requirements consider, among other factors, the applying AO's requirements for accreditation; survey procedures; resources for conducting required surveys; capacity to furnish information for use in enforcement activities; monitoring procedures for provider entities found not in compliance with the conditions or requirements; and ability to provide CMS with the necessary data for validation.

Section 1865(a)(3)(A) of the Act further requires that we publish, within 60 days of receipt of an organization's complete application, a notice identifying the national accrediting body making the request, describing the nature of the request, and providing at least a 30-day public comment period. We have 210 days from the receipt of a complete application to publish notice of approval or denial of the application.

The purpose of this notice is to inform the public of ACHC's request for continued approval of its hospital accreditation program. This notice also solicits public comment on whether ACHC's requirements meet or exceed the Medicare conditions of participation (CoPs) for hospitals.

III. Evaluation of Deeming Authority Request

ACHC submitted all the necessary materials to enable us to make a determination concerning its request for continued approval of its hospital accreditation program. This application was determined to be complete on February 27, 2023. Under section 1865(a)(2) of the Act and our regulations at § 488.5 (Application and re-application procedures for national accrediting organizations), our review and evaluation of ACHC will be conducted in accordance with, but not necessarily limited to, the following factors:

- The equivalency of ACHC's standards for hospitals as compared with CMS' hospital CoPs.
- ACHC's survey process to determine the following:

++ The composition of the survey team, surveyor qualifications, and the ability of the organization to provide continuing surveyor training.

++ The comparability of ACHC's processes to those of state agencies, including survey frequency, and the ability to investigate and respond appropriately to complaints against accredited facilities.

++ ACHC's processes and procedures for monitoring a hospital found out of compliance with ACHC's program requirements. These monitoring procedures are used only when ACHC identifies noncompliance. If noncompliance is identified through validation reviews or complaint surveys, the SA monitors corrections as specified at § 488.9.

++ ACHC's capacity to report deficiencies to the surveyed facilities and respond to the facility's plan of correction in a timely manner.

++ ACHC's capacity to provide CMS with electronic data and reports necessary for effective validation and assessment of the organization's survey process.

++ The adequacy of ACHC's staff and other resources, and its financial viability.

++ ACHC's capacity to adequately fund required surveys.

++ ACHC's policies with respect to whether surveys are announced or unannounced, to assure that surveys are unannounced.

++ ACHC's policies and procedures to avoid conflicts of interest, including the appearance of conflicts of interest, involving individuals who conduct surveys or participate in accreditation decisions.

++ ACHC's agreement to provide CMS with a copy of the most current accreditation survey together with any other information related to the survey as we may require (including corrective action plans).

IV. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping or third party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

V. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Chiquita Brooks-LaSure, having reviewed and approved this document, authorizes Evell J. Barco Holland, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Dated: April 11, 2023.

Evell J. Barco Holland,

Federal Register Liaison, Centers for Medicare & Medicaid Services.

[FR Doc. 2023–07930 Filed 4–13–23; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–D–5422]

Peripheral Percutaneous Transluminal Angioplasty and Specialty Catheters—Premarket Notification (510(k)) Submissions; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance entitled ''Peripheral Percutaneous Transluminal Angioplasty (PTA) and Specialty Catheters—Premarket Notification (510(k)) Submissions.'' FDA is issuing this final guidance document to provide recommendations for 510(k) submissions for peripheral percutaneous transluminal angioplasty (PTA) balloons and specialty catheters (*e.g.,* infusion catheters, PTA balloon catheters for in-stent restenosis (ISR), scoring/cutting balloons).

DATES: The announcement of the guidance is published in the **Federal Register** on April 14, 2023.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact

information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*

• If you want to submit a comment with confidential information that you 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–2019–D–5422 for ''Peripheral Percutaneous Transluminal Angioplasty and Specialty Catheters—Premarket Notification (510(k)) Submissions.'' 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, 240–402–7500.

• 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.govinfo.gov/content/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, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)). An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled ''Peripheral Percutaneous Transluminal Angioplasty (PTA) and Specialty Catheters—Premarket Notification (510(k)) Submissions'' to the Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Eleni Whatley, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2267, Silver Spring, MD 20993–0002, 301–796–6372.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is issuing this guidance to clarify FDA's recommendations for testing and information to include in 510(k) submissions for PTA catheters and specialty catheters to promote consistency across submissions. These devices are catheter-based devices intended to treat lesions in the peripheral vasculature. This guidance expands on FDA's current thinking for testing of PTA balloon catheters and specialty catheters (*e.g.,* infusion catheters, PTA balloon catheters for ISR, scoring/cutting balloons), and provides specific recommendations regarding performance testing and anatomy-specific assessments. This document supplements other FDA documents regarding the specific content requirements of premarket submissions.

