

during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: Must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to <https://www.regulations.gov> at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: February 8, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2018–02992 Filed 2–13–18; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Agency Information Collection

**Activities: Submission to OMB for Review and Approval; Public Comment Request; Information Collection Request Title: Health Professions Student Loan (HPSL) Program and Nursing Student Loan (NSL) Program Administrative Requirements (Regulations and Policy). 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 of the Paperwork Reduction Act of 1995, HRSA has 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.

**DATES:** Comments on this ICR should be received no later than March 16, 2018.

**ADDRESSES:** Submit your comments, including the ICR Title, to the desk officer for HRSA, either by email to [OIRA\\_submission@omb.eop.gov](mailto:OIRA_submission@omb.eop.gov) or by fax to 202–395–5806.

**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:** When submitting comments or requesting information, please include the information request collection title for reference.

*Information Collection Request Title:* Health Professions Student Loan (HPSL) Program and Nursing Student Loan (NSL) Program Administrative Requirements (Regulations and Policy). OMB No. 0915–0047–Revision.

*Abstract:* 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 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 and degrees in nursing, including an associate degree, a baccalaureate degree, or graduate degree in nursing. It also contains a number of recordkeeping and reporting requirements for academic institutions and loan applicants. The applicable regulations for these programs under 42 CFR part 57 implement and detail the various statutory requirements (see chart below). In an effort to consolidate information collection requests and achieve greater programmatic efficiency, HRSA is incorporating the Deferment Form (Deferment–HRSA Form 519) and the Annual Operating Report (AOR–HRSA Form 501) both formerly incorporated under OMB No. 0915–0044, into this information collection request. As a result, the OMB No. 0915–0044 package will be discontinued.

*Need and Proposed Use of the Information:* Participating HPSL and NSL schools are responsible for

determining eligibility of applicants, making loans, and collecting monies owed by borrowers on their outstanding loans. The Deferment Form (Deferment–HRSA Form 519), provides the schools with documentation of a borrower's deferment status, as detailed for the HPSL Program under 42 CFR part 57.210 and for NSL under 42 CFR part 57.310. The Annual Operating Report (AOR–HRSA Form 501), provides HHS with information from participating schools (including 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) relating to HPSL and NSL Program operations and financial activities. Moreover, the HPSL and NSL Program requirements are essential for assuring that borrowers are aware of their rights and responsibilities, academic institutions have accurate records of the history and status of each loan account in order to pursue aggressive collection efforts to reduce default rates, and that academic institutions maintain adequate records for audit and assessment purposes to help HHS safeguard federal funds expended through the Federal Capital Contribution (FCC). Academic institutions are free to use improved information technology to manage the information required by the regulations.

*Likely Respondents:* Financial Aid Directors working at institutions participating in the HPSL and 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 & NSL)	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
Deferment—HRSA Form 519 .....	3,125	1	3,125	0.5	1,562.5
AOR—HRSA—Form 501 .....	768	1	768	12.0	9,216.0
<b>Total .....</b>	<b>3,893</b>	<b>.....</b>	<b>3,893</b>	<b>.....</b>	<b>10,778.5</b>

RECORDKEEPING REQUIREMENTS

Regulatory/section requirements	Number of record keepers	Hours per year	Total burden hours
<b>HPSL Program</b>			
57.206(b)(2), Documentation of Cost of Attendance .....	432	1.05	454
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 .....	475	0.37	176
57.215(a)&(d), Program Records .....	475	10.00	4,750
57.215(b), Student Records .....	475	10.00	4,750
57.215(c), Repayment Records .....	475	19.55	9,286
<b>HPSL Subtotal .....</b>	<b>.....</b>	<b>.....</b>	<b>20,496</b>
<b>NSL Program</b>			
57.306(b)(2)(ii), Documentation of Cost of Attendance .....	304	0.25	76
57.308(a), Promissory Note .....	304	0.50	152
57.310(b)(1)(i), Documentation of Entrance Interview .....	304	0.50	152
57.310(b)(1)(ii), Documentation of Exit Interview .....	486	0.14	68
57.315(a)(1)&(a)(4), Program Records .....	486	5.00	2,430
57.315(a)(2), Student Records .....	486	1.00	486
57.315(a)(3), Repayment Records .....	486	2.51	1,220
<b>NSL Subtotal .....</b>	<b>.....</b>	<b>.....</b>	<b>4,584</b>

