee; or (d) the United States or any agency thereof, where HHS determines that the litigation is likely to affect HHS or any of its components, is a party to litigation or has an interest in such litigation, and HHS determines that the use of such records by the Department of Justice, the court or other tribunal is relevant and necessary to the litigation and would help in the effective representation of the governmental party, provided, however, that in such case HHS determines that such disclosure is compatible with the purpose for which the records were collected.

4. In the event that a system of records maintained by this agency to carry out its functions indicates a violation or potential violation of law, whether civil, criminal, or regulatory in nature and whether arising by general statute or particular program statute, or by regulation, rule, or order issued pursuant thereto, the relevant records in the system of records may be referred to the appropriate agency, whether Federal, State or local, charged with the responsibility of investigating or prosecuting such violation or charged with enforcing or implementing the statute or rule, regulation or order issued pursuant thereto.

5. HRSA may disclose from this system of records a delinquent debtor's name, address, Social Security number, and other information necessary to identify him/her; the amount, status, and history of the claim, and the agency or program under which the claim arose, to the Treasury Department, Internal Revenue Service (IRS), to request a debtor's current mailing address to locate him/her for purposes of collecting a debt. This address may be disclosed by HRSA to any school from which the defaulted borrower received the student loan, for use only by officers, employees, or agents of the school whose duties relate to the collection of health professions or nursing student loan funds, to locate the defaulted borrower to collect the loan. Any school which requests and obtains this address information must comply

with the requirements of HRSA and the IRS regarding the safeguarding and proper handling of this information.

STORAGE:

Records are maintained in the DMS or in file folders and/or computer data files.

RETRIEVABILITY:

Retrieval of data and case files is by subject's name or institution ID.

SAFEGUARDS:

1. Authorized users: Access is limited to authorized HHS staff in performance of their duties. Authorized personnel include the contractor/system manager and his staff who have responsibilities for administering the programs. HRSA maintains current lists of authorized users. Educational institutions may request or access information they submitted to CBB. However, they do not have access to information submitted by other institutions.

2. Physical safeguards: The DMS is housed on a HRSA server behind a firewall. The DMS is an intra-office system only for the sole use of CBB staff. All computer equipment and files and hard copy files are stored in areas where fire and life safety codes are strictly enforced. All automated and non-automated documents are protected on a 24-hour basis. Perimeter security includes intrusion alarms, on-site guard force, random guard patrol, key/passcard/combination controls, and receptionist controlled area. Hard copy files are maintained in a file room used solely for this purpose with access limited by combination lock to authorized users identified above. Computer files are password protected and are accessible only by use of computers which are password protected.

3. Procedural safeguards: A password is required to access computer files. All users of personal information in connection with the performance of their jobs protect information from public view and from unauthorized personnel entering an unsupervised area. All passwords, keys and/or combinations are changed when a person leaves or no longer has authorized duties. Access to records is limited to those authorized personnel trained in accordance with the Privacy Act and ADP security procedures. The safeguards described above were established in accordance with DHHS chapter 45-13 and supplementary chapter PHS hf: 45-13 of the General Administration Manual; and the DHHS Information Resources Management Manual, Part 6, "ADP Systems Security."

RETENTION AND DISPOSAL:

Records in the DMS are retained for at least 6 years after full payment of the loan, completion of service obligation, or repayment to the Secretary in the case of a default. Contact the System Manager at the following address for further information.

SYSTEM MANAGERS(S) AND ADDRESS:

Director, Division of Health Careers Diversity and Development, Bureau of Health Professions, Health Resources and Services Administration, Department of Health and Human Services, 5600 Fishers Lane, Room 8-42, Rockville, Maryland 20857.

NOTIFICATION PROCEDURE:

Requests concerning whether the system contains records about you should be made to the Systems Manager.

