

Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” 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 <https://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.

Submit written requests for single copies of the draft guidance to the Center for Tobacco Products, Food and Drug Administration, Document Control Center, Bldg. 71, Rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist the office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

**FOR FURTHER INFORMATION CONTACT:** Paul Hart or Samantha Loh Collado, Center for Tobacco Products, Food and Drug Administration, Document Control Center, Bldg. 71, Rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 1–877–287–1373, [AskCTP@fda.hhs.gov](mailto:AskCTP@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Background**

FDA is announcing the availability of a draft guidance for industry entitled “The Prohibition of Distributing Free Samples of Tobacco Products; Draft Guidance for Industry.” Title 21 of the Code of Federal Regulations (CFR) section 1140.16(d)(1) prohibits, with a limited exception, tobacco product manufacturers, distributors, and retailers from distributing or causing to be distributed any free samples of cigarettes, smokeless tobacco, or other tobacco products. The draft guidance describes, among other things, how the prohibition of distributing free samples of tobacco products applies to non-monetary exchanges, coupons and

discounts, membership and rewards programs, contests and games of chance, and the business-to-business exchange of free samples. FDA requests that interested parties submit comments concerning its draft interpretation of the prohibition of distributing free samples.

**II. Significance of Draft Guidance**

FDA is issuing this draft guidance consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on “The Prohibition of Distributing Free Samples of Tobacco Products.” It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

**III. Electronic Access**

Persons with access to the Internet may obtain an electronic version of the draft guidance at either <https://www.regulations.gov> or <http://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/default.htm>.

Dated: January 11, 2017.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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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 Corps Loan Repayment Program**

**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).

**DATES:** Comments on this ICR should be received no later than March 20, 2017.

**ADDRESSES:** Submit your comments to [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or mail the HRSA Information Collection Clearance Officer, Room 14N–39, 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](mailto: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.

*Information Collection Request Title:* NURSE Corps Loan Repayment Program OMB No. 0915–0140—Revision

*Abstract:* The NURSE Corps Loan Repayment Program (NURSE Corps LRP), formerly known as the Nursing Education Loan Repayment Program, assists in the recruitment and retention of professional Registered Nurses (RNs), including advanced practice RNs (e.g., nurse practitioners, certified registered nurse anesthetists, certified nurse-midwives, clinical nurse specialists), dedicated to working at eligible health care facilities with a critical shortage of nurses (i.e., a Critical Shortage Facility) or working as nurse faculty in eligible, accredited schools of nursing, by decreasing the financial barriers associated with pursuing a nursing education. The NURSE Corps LRP provides loan repayment assistance to these nurses to repay a portion of their qualifying educational loans in exchange for full-time service at a public or private nonprofit Critical Shortage Facility or in an eligible, accredited school of nursing.

*Need and Proposed Use of the Information:* The need and purpose of this information collection is to obtain information for NURSE Corps LRP applicants and participants. The information is used to consider an applicant for a NURSE Corps LRP contract award and to monitor a participant’s compliance with the service requirements. Individuals must submit an application to participate in the program. The application asks for personal, professional, educational, and financial information required to determine the applicant’s eligibility to participate in the NURSE Corps LRP. The semi-annual employment verification form asks for personal and employment information to determine if a participant is in compliance with the service requirements. The Authorization to Release Employment Information form is now a self-certification within the NURSE Corps LRP application process with applicants clicking a box. This decreases the overall time burden by eliminating a form and not increasing

the “average” time required to complete the NURSE Corps LRP application.

*Likely Respondents:* Professional RNs or advanced practice RNs who are interested in participating in the NURSE Corps LRP, and official representatives at their service sites.

*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 Information Collection Request are summarized in the tables below.

*Total Estimated Annualized Burden Hours:*

The estimates of reporting burden for applicants are as follows:

Instrument	Number of respondents	Responses/ respondents	Total responses	Hours per response	Total burden hours
NURSE Corps LRP Application * .....	5,500	1	5,500	2.0	11,000
Authorization to Release Information Form .....	5,500	1	5,500	.10	550
<b>Total</b> .....	<b>5,500</b>	<b>.....</b>	<b>11,000</b>	<b>.....</b>	<b>11,550</b>

\* Please note that the burden hours associated with this instrument account for both new and continuation applications. Additional (uploaded) supporting documentation is included as part of this instrument and reflected in the burden hours.

The estimates of reporting burden for participants are as follows:

Instrument	Number of respondents	Responses/ respondents	Total responses	Hours per response	Total burden hours
Participant Semi-Annual Employment Verification Form .....	2,300	2	4,600	.5	2,300
<b>Total</b> .....	<b>2,300</b>	<b>.....</b>	<b>4,600</b>	<b>.....</b>	<b>2,300</b>
<b>Total for Applicants and Participants</b> .....	<b>7,800</b>	<b>.....</b>	<b>15,600</b>	<b>.....</b>	<b>13,850</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.

**Jason E. Bennett,**  
 Director, Division of the Executive Secretariat.  
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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Indian Health Service**

**Reimbursement Rates for Calendar Year 2017**

**AGENCY:** Indian Health Service, HHS.  
**ACTION:** Notice.

Notice is given that the Principal Deputy Director of the Indian Health Service (IHS), under the authority of sections 321(a) and 322(b) of the Public Health Service Act (42 U.S.C. 248 and

249(b)), Public Law 83-568 (42 U.S.C. 2001(a)), and the Indian Health Care Improvement Act (25 U.S.C. 1601 *et seq.*), has approved the following rates for inpatient and outpatient medical care provided by IHS facilities for Calendar Year 2017 for Medicare and Medicaid beneficiaries, beneficiaries of other Federal programs, and for recoveries under the Federal Medical Care Recovery Act (42 U.S.C. 2651-2653). The Medicare Part A inpatient rates are excluded from the table below as they are paid based on the prospective payment system. Since the inpatient per diem rates set forth below do not include all physician services and practitioner services, additional payment shall be available to the extent that those services are provided.

**Inpatient Hospital Per Diem Rate (Excludes Physician/Practitioner Services)**

*Calendar Year 2017*  
 Lower 48 States: \$2,933  
 Alaska: \$3,235

**Outpatient Per Visit Rate (Excluding Medicare)**

*Calendar Year 2017*  
 Lower 48 States: \$391  
 Alaska: \$616

**Outpatient Per Visit Rate (Medicare)**

*Calendar Year 2017*  
 Lower 48 States: \$349  
 Alaska: \$577

**Medicare Part B Inpatient Ancillary Per Diem Rate**

*Calendar Year 2017*  
 Lower 48 States: \$679  
 Alaska: \$1,046

**Outpatient Surgery Rate (Medicare)**

Established Medicare rates for freestanding Ambulatory Surgery Centers.

**Effective Date for Calendar Year 2017 Rates**

Consistent with previous annual rate revisions, the Calendar Year 2017 rates will be effective for services provided on/or after January 1, 2017, to the extent consistent with payment authorities including the applicable Medicaid State plan.

Dated: January 11, 2017.  
**Elizabeth A. Fowler,**  
 Deputy Director for Management Operations,  
 Indian Health Service.

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