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
<b>HPSL Program</b>					
57.206(a)(2), Student Financial Aid Transcript .....	4,600	1.0	4,600	0.25	1,150
57.208(c), Loan Information Disclosure .....	325	299.5	97,338	0.63	61,323
57.210(b)(1)(i), Entrance Interview .....	325	139.5	45,338	0.50	22,669
57.210(b)(1)(ii), Exit Interview .....	334	113.5	37,909	1.00	37,909
57.210(b)(1)(iii), Notification of Repayment .....	334	862.5	288,075	0.38	109,469
57.210(b)(1)(iv), Notification During Deferment .....	333	17.0	5,661	0.63	3,566
57.210(b)(1)(vi), Notification of Delinquent Accounts .....	334	172.5	57,615	1.25	72,019
57.210(b)(1)(x), Credit Bureau Notification .....	334	6.0	2,004	0.50	1,002
57.210(b)(4)(i), Write-off of Uncollectible Loans .....	520	1.0	520	3.00	1,560
57.211(a) Disability Cancellation .....	3	1.0	3	1.00	3
57.215(a)(2), Administrative Hearings .....	0	0.0	0	0.00	0
57.215(a)(d), Administrative Hearings .....	0	0.0	0	0.00	0
<b>HPSL Subtotal .....</b>	<b>*334</b>	<b>.....</b>	<b>539,063</b>	<b>.....</b>	<b>310,670</b>
<b>NSL Program</b>					
57.306(a)(2), Student Financial Aid Transcript .....	4,100	1.0	4,100	0.25	1,025
57.310(b)(1)(i), Entrance Interview .....	282	17.5	4,935	0.42	2,073
57.310(b)(1)(ii), Exit Interview .....	348	9.0	3,132	0.42	1,315
57.301(b)(1)(iii), Notification of Repayment .....	348	9.0	3,132	0.27	846
57.310(b)(1)(iv), Notification During Deferment .....	348	1.5	522	0.29	151

## REPORTING REQUIREMENTS—Continued

Regulatory/section requirements	Number of respondents	Responses per respondent	Total annual responses	Hours per response	Total hour burden
57.310(b)(1)(vi), Notification of Delinquent Accounts .....	348	42.5	14,790	0.04	592
57.310(b)(1)(x), Credit Bureau Notification .....	348	709.0	246,732	0.006	1,480
57.310(b)(4)(i), Write-off of Uncollectible Loans .....	23	1.0	23	3.00	69
57.311(a), Disability Cancellation .....	16	1.0	16	1.00	16
57.315(a)(1)(ii), Administrative Hearings .....	0	0.0	0	0.00	0
57.316a, Administrative Hearings .....	0	0.0	0	0.00	0
NSL Subtotal .....	*348	.....	277,382	.....	7,567

\* Includes active and closing schools.

#### Amy McNulty.

Acting Director, Division of the Executive Secretariat.

[FR Doc. 2018-02958 Filed 2-13-18; 8:45 am]

BILLING CODE 4165-15-P

### DEPARTMENT OF HEALTH AND HUMAN SERVICES

#### Privacy Act of 1974; System of Records.

**AGENCY:** Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

**ACTION:** Notice of a New System of Records.

**SUMMARY:** The Department of Health and Human Services (HHS), Centers for Medicare & Medicaid Services (CMS) proposes to establish a new system of records subject to the Privacy Act, System No. 09-70-0539, titled "Quality Payment Program (QPP)." The new system of records will cover quality and performance data collected and used by CMS in determining merit-based payment adjustments for health care services provided by clinicians to Medicare beneficiaries, and in providing expert feedback to clinicians and third party data submitters for the purpose of helping clinicians provide high-value care to patients.