REQUESTS IN PERSON:

A subject individual who appears in person at a specific location seeking access or disclosure of records relating to him/her shall provide his/her name, current address, Social Security number and at least one piece of tangible identification such as driver's license, passport, voter registration card, or union card. Identification papers with current photographs are preferred but not required. Additional identification may be requested when there is a request for access to records which contain an apparent discrepancy between information contained in the records and that provided by the individual requesting access to the records. Where the subject individual has no identification papers, the responsible agency official shall require that the subject individual certify in writing that he/she is the individual who he/she claims to be and that he/she understands that the knowing and willful request or acquisition of a record concerning an individual under false pretenses is a criminal offense subject to a \$5,000 fine.

REQUESTS BY TELEPHONE:

Because positive identification of the caller cannot be established, no requests by telephone will be honored.

REQUESTS BY MAIL:

A written request must contain the name and address of the requester, Social Security number or other identifying numbers, and his/her signature which is either notarized to verify his/her identity or includes a written certification that the requester is a person he/she claims to be and that he/she understands that the knowing and willful request or acquisition of

records pertaining to an individual under false pretenses is a criminal offense subject to a \$5,000 fine.

RECORD ACCESS PROCEDURES:

Same as notification procedures. Requesters should also reasonably specify the record contents being sought. Individuals may also request an accounting of disclosures that may have been made of their records, if any.

CONTESTING RECORD PROCEDURES:

Any record subject may contest the accuracy of information on file at CBB by writing to the Director, Division of Health Careers Diversity and Development, Bureau of Health Professions, Health Resources and Services Administration, Department of Health and Human Services, 5600 Fishers Lane, Room 8-42, Rockville, Maryland 20857. The request should contain a reasonable description of the record, specify the information being contested, the corrective action sought, and the reasons for requesting the correction, along with supporting information to show how the record is inaccurate, incomplete, untimely or irrelevant.

RECORD SOURCE CATEGORIES:

1. Educational institutions participating in CBB programs
2. Financial aid officers administering CBB programs
3. Student borrowers and recipients participating in CBB programs
4. Borrowers submitted for uncollectible debt write-offs
5. Borrowers submitted for total disability write-offs

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

[FR Doc. 07-5379 Filed 10-29-07; 8:45 am]

BILLING CODE 4165-15-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Health Resources and Services Administration****Reimbursement of Travel and Subsistence Expenses Toward Living Organ Donation Proposed Eligibility Guidelines and Publication of Final Program Eligibility Guidelines**

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Correction of Web site.

SUMMARY: The Health Resources and Services Administration published a notice in the **Federal Register** of

October 5, 2007 (FR Doc. E7-19747), on pages 57049-57052, regarding response to solicitation of comments and publication of final program eligibility guidelines.

Correction

In the **Federal Register** issue of October 5 (FR Doc. E7-19747), on page 57050, second column, under section V. Response to Comment that Overall Reimbursement Level Should Exceed \$6,000, Conclusion, correct the Web site to read: <http://www.livingdonorassistance.org>.

Dated: October 23, 2007.

Dennis P. Williams,
Deputy Administrator.

[FR Doc. E7-21309 Filed 10-29-07; 8:45 am]

BILLING CODE 4165-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Substance Abuse and Mental Health Services Administration****Agency Information Collection Activities: Submission for OMB Review; Comment Request**

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (240) 276-1243.

Proposed Project: Participant Feedback on Training Under the Cooperative Agreement for Mental Health Care Provider Education in HIV/AIDS Program (OMB No. 0930-0195)—Revision

The Substance Abuse and Mental Health Services Administration's (SAMHSA) Center for Mental Health Services (CMHS) intends to continue to conduct a multi-site assessment for the Mental Health Care Provider Education in HIV/AIDS Program. The education programs funded under this cooperative agreement are designed to disseminate knowledge of the psychological and neuropsychiatric sequelae of HIV/AIDS to both traditional (e.g., psychiatrists, psychologists, nurses, primary care physicians, medical students, and social workers) and non-traditional (e.g., clergy, and alternative health care workers) first-line providers of mental health services, in particular to providers in minority communities.

The multi-site assessment is designed to assess the effectiveness of particular