

will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Kenneth Quinto, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5145, Silver Spring, MD 20993, 240-402-2221, email: kenneth.quinto@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: FDA is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our Nation's food supply, cosmetics, and products that emit radiation.

FDA is establishing a public docket FDA-2017-N-0595 to receive input on pediatric postmarketing pharmacovigilance and drug utilization reviews posted between September 17, 2016, and February 24, 2017, on the FDA Web site at <http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/PediatricAdvisoryCommittee/ucm510701.htm>, but will not be presented at the March 6-7, 2017, PAC meeting (82 FR 1345, January 5, 2017). FDA welcomes comments by members of the PAC, as mandated by the Best Pharmaceuticals for Children Act (Pub. L. 107-109) and the Pediatric Research Equity Act (Pub. L. 108-155), interested parties (such as academic researchers, regulated industries, consortia, and patient groups), and the general public. The docket will open on February 27, 2017, and remain open until March 10, 2017. These pediatric postmarketing pharmacovigilance and drug utilization reviews are for the following products:

- ALEVE PM (diphenhydramine hydrochloride/naproxen sodium)
- ASTEPRO (azelastine hydrochloride)
- ECOZA (econazole nitrate)
- JETREA (ocriplasmin)
- QUARTEETTE (levonorgestrel/ethinyl estradiol and ethinyl estradiol)

- TRUVADA (emtricitabine/tenofovir disoproxil fumarate)
- XERESE (acyclovir/hydrocortisone)

Dated: February 15, 2017.

Janice M. Soreth,

Associate Commissioner for Special Medical Programs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request; Nurse Faculty Loan Program, Annual Performance Report Financial Data Form

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

ACTION: Notice.

SUMMARY: In compliance with the requirement for 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 April 24, 2017.

ADDRESSES: Submit your comments to paperwork@hrsa.gov or mail the HRSA Information Collection Clearance Officer, 14N39, 5600 Fishers Lane, Rockville, MD 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 the HRSA Information Collection Clearance Officer at (301) 443-1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference, in compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995.

Information Collection Request Title: Nurse Faculty Loan Program, Annual Performance Report Financial Data Form, OMB No. 0915-0314—Revision.

Abstract: This collection request is for continued approval of the Nurse Faculty Loan Program's revised Annual

Performance Report (NFLP-APR) Financial Data Form. The form was previously titled as the Nurse Faculty Loan Program, Annual Operating Report (NFLP-AOR).

Section 846A of the Public Health Service Act provides the Secretary of HHS with the authority to enter into an agreement with schools of nursing for the establishment and operation of a student loan fund to increase the number of qualified nurse faculty. Under the agreement, HRSA makes awards to schools for the NFLP loan fund, which must be maintained in a distinct account. A school of nursing makes loans from the NFLP account to students enrolled full-time or, at the discretion of the Secretary, part-time in a master's or doctoral nursing education program that will prepare them to become qualified nursing faculty. Following graduation from the NFLP lending school, loan recipients may receive up to 85 percent NFLP loan cancellation over a consecutive 4-year period in exchange for service as full-time faculty at a school of nursing. The NFLP lending school collects any portion of the loan that is not cancelled and any loans that go into repayment due to default, and deposits these monies into the NFLP loan fund to make additional NFLP loans.

Need and Proposed Use of the Information: The online NFLP-APR Financial Data Form is an online form in the HRSA Electronic Handbooks (EHBs) Performance Report module as part of the NFLP, Bureau of Health Workforce performance report (OMB No: 0915-0061, expiration date of 6/30/2019). The revised NFLP-APR financial data form will collect less data from applicants and will no longer include nursing student demographic data. The nursing student demographic data is currently collected under OMB approval number No: 0915-0061. The revised NFLP-APR form will only collect financial data to capture the NFLP loan fund account activity related to financial receivables, disbursements, and borrower account data related to employment status, loan cancellation, loan repayment, and collections. Participating schools will provide HRSA with current and cumulative information on: (1) NFLP loan funds received, (2) number and amount of NFLP loans made, (3) number and amount of loans cancelled, (4) number and amount of loans in repayment, (5) loan default rate percent, (6) number of NFLP graduates employed as nurse faculty, and (7) other related loan fund costs and activities.

The school of nursing must keep records of all NFLP loan fund

transactions. The NFLP-APR financial data form is used to monitor grantee performance by collecting information related to the NFLP loan fund operations and financial activities for a specified reporting period (July 1 through June 30 of the academic year). Participating schools are required to complete and submit the NFLP-APR financial data form annually. The revised NFLP-APR financial data form

will allow HRSA to better determine future awards to nursing schools.

Likely Respondents: Participating NFLP schools are required to adhere to reporting requirements.

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

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Nurse Faculty Loan Program—Annual Performance Report Financial Data Form	260	1	260	6	1,560
Total Burden	260	260	1,560

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.

Jason E. Bennett,

Director, Division of the Executive Secretariat.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: Nurse Faculty Loan Program—Revised Program Specific Data Form, OMB No. 0915-0378—Revision

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

ACTION: Notice.

SUMMARY: In compliance with the requirement for 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 April 24, 2017.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, 14N39, 5600 Fishers Lane, Rockville, MD 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 the HRSA Information Collection Clearance Officer at (301) 443-1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference, in compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995.

Information Collection Request Title: Nurse Faculty Loan Program—Revised Program Specific Data Form, OMB No. 0915-0378—Revision.

Abstract: This clearance request is for continued approval of the Nurse Faculty Loan Program (NFLP) revised Program Specific Data Form. HRSA is streamlining the data collection forms by making the following changes:

- Line Item D will be renamed “D1. NFLP Loan Fund Balance/Unused Accumulation.”
- Addition of Line Item D2 entitled “NFLP Loan Fund Default Rate,”

requesting information regarding the status of an institution's default rate.

- Addition of Line Item D3 entitled “Last NFLP Student Loan Award,” requesting information regarding the disbursement of NFLP loan funds within the last 2 academic years.

- Line Item E2 Column Header will be renamed “E.2 NFLP Enrollees Information by Degree—New Students Expected to Request NFLP Support.”

- Under Section B of instructions, “other attachments” will be updated to reflect the current list of NFLP Funding Opportunity Announcement attachments.

Need and Proposed Use of the Information: The NFLP—Program Specific Data Form is a required electronic attachment within the NFLP application materials. The data provided in the form is essential for the formula-based criteria used to determine the award amount to the applicant schools. Continued approval of the revised NFLP—Program Specific Data Form will allow HRSA to more efficiently capture data to generate the formula-based award.

Addition of Line Item D2, NFLP Loan Fund Default Rate, will allow HRSA to easily assess and consider an existing performance standard for those applicants with existing NFLP loan accounts. Used in combination with an existing NFLP institution's self-reported NFLP loan balance, addition of Line Item D3, Last NFLP Student Loan Award, will allow HRSA to assess the loan fund activity (*i.e.*, incidence of loans to students) of an existing NFLP institution applying for additional funding.