**DATES:** In accordance with 5 U.S.C. 552a(e)(4) and (11), this notice is effective upon publication, subject to a 30-day period in which to comment on the routine uses, described below. Please submit any comments by March 16, 2018.

**ADDRESSES:** Written comments should be submitted by mail or email to: CMS Privacy Act Officer, Division of Security, Privacy Policy & Governance, Information Security & Privacy Group, Office of Information Technology, CMS, 7500 Security Boulevard, Baltimore, MD 21244-1870, Location N1-14-56, or [walter.stone@cms.hhs.gov](mailto:walter.stone@cms.hhs.gov). Comments received will be available for review

without redaction unless otherwise advised by the commenter at this location, by appointment, during regular business hours, Monday through Friday from 9:00 a.m.–3:00 p.m., Eastern Time zone.

#### FOR FURTHER INFORMATION CONTACT:

General questions about the new system of records should be submitted by mail or email to: Michelle Peterman, Health Insurance Specialist, Division of Electronic Clinician and Quality, Quality Measurement and Value-Based Incentives Group, Center for Clinical Standards and Quality, CMS, 7500 Security Boulevard, Baltimore, MD 21244-1870, Mailstop: S3-02-01, or [michelle.peterman@cms.hhs.gov](mailto:michelle.peterman@cms.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Background on the New Quality Payment Program Supported by the New System of Records

The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) amended title XVIII of the Social Security Act (the Act) to repeal the way physicians were paid under the previous Sustainable Growth Rate (SOR) formula and replaced it with a new approach known as the Quality Payment Program. The Quality Payment Program streamlines and consolidates components of three existing incentive programs that reward high-value patient centered care: (1) Physician Quality Reporting System (PQRS) (§ 1848(k) and (m) of the Act (42 U.S.C. 1395w-4)), (2) Medicare Electronic Health Records (EHR) Incentive Program for Eligible Professionals (§ 1848(0) of the Act), and (3) Physician Value-Based Payment Modifier (VM) (§ 1848(p) of the Act). For more information, see rulemakings implementing the existing programs, at 80 Fed. Reg. 71135 (November 16, 2015) (PQRS); 80 FR 62761 (October 16, 2015) (EHR); and 80 FR 71273 (November 16, 2015) (VM).

There are two separate pathways within the Quality Payment Program, Advanced Alternative Payment Models

(Advanced APM) and Merit-based Incentive Payment System (MIPS), both of which contribute toward the goal of seamless integration of the Quality Payment Program into clinical practice workflows. MIPS provides clinicians measures and activities to assist them in providing high-value, patient-centered care to Medicare patients, and to encourage and reward their use of the same. The participants generate and submit to CMS data on health care coordination. The data will be submitted to CMS by eligible clinicians and approved third party data submitters (for example, registries which collect and submit disease tracking data; health information technology (IT) vendors which submit data from clinicians' Certified Electronic Health Record Technology (CEHRT) systems). The data will include information about, and will be retrieved by personal identifiers for: (1) The clinicians, (2) any third party data submitters who are individuals (*e.g.*, sole proprietor vendors), (3) individuals who submit data for clinicians or third party data submitters as their representatives or contact persons, and (4) Medicare beneficiaries and any non-Medicare beneficiaries receiving the health care services referenced in the Quality Payment Program data. The records are described below.

The data submission process will require that clinicians and third party submitters use their identifying and contact information, tax identification number (TIN/EIN), national provider identifier (NPI), and information about health care services provided to patients for the performance categories of the MIPS including (1) quality-including a set of evidence-based, specialty-specific standards; (2) cost of services provided; (3) improvement activities that improved or are likely to improve clinical practice or care delivery; and (4) advancing care information which focuses on the use of CEHRT to support interoperability and avoid