

741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's website at <https://www.fda.gov/advisory-committees> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before joining the meeting.

**SUPPLEMENTARY INFORMATION:**

*Agenda:* The meeting presentations will be heard, viewed, captioned, and recorded through an online teleconferencing platform. The committee will meet in open session to discuss EUA of the Janssen Biotech Inc. COVID–19 Vaccine for active immunization to prevent COVID–19 caused by SARS–CoV–2 in individuals 18 years and older. EUA authority allows FDA to help strengthen the nation's public health protections against chemical, biological, radiological, nuclear (CBRN) threats by facilitating the availability and use of Medical Countermeasures (MCMs) needed during public health emergencies. Under section 564 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–3), FDA may allow unapproved medical products or unapproved uses of approved medical products to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by CBRN threat agents when certain statutory criteria have been met, including that there are no adequate, approved, and available alternatives. Additional information about EUAs can be found at <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, background material will be made publicly available on FDA's website at the time of the advisory committee meeting. Background material and the link to the online teleconference meeting room will be available at <https://www.fda.gov/advisory-committees/advisory-committee-calendar>. Scroll down to the appropriate advisory committee meeting link. The meeting will include slide presentations with audio components to

allow the presentation of materials in a manner that most closely resembles an in-person advisory committee meeting.

*Procedure:* Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. All electronic and written submissions submitted to the Docket (see **ADDRESSES**) on or before February 18, 2021, will be provided to the committee. Comments received after February 18, 2021, and by February 25, 2021, will be taken into consideration by FDA. Oral presentations from the public will be scheduled between approximately 1:25 p.m. Eastern Time and 2:25 p.m. Eastern Time. Those individuals interested in making formal oral presentations should notify the contact 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 February 17, 2021. 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 February 18, 2021.

For press inquiries, please contact the Office of Media Affairs at [fdaoma@fda.hhs.gov](mailto:fdaoma@fda.hhs.gov) or 301–796–4540.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Prabhakara Atreya or Kathleen Hayes ([CBERVBPAC@fda.hhs.gov](mailto:CBERVBPAC@fda.hhs.gov)) at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at: <https://www.fda.gov/advisory-committees/about-advisory-committees/public-conduct-during-fda-advisory-committee-meetings> 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: February 8, 2021.

**Lauren K. Roth,**

*Acting Principal Associate Commissioner for Policy.*

[FR Doc. 2021–02845 Filed 2–10–21; 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, 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 (HHS).

**ACTION:** Notice.

**SUMMARY:** In compliance with the Paperwork Reduction Act of 1995, HRSA submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA's ICR only after the 30 day comment period for this notice has closed.

**DATES:** Comments on this ICR should be received no later than March 15, 2021.

**ADDRESSES:** Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to [www.reginfo.gov/public/do/PRAMain](http://www.reginfo.gov/public/do/PRAMain). Find this particular information collection by selecting "Currently under Review—Open for Public Comments" or by using the search function.

**FOR FURTHER INFORMATION CONTACT:** To request a copy of the clearance requests submitted to OMB for review, email Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or call (301) 443–1984.

**SUPPLEMENTARY INFORMATION:**

*Information Collection Request Title:* Health Professions Student Loan (HPSL) Program, Loans for Disadvantaged Students, Primary Care Loan Program (PCL), and Nursing Student Loan Program Administrative Requirements.

OMB No. 0915–0047—Revision

*Abstract:* This clearance request is for approval of the Health Professions Student Loan (HPSL) Program, Loans for Disadvantaged Students (LDS), Primary Care Loan Program (PCL), and Nursing Student Loan (NSL) Program

Administrative Requirements. The form was previously titled as the HPSL Program and NSL Program Administrative Requirements (Regulations and Policy). This request seeks to add LDS and PCL as the forms discussed in this notice are also used for these programs.

The HPSL Program, as authorized by Public Health Service (PHS) Act sections 721–722 and 725–735, provides long-term, low-interest loans to students attending schools of medicine, osteopathic medicine, dentistry, veterinary medicine, optometry, podiatric medicine, and pharmacy. The LDS Program, as authorized by PHS Act sections 721–722 and 724–735, provides long-term, low interest loans to students attending schools of allopathic medicine, osteopathic medicine, podiatric medicine, dentistry, optometry, pharmacy, and veterinary medicine. The PCL Program, as authorized by PHS Act sections 721–723 and 725–735, provides long-term, low interest loans to students attending schools of allopathic medicine and osteopathic medicine to practice primary health care. The NSL Program, as authorized by PHS Act sections 835–842, provides 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 requirements for these programs are outlined 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.

