do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2018–D–1201 for ''Pregnant Women: Scientific and Ethical Considerations for Inclusion in Clinical Trials; Draft Guidance; Availability.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. 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: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Denise Johnson-Lyles, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6469, Silver Spring, MD 20993, 301–796–6169.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Pregnant Women: Scientific and Ethical Considerations for Inclusion in Clinical Trials.'' Currently, collection of safety data on prescription drugs and biological products used during pregnancy usually occurs after approval, and clinicians and patients must undertake a risk-benefit analysis for the use of such products in pregnant women with limited human safety information. Historically, pregnant women have been an understudied population and there have been barriers to obtaining data from pregnant women in clinical trials, including concerns about protecting women and their fetuses from research-related risks. However, data are needed to inform safe and effective treatment during pregnancy, and in certain situations, it is ethically and scientifically appropriate to collect data in pregnant women in clinical trials conducted during drug development.

This draft guidance discusses the ethical and scientific issues when considering the inclusion of pregnant women in clinical trials of drugs and biological products. This draft guidance is intended to advance scientific research in pregnant women, and discusses issues that should be considered within the framework of human subject protection regulations.

This draft guidance is being issued 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 scientific and ethical considerations for inclusion of pregnant women in clinical trials. 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. This guidance is not subject to Executive Order 12866.

II. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *https://www.regulations.gov.*

Dated: April 3, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–07151 Filed 4–6–18; 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; NURSE Corps Loan Repayment Program, OMB #0915–0140—Revision

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

ACTION: Notice.

SUMMARY: In compliance with 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 May 9, 2018.

ADDRESSES: Submit your comments, including the ICR Title, to the desk officer for HRSA, either by email to

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* or call (301) 443–1984.

SUPPLEMENTARY INFORMATION:

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

Abstract: The NURSE Corps Loan Repayment Program (NURSE Corps LRP) assists in the recruitment and retention of professional Registered Nurses (RNs), including advanced practice RNs (*i.e.,* nurse practitioners, certified registered nurse anesthetists, certified nurse-midwives, and 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 profession. 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 (CSF) 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. HRSA uses this information 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 in order 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.

This revision to the clearance package will incorporate two new forms: (1) The CSF Verification Form is used to verify transfers to CSFs not already recorded in the online portal; and (2) the NURSE Corps Nurse Faculty Employment Verification Form asks for personal and employment information to specifically determine if nurse faculty participants are eligible to transfer to another approved accredited school of nursing.

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 ICR are summarized in the table below.

Total Estimated Annualized Burden Hours:

The estimates of reporting burden for Applicants are as follows:

Instrument	Number of respondents	Responses/ respondent	Total responses	Hours per response	Total burden hours
NURSE Corps LRP Application *	5,500	1	5,500	2.0	11,000
Authorization to Release Employment Information Form **	5,500	1	5,500	0.1	550
Total for Applicants	5,500		11,000		11,550

* 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 same respondents are completing these instruments.

The estimates of reporting burden for participants are as follows:

Instrument	Number of respondents	Responses/ respondent	Total responses	Hours per response	Total burden hours
Participant Semi-Annual Employment Verification Form	2,300	2	4,600	0.5	2,300
NURSE Corps CSF Verification Form	550	1	550	0.1	55
NURSE Corps Nurse Faculty Employment Verification Form	250	1	250	0.2	50
Total for Participants	3,100	4	5,400	.8	2,405
Total for Applicants and Participants	8,600		16,400		* 13,955

* The 13,955 figure is a combination of burden hours for applicants and participants. This revision adds two forms (the CSF Verification Form and NURSE Corps Nurse Faculty Employment Verification Form). Participants, not applicants, only use these forms. The 13,955 total burden hours represents the net decrease in applicant burden, and the net increase in participant burden.

Dated: April 3, 2018.

Lori Roche,

Acting Deputy Director, Division of the Executive Secretariat.

[FR Doc. 2018–07176 Filed 4–6–18; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request; Telehealth Resource Center Performance Measurement Tool, OMB No. 0915–0361, 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 must be received no later than June 8, 2018.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail Lisa Wright-Solomon, HRSA Information Collection Clearance Officer, Room 10–29, 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 Lisa Wright-Solomon at *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: Telehealth Resource Center Performance Measurement Tool, OMB No. 0915–0361, Revision.

Abstract: To ensure the best use of public funds and to meet the Government Performance Review Act requirements, the Office for the Advancement of Telehealth (OAT) in collaboration with the Telehealth Resource Centers (TRCs) created a set of performance measures that grantees can use to evaluate the technical assistance services provided by the TRCs. Grantee goals are to provide customized telehealth technical assistance across the country. The TRCs provide technical assistance to health care organizations, health care networks and health care providers in the implementation of cost-effective telehealth programs to serve rural and medically underserved areas and populations.

Need and Proposed Use of the Information: In order to evaluate existing programs, data are submitted to OAT through HRSA's Performance Improvement Management System (PIMS). The data are used to measure the effectiveness of the technical assistance. There are two data reporting periods each year; during these biannual reporting periods data are reported for the previous six months of activity. Programs have approximately six weeks to enter their data into the PIMS system during each biannual reporting period.

The instrument was developed with the following four goals in mind:

1. Improving access to needed services,
2. reducing rural practitioner isolation,
3. improving health system productivity and efficiency, and
4. improving patient outcomes.

The TRCs currently report on existing performance data elements using PIMS. The performance measures are designed to assess how the TRC program is meeting its goals to:

1. Expand the availability of telehealth services in underserved communities,
2. Improve the quality, efficiency, and effectiveness of telehealth services, and
3. Promote knowledge exchange and dissemination about efficient and effective telehealth practices and technology.
4. Establish sustainable technical assistance (TA) centers providing quality, unbiased TA for the development and expansion of effective and efficient telehealth services in underserved communities.

Additionally, the PIMS tool allows OAT to:

1. Determine the value added from the TRC Cooperative Agreement;
2. Justify budget requests;
3. Collect uniform, consistent data which enables OAT to monitor programs;
4. Provide guidance to grantees on important indicators to track over time for their own internal program management;
5. Measure performance relative to the mission of OAT/HRSA as well as individual goals and objectives of the program;
6. Identify topics of interest for future special studies; and
7. Identify changes in healthcare needs within rural communities, allowing programs to shift focus in order to meet those needs.

This renewal request proposes changes to existing measures. After compiling data from the previous tool over the last three years, OAT conducted an analysis of the data and compared the findings with the program needs. Based on the findings, the measures are being revised to better capture information necessary to measure the effectiveness of the program. The measure changes include: Additional demographic details from organizations requesting technical assistance, streamlined methods of inquiry, additional topics of technical assistance inquiries aligning with the current telehealth landscape, streamlined types of services provided by the grantees, deletion of client satisfaction survey results, and deletion of telehealth sites developed as a result of grantee technical assistance.

Likely Respondents: The likely respondents will be telehealth associations, telehealth providers, rural health providers, clinicians that deliver services via telehealth, technical assistance providers, research organizations, and academic medical centers.

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: