

regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products. These guidance documents are also available at <https://www.regulations.gov>, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>, or <https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics>. Persons unable to download an electronic copy of “Evidentiary Expectations for 510(k) Implant Devices” (document number

GUI00020017), “Recommendations for the Use of Clinical Data in Premarket Notification [510(k)] Submissions” (document number GUI00020016), or “Best Practices for Selecting a Predicate Device to Support a Premarket Notification [510(k)] Submission” (document number GUI00020006) may send an email request to CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the document. Please use the document number and complete title to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

While these guidances contain no new collection of information, they do refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in the following table have been approved by OMB:

21 CFR part; guidance; or FDA form	Topic	OMB control No.
807, subpart E “Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program”.	Premarket notification Q-Submissions and Early Payor Feedback Request Programs for Medical Devices	0910–0120 0910–0756
800, 801, 809, and 830 803	Medical Device Labeling Regulations; Unique Device Identification Medical Devices; Medical Device Reporting; Manufacturer reporting, importer reporting, user facility reporting, distributor reporting.	0910–0485 0910–0437
810 820 822	Medical Device Recalls Current Good Manufacturing Practice (CGMP); Quality System (QS) Regulation Postmarket Surveillance of Medical Devices	0910–0432 0910–0073 0910–0449
Forms FDA 3500 and FDA 3500A 58	Medical device adverse event reporting—MedWatch Good Laboratory Practice (GLP) Regulations for Nonclinical Laboratory Studies	0910–0291 0910–0119

Dated: September 1, 2023.

Lauren K. Roth,
Associate Commissioner for Policy.

[FR Doc. 2023–19283 Filed 9–6–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Public Comment Request; Information Collection Request Title: Health Professions Student Loan Program, Loans for Disadvantaged Students Program, Primary Care Loan Program, and Nursing Student Loan Program Administrative Requirements, OMB No. 0915–0047—Revision

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the requirement for the opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA

seeks comments from the public regarding the burden estimate below; or any other aspect of the ICR.

DATES: Comments on this ICR should be received no later than November 6, 2023.

ADDRESSES: Submit your comments to paperwork@hrsa.gov or mail the HRSA Information Collection Clearance Officer, Room 14N136B, 5600 Fishers Lane, Rockville, Maryland 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email paperwork@hrsa.gov or call Joella Roland, the HRSA Information Collection Clearance Officer, at 301–443–3983.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the ICR title for reference.

Information Collection Request Title: Health Professions Student Loan (HPSL) Program, Loans for Disadvantaged Students (LDS) Program, Primary Care Loan (PCL) Program, and Nursing Student (Loan (NSL) Program Administrative Requirements, OMB No. 0915–0047—Revision.

Abstract: This clearance request is for approval of the HPSL Program, LDS Program, PCL Program, and NSL Program Administrative Requirements.

The HPSL Program, authorized by Public Health Service (PHS) Act

sections 721–722 and 725–735, is a grant program where recipients provide long-term, low-interest loans to students attending schools of medicine, osteopathic medicine, dentistry, veterinary medicine, optometry, podiatric medicine, and pharmacy. The LDS Program, authorized by PHS Act sections 721–722 and 724–735, is a grant program where recipients provide long-term, low interest loans to certain students attending schools of allopathic medicine, osteopathic medicine, podiatric medicine, dentistry, optometry, pharmacy, and veterinary medicine. The PCL Program, authorized by PHS Act sections 721–723 and 725–735, is a grant program where recipients provide long-term, low interest loans to students attending schools of allopathic medicine and osteopathic medicine to practice primary health care. The NSL Program, authorized by PHS Act sections 835–842, is a grant program where recipients provide long-term, low-interest loans to students who attend eligible schools of nursing in programs leading to a diploma degree, an associate degree, a baccalaureate degree, or a graduate degree in nursing. These programs also have a number of recordkeeping and reporting requirements for academic institutions and loan applicants. The applicable program regulations are found in 42 CFR 57.201–218 and 57.301–318. HRSA proposes revisions to the Annual

Operating Report (AOR)—HRSA Form 501 completed by institutions participating in the HPSL, LDS, PCL, and NSL programs to obtain additional information about those institutions and their student borrowers.

Need and Proposed Use of the Information: Participating HPSL, LDS, PCL, and NSL schools are responsible for determining the eligibility of applicants, making loans, and collecting monies owed by borrowers on their outstanding loans. Participating schools include schools that are no longer disbursing loans but are required to report and maintain program records, student records, and repayment records until all student loans are repaid in full, and all monies due to the federal government are returned. The Deferment Form—HRSA Form 519, provides the schools with documentation of a borrower’s

deferment status, as detailed for the HPSL program under 42 CFR 57.210 and NSL under 42 CFR 57.310, and is included with minor revisions. The proposed revisions to the AOR are to modify the options selected for gender identification consistent with Executive Order 14075—Executive Order on Advancing Equality for Lesbian, Gay, Bisexual, Transgender, Queer, and Intersex Individuals.

