such as abdominal pain and distension. Finally, FDA considered additional available mitigations for the spread of uterine tissue. Since 2014, FDA has provided marketing authorization for LPM containment systems intended to isolate and contain tissue that is considered benign. These products have been shown, through bench testing and simulated use testing, to contain such tissue during morcellation.

For these reasons, FDA is proposing in this draft guidance to update its recommendations, as originally described in the 2014 guidance document, concerning the content and format of certain labeling information for LPMs. Specifically, FDA is recommending that manufacturers incorporate into the labeling for these devices information providing greater specificity regarding the risks of use as it relates to age, information regarding the risk of spreading benign uterine tissue, and information regarding the use of LPM containment systems.

FDA considered comments received on the final guidance document that appeared in the **Federal Register** of November 25, 2014 (79 FR 70193). FDA revised the guidance as appropriate in response to the comments.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Product Labeling for Laparoscopic Power Morcellators.'' 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Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the internet.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/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* This guidance document is also available at *https://www.regulations.gov.* Persons unable to download an electronic copy of ''Product Labeling for Laparoscopic Power Morcellators'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1400052 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in the following FDA regulations have been approved by OMB as listed in the following table:

21 CFR part	Topic	OMB control No.
807, subpart E	Premarket notification	0910–0120
800, 801, and 809	Medical Device Labeling Regulations	0910–0485
803	Medical Devices; Medical Device Reporting; Manufacturer reporting, importer reporting, user facility reporting, distributor reporting.	0910–0437

Dated: February 20, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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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: Shortage Designation Management System

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 27, 2020.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14N136B, 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 Lisa Wright-Solomon, 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: Shortage Designation Management System OMB No. 0906–0029—Revision.

Abstract: HRSA's Bureau of Health Workforce is committed to improving the health of the Nation's underserved communities and vulnerable populations by developing, implementing, evaluating, and refining programs that strengthen the nation's health workforce. HHS relies on two federal shortage designations to identify and dedicate resources to areas and populations in greatest need of providers: Health Professional Shortage Area (HPSA) designations and Medically Underserved Area/Medically Underserved Population (MUA/P) designations. HPSA designations are geographic areas, population groups, and facilities that are experiencing a shortage of health professionals. The authorizing statute for the National Health Service Corps (NHSC) created HPSAs to fulfill the statutory requirement that NHSC personnel be directed to areas of greatest need. To further differentiate areas of greatest need, HRSA calculates a score for each HPSA. There are three categories of HPSAs based on health discipline: Primary care, dental health, and mental health. Scores range from 1 to 25 for

primary care and mental health and from 1 to 26 for dental, with higher scores indicating greater need. They are used to prioritize applications for NHSC Loan Repayment Program award funding, and determine service sites eligible to receive NHSC Scholarship and Students-to-Service participants.

MUA/P designations are geographic areas, or population groups within geographic areas, that are experiencing a shortage of primary care health care services based on the Index of Medical Underservice. MUAs are designated for the entire population of a particular geographic area. MUA/P designations are limited to particular subset of the population within a geographic area. Both designations were created to aid the federal government in identifying areas with healthcare workforce shortages.

As part of HRSA's cooperative agreement with the State Primary Care Offices (PCOs), the State PCOs conduct needs assessment in their states, determine what areas are eligible for designations, and submit designation applications for HRSA review via the Shortage Designation Management System (SDMS). Requests that come from other sources are referred to the PCOs for their review, concurrence, and submission via SDMS. In order to obtain a federal shortage designation for an area, population, or facility, PCOs must submit a shortage designation application through SDMS for review and approval by HRSA. Both the HPSA and MUA/P application request local, state, and national data on the population that is experiencing a shortage of health professionals and the number of health professionals relative to the population covered by the proposed designation. The information collected on the applications is used to determine which areas, populations, and facilities have qualifying shortages. In addition, interested parties, including the Governor, the State Primary Care Association, state professional associations, etc. are notified of each designation request submitted via SDMS for their comments and recommendations.

Previously, PCOs were required to provide HRSA with Census, American Community Survey, and Centers for Disease Control and Prevention data specific to the intended geographic area for designation known as a rational service area. With the development of the SDMS, PCOs are no longer required to provide this information as it is automatically populated in the system when they select the service area for designation.

HRSA reviews the HPSA applications submitted by the State PCOs, and—if they meet the designation eligibility criteria for the type of HPSA or MUA/P the application is for—designates the HPSA or MUA/P on behalf of the Secretary. HPSAs are statutorily required to be annually reviewed and revised as necessary after initial designation to reflect current data. HPSAs scores, therefore, may and do change from time to time. Currently, MUA/Ps do not have a statutorily mandated review period.

The lists of designated HPSAs are published annually in the **Federal Register**. In addition, lists of HPSAs are updated on the HRSA website, *https://data.hrsa.gov/tools/shortage-area,* so that interested parties can access the information.

Need and Proposed Use of the Information: In 2014, SDMS was launched to facilitate the collection of information needed to designate HPSAs and MUA/Ps. The information obtained from the SDMS Application is used to determine which areas, populations, and facilities have critical shortages of health professionals per PCO application submission. The SDMS HPSA application and SDMS MUA/P Application are used for these designation determinations. Applicants must submit a SDMS application to HRSA to obtain a federal shortage designation. The application asks for local, state, and national data required to determine the application's eligibility to obtain a federal shortage designation. In addition, applicants must enter in detailed information explaining how the area, population, or facility faces a critical shortage of health professionals.

Likely Respondents: State Primary Care Offices interested in obtaining a primary care, dental, or mental HPSA designation or a MUA/P in their state.

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
Designation Planning and Preparation	54	48	2,592	8.00	20,736
SDMS Application	54	83	4,482	4.00	17,928
Total	54	.....	7,074	.....	38,664

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.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2020–03783 Filed 2–25–20; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–0990–0438–60D]

Agency Information Collection Request; 60-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.