A notice of availability of the draft guidance appeared in the **Federal Register** of January 13, 2020 (85 FR 1812). FDA considered comments received and revised the guidance as appropriate in response to the comments, including addition of details and clarification for non-clinical test recommendations, and minor revisions to ensure consistency with FDA-recognized consensus standards and other FDA guidances.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Peripheral Percutaneous Transluminal Angioplasty (PTA) and Specialty Catheters—Premarket Notification (510(k)) Submissions.'' 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.

II. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products.* This guidance document is also available at *https://www.regulations.gov* and *https://www.fda.gov/regulatory-information/search-fda-guidance-documents.* Persons unable to download an electronic copy of ''Peripheral Percutaneous Transluminal Angioplasty (PTA) and Specialty Catheters—Premarket Notification (510(k)) Submissions'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number GUI00016018 and complete title to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

While this guidance contains no new collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by

OMB under the PRA. The collections of information in the following FDA regulations, guidance, and forms have been approved by OMB as listed in the following table:

21 CFR part or guidance	Topic	OMB control No.
807, subpart E	Premarket notification	0910–0120
812	Investigational Device Exemption	0910–0078
"Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program".	Q-submissions	0910–0756
800, 801, and 809	Medical Device Labeling Regulations	0910–0485
50, 56	Protection of Human Subjects and Institutional Review Boards	0910–0130
58	Good Laboratory Practice (GLP) Regulations for Nonclinical Laboratory Studies.	0910–0119

Dated: April 10, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–07896 Filed 4–13–23; 8:45 am]

BILLING CODE 4164–01–P

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 Corps Supplemental Funding Evaluation

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 June 13, 2023.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14N136B, 5600 Fishers Lane, Rockville, Maryland 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 Samantha Miller, the Acting HRSA Information Collection Clearance Officer, at 301–594–4394.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the ICR title for reference.

Information Collection Request Title: Nurse Corps Supplemental Funding Evaluation, *OMB No.* 0915–xxxx—New.

Abstract: The objective of Nurse Corps Loan Repayment Program (LRP) and Scholarship Program (SP) is to lessen the financial burden of those pursuing nursing careers in the hope of increasing nursing workforce participation in underserved areas. The programs support HRSA's overall mission to improve health outcomes and achieve health equity through access to quality services by optimizing the distribution of the nursing workforce. The Nurse Corps LRP reimburses educational loans for nurses who serve a minimum 2-year commitment in a critical shortage facility or work as nurse faculty in accredited schools of nursing. The Nurse Corps SP similarly pays for educational expenses of nursing students who agree to a minimum 2-year service commitment in critical shortage facilities upon graduation.

HRSA last conducted a comprehensive evaluation of the Nurse Corps Programs in 2006. This notice describes plans for conducting an updated program evaluation to understand more recent program successes and challenges, including how the COVID–19 pandemic effected the programs. Additionally, HRSA seeks to understand the impact of additional funding for the Nurse Corps Programs from the American Rescue Plan Act of 2021. The evaluation will seek information from participants and alumni of the Nurse Corps Programs from 2017 through 2023 and will assess program outcomes from before, during, and after the COVID–19 pandemic, as well as the impact of the American Rescue Plan funds. This mixed-methods evaluation will have three major components: analysis of existing information, a national survey of Nurse Corps participants and alumni, and in-depth interviews (IDIs) with participants and alumni.

The national survey of Nurse Corps participants will target the following groups of respondents: LRP clinical nurse participants and alumni, LRP nurse faculty participants and alumni, SP participants (both in school and completing service obligation) and alumni. The survey will be designed and delivered via web and telephone, with reminders and a web address and a personal identification number for the survey sent by both mail and email. The survey will be conducted on a census of participants from 2017 through 2023, an estimated 7,302 participants. The survey will be tested with a small number of program participants to ensure that respondents are interpreting items as intended. An interview will be completed with each respondent during which the interviewer will ask for more in-depth explanations about the participants' understanding and response to the survey questions. Each question will be tested on no more than nine Nurse Corps participants.

As part of a comprehensive questionnaire design process, questions will be limited and refined to collect information not available through other sources. Any data collected will not be duplicative of that collected by HRSA for program monitoring. The questions will cover satisfaction with the program and service obligation site, intention to remain at the site, actual location of current practice (for alumni), training on preparedness for disasters and disease outbreaks in schools of nursing and on site, types of services provided on site, panel size and visit load, and the impact of the COVID–19 pandemic on service delivery. The survey will display only questions relevant to their programs and timeframes. Participation in the survey is voluntary, and participants will complete the survey one time.

The IDIs will be conducted with 54 participants and alumni representing the range of respondent groups: 18 IDIs