Additionally, the deferment form is being updated to provide specific directions for the submission requirements to notify students that the deferment request must be submitted to the institution 30 days prior to the payment due date. The institution must respond to the student 30 days after receipt of the student request.

- *Likely Respondents:* Institutions who have received HPSL, LDS, PCL, and/or NSL Program awards.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Instrument (HPSL, LDS, PCL, & NSL)	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
Deferment—HRSA Form 519	2,060	1	2,060	.50	1,030
AOR—HRSA—Form 501	726	1	726	12.00	8,712
Total	2,786	2,786	9,742
Grand Total (instruments and record-keeping reporting requirements)	327,979

RECORDKEEPING REQUIREMENTS

Data required to be submitted	Number of record keepers	Hours per year	Total burden hours
<i>HPSL, LDS, and PCL Program:</i>			
Documentation of Cost of Attendance	432	1.05	454
Promissory Note	432	1.25	540
Documentation of Entrance Interview	432	1.25	540
Documentation of Exit Interview	* 475	0.37	176
Program Records	* 475	10.00	4,750
Student Records	* 475	10.00	4,750
Repayment Records	* 475	19.55	9,286
HPSL/LDS/PCL Subtotal	475	20,496
<i>NSL Program:</i>			
Documentation of Cost of Attendance	304	0.25	76
Promissory Note	304	0.50	152
Documentation of Entrance Interview	304	0.50	152
Documentation of Exit Interview	* 486	0.14	68
Program Records	* 486	5.00	2,430
Student Records	* 486	1.00	486
Repayment Records	* 486	2.51	1,220
NSL Subtotal	486	4,584

* Includes active and closing schools.

REPORTING REQUIREMENTS

	Number of respondents	Responses per respondent	Total annual responses	Hours per response	Total burden hours
<i>HPSL, LDS, and PCL:</i>					

REPORTING REQUIREMENTS—Continued

	Number of respondents	Responses per respondent	Total annual responses	Hours per response	Total burden hours
Student Financial Aid Transcript	4,600	1	4,600	0.25	1,150
Loan Information Disclosure	325	299.5	97,338	0.63	61,323
Entrance Interview	325	139.5	45,338	0.50	22,669
Exit Interview	* 334	113.5	37,909	1.00	37,909
Notification of Repayment	* 334	862.5	288,075	0.38	109,469
Notification During Deferment	* 333	17	5,661	0.63	3,566
Notification of Delinquent Accounts	334	172.5	57,615	1.25	72,019
Credit Bureau Notification	334	6	2,004	0.50	1,002
Write-off of Uncollectable Loans	520	1	520	3.00	1,560
Disability Cancellation	3	1	3	1.00	3
Administrative Hearings record retention	0	0	0	0.00	0
Administrative Hearings reporting requirements	0	0	0	0.00	0
HPSL Subtotal					310,670
NSL:					
Student Financial Aid Transcript	4,100	1	4,100	0.25	1,025
Entrance Interview	282	17.5	4,935	0.42	2,073
Exit Interview	348	9	3,132	0.42	1,315
Notification of Repayment	348	9	3,132	0.27	846
Notification During Deferment	348	1.5	522	0.29	151
Notification of Delinquent Accounts	348	42.5	14,790	0.04	592
Credit Bureau Notification	348	709	246,732	0.06	1,480
Write-off of Uncollectable Loans	23	1	23	3.00	69
Disability Cancellation	16	1	16	1.00	16
Administrative Hearings	0	0	0	0.00	0
NSL Subtotal					7,567

HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2023-19203 Filed 9-6-23; 8:45 am]

BILLING CODE 4165-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting 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: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; RFA-DK-22-028 Pilot and Feasibility R01s to Integrate Soc and Med Care in Type 1 Diabetes.

Date: October 12, 2023.

Time: 12:00 p.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, NIDDK, Democracy II, Suite 7000A, 6707 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Cheryl Nordstrom, Ph.D., MPH, Scientific Review Officer, NIDDK/Scientific Review Branch, National Institutes of Health, 6707 Democracy Blvd., Room 7013, Bethesda, MD 20892, 301-402-6711, cheryl.nordstrom@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: August 31, 2023.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023-19260 Filed 9-6-23; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Dental and Craniofacial Research; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

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: National Institute of Dental and Craniofacial Research Special