A 60-day notice published in the **Federal Register** on December 14, 2020, vol. 85, No. 240; pp. 80791–93. There were no public comments.

*Need and Proposed Use of the Information:* Participating HPSL, LDS, PCL, and NSL schools are responsible for determining 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 for NSL under 42 CFR 57.310, and is included without revision.

The AOR–HRSA Form 501 provides HHS with information from participating schools relating to HPSL, LDS, PCL and NSL program operations and financial activities. The proposed revisions to the AOR include the addition of a part-time option to select questions to allow institutions to report data on their part-time students, who are eligible to receive funding through the NSL program.

Specifically, the “part-time” option will be added to the following questions for the NHL program:

- Question 3, page 1A of the non-PCL section of the AOR (total full-time enrollment for the Nursing discipline for the academic year – NSL loan recipients),
- Question 13 (total number of full time graduates – NSL loan recipients) at the school during the current reporting period),
- Question 14 (total number of full time NSL graduates – NSL loan recipients) during the current reporting period who indicate intent to serve in a rural area),
- Question 15b (of the total graduates reported in question 15a, the number of full-time NSL graduates – NSL loan recipients in academic year 20XX–20XX serving in medically underserved communities),

- Question 15c (of the total graduates reported in question 15a, the number of Full-Time NSL graduates—NSL loan recipients in academic year 20XX–20XX serving in primary care), and

- Question 15d (of the total graduates in question 15a, the number of full-time NSL graduates – NSL loan recipients in Academic Year 20XX–20XX who entered the field for which they received their degree).

HRSA also proposes to revise the AOR–HRSA Form 501 form to include four additional questions at the bottom of Page 1A of all AORs:

- 16a. Are you a Community College?
- 16b. Are you a Historically Black College or University?
- 16c. Are you a Tribal college or university? and
- 16d. Are you an institution located in a rural area?

In addition, HRSA proposes to revise Page 4 (the excess cash worksheet) of the AOR–HRSA Form 501 form to limit the grantees’ ability to make projections to 1 year. This proposed revision will allow HRSA to improve the overall management of funding.

*Likely Respondents:* Institutions participating in the HPSL, LDS, PCL, and/or NSL Programs.

*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 .....	2060	1	2060	.5	1,030
AOR—HRSA—Form 501 .....	726	1	726	12	8,712
Total .....	2786	.....	2786	.....	9,742
Grand Total (instruments and recordkeeping requirements) .....	.....	.....	.....	.....	327,979

RECORDKEEPING REQUIREMENTS

Data required to be submitted	Number of record keepers	Hours per year	Total burden hours
<b>HPSL, LDS, and PCL Program:</b>			
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
<b>HPSL/LDS/PCL Subtotal .....</b>	<b>475</b>	<b>.....</b>	<b>20,496</b>
<b>NSL Program:</b>			
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
<b>NSL Subtotal .....</b>	<b>486</b>	<b>.....</b>	<b>4,584</b>

\* Includes active and closing schools.

REPORTING REQUIREMENTS

	Number of respondents	Responses per respondent	Total annual responses	Hours per response	Total burden hours
<b>HPSL, LDS, and PCL:</b>					
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
<b>HPSL Subtotal .....</b>	<b>.....</b>	<b>.....</b>	<b>.....</b>	<b>.....</b>	<b>310,670</b>
<b>NSL:</b>					
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
<b>NSL Subtotal .....</b>	<b>.....</b>	<b>.....</b>	<b>.....</b>	<b>.....</b>	<b>7,567</b>

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. 2021-02807 Filed 2-10-21; 8:45 am]

**BILLING CODE 4165-15-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Request for Information (RFI): Accelerating Innovation in Diagnostic Testing for Lyme Disease**

**AGENCY:** Office of the Assistant Secretary for Health (OASH), Office of the Secretary, Department of Health and Human Services (HHS).