

at this time. Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the draft guidance. 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 the brackets in the heading of this document. A copy of the draft guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at <http://www.regulations.gov>.

IV. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either 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

Dated: October 1, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: 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: Health Professions Student Loan (HPSL) Program and Nursing Student Loan (NSL) Program Administrative Requirements (Regulations and Policy) (OMB No. 0915-0047)—Extension

The regulations for the Health Professions Student Loan (HPSL) Program and Nursing Student Loan (NSL) Program contain a number of reporting and recordkeeping requirements for schools and loan applicants. The requirements are essential for assuring that borrowers are aware of rights and responsibilities, that schools know the history and status of each loan account, that schools pursue aggressive collection efforts to reduce default rates, and that they maintain adequate records for audit and assessment purposes. Schools are free to use improved information technology to manage the information required by the regulations.

The annualized estimates of burden are as follows:

RECORDKEEPING REQUIREMENTS

Regulatory/section requirements	Number of recordkeepers	Hours per year	Total burden hours
HPSL Program:			
57.206(b)(2), Documentation of Cost of Attendance	432	1.17	505
57.208(a), Promissory Note	432	1.25	540
57.210(b)(1)(i), Documentation of Entrance Interview	432	1.25	540
57.210(b)(1)(ii), Documentation of Exit Interview	* 472	0.33	156
57.215(a)&(d), Program Records	* 472	10	4,720
57.215(b), Student Records	* 472	10	4,720
57.215(c), Repayment Records	* 472	18.75	8,850
HPSL Subtotal	472	20,031
NSL Program:			
57.306(b)(2)(ii), Documentation of Cost of Attendance	300	0.3	90
57.308(a), Promissory Note	300	0.5	150
57.310(b)(1)(i), Documentation of Entrance Interview	300	0.5	150
57.310(b)(1)(ii), Documentation of Exit Interview	* 435	0.17	74
57.315(a)(1)&(a)(4), Program Records	* 435	5	2,175
57.315(a)(2), Student Records	* 435	1	435
57.315(a)(3), Repayment Records	* 435	2.51	1,092
NSL Subtotal	435	4,166

* Includes active and closing schools.

HPSL data includes active and closing Loans for Disadvantaged Students (LDS) program schools.

REPORTING REQUIREMENTS

Regulatory/section requirements	Number of respondents	Responses per respondent	Total annual responses	Hours per response	Total hour burden
HPSL Program:					
57.206(a)(2), Student Financial Aid Transcript	4,600	1	4,670	.25	1,150
57.208(c), Loan Information Disclosure	432	68.73	29,692	.0833	2,473
57.210(b)(1)(i), Entrance Interview	432	68.73	29,692	0.167	4,959
57.210(b)(1)(ii), Exit Interview	* 472	12	5,664	0.5	2,832

REPORTING REQUIREMENTS—Continued

Regulatory/section requirements	Number of respondents	Responses per respondent	Total annual responses	Hours per response	Total hour burden
57.210(b)(1)(iii), Notification of Repayment	* 472	30.83	14,552	0.167	2,430
57.210(b)(1)(iv), Notification During Deferment	* 472	24.32	11,479	0.0833	957
57.210(b)(1)(vi), Notification of Delinquent Accounts	* 472	10.28	4,853	0.167	811
57.210(b)(1)(x), Credit Bureau Notification	* 472	8.03	3,790	0.6	2,274
57.210(b)(4)(i), Write-off of Uncollectible Loans	20	1.00	20	3.0	60
57.211(a) Disability Cancellation	10	1	10	.75	8
57.215(a)(2), Administrative Hearings ..	0	0	0	0	0
57.215(a)(d), Administrative Hearings ..	0	0	0	0	0
HPSL Subtotal	7,854	104,352	17,954
NSL Program:					
57.306(a)(2), Student Financial Aid Transcript	4,100	1	4,100	0.25	1,025
57.310(b)(1)(i), Entrance Interview	300	23.51	7,053	0.167	1,178
57.310(b)(1)(ii), Exit Interview	* 435	3.77	1,640	0.5	820
57.301(b)(1)(iii), Notification of Repayment	* 435	6.18	2,688	0.167	449
57.310(b)(1)(iv), Notification During Deferment	* 435	0.65	283	0.083	24
57.310(b)(1)(vi), Notification of Delinquent Accounts	* 435	4.61	2,006	0.167	335
57.310(b)(1)(x), Credit Bureau Notification	* 435	8.3	3,611	0.6	2,167
57.310(b)(4)(i), Write-off of Uncollectible Loans	20	1.0	20	3.5	70
57.311(a), Disability Cancellation	10	1.0	10	0.8	8
57.315(a)(1)(ii), Administrative Hearings	0	0	0	0	0
57.316(a)(d), Administrative Hearings ..	0	0	0	0	0
NSL Subtotal	6,605	21,411	6,076

* Includes active and closing schools.

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to the desk officer for HRSA, either by e-mail to OIRA_submission@omb.eop.gov or by fax to 202-395-6974. Please direct all correspondence to the attention of the desk officer for HRSA.

Dated: October 3, 2008.

Alexandra Huttinger,

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 (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: Application for Certification and Recertification as a Federally Qualified Health Center (FQHC) Look-Alike (OMB No. 0915-0142): Revision

The Health Resources and Services Administration (HRSA) collects applicant information for organizations applying for certification or recertification as a Federally Qualified Health Center (FQHC) Look-Alike for purposes of cost-based reimbursement under the Medicaid and Medicare programs. The information contained in the application guidance reflects legislative, policy, and technical requirements for applicant organizations.

The estimated burden is as follows: