

amendments/completed-pdufa-vii-deliverables.

III. Public Meeting Information

A. Purpose and Scope of the Meeting

In general, the public meeting's format will include presentations by FDA and other interested parties, which may include scientific and academic experts, healthcare professionals, representatives of patient and consumer advocacy groups, the prescription drug industry, and the general public. A draft agenda and other background information for the public meeting will be posted at: <https://www.fda.gov/industry/public-meeting-reauthorization-prescription-drug-user-fee-act-pdufa-07142025>.

B. Participating in the Public Meeting

Registration: To register for the public meeting, please visit the following web page: <https://publicmeetingonthereauthorizationofpdufa.eventbrite.com>. Please provide complete contact information for each attendee, including name, title, affiliation, and email.

Registration is free for both in person and virtual attendance. In person attendance is based on space availability, with priority given to early registrants. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. If you need special accommodations due to a disability, please contact Andrew.Kish@fda.hhs.gov no later than June 30, 2025.

Opportunity for Public Comment: Those who register online by June 16, 2025, at 11:59 p.m. Eastern Time will receive a notification about an opportunity to participate in the public comment session of the meeting. If you wish to speak during the public comment session, follow the instructions in the notification and identify which topic(s) you wish to address. All requests to make a public comment during the meeting must be received by June 30, 2025, 11:59 p.m. Eastern Time. We will do our best to accommodate requests to make public comments. Individuals and organizations with common interests are urged to consolidate or coordinate their comments and request time jointly. We will determine the amount of time allotted to each commenter, the approximate time each comment is to begin, and will select and notify participants by July 7, 2025. No commercial or promotional material will be permitted to be presented at the public meeting.

Streaming Webcast of the Public Meeting: The webcast for this public meeting is available at https://teams.microsoft.com/!meetup-join/19%3ameeting_OWnhMmRmMTMtYjZiOS00MWQ3LWI5MTgtOTUzMzRlNDUwMWJj%40thread.v2/0?context=%7b%22tid%22%3a%2227d2fdb41-339c-4257-87f2-a665730b31fc%22%2c%22oid%22%3a%22f8076904-2170-423d-ae92-b261e8a4d877%22%7d.

Transcripts: Please be advised that as soon as a transcript of the public meeting is available, it will be accessible at <https://www.regulations.gov>. It may be viewed at the Dockets Management Staff (see **ADDRESSES**). A link to the transcript will also be available on the internet at: <https://www.fda.gov/industry/public-meeting-reauthorization-prescription-drug-user-fee-act-pdufa-07142025>.

Notice of this meeting is given pursuant to 21 CFR 10.65.

Dated: May 7, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025-08824 Filed 5-16-25; 8:45 am]

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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: Shortage Designation Management System, OMB No. 0906-0029—Extension

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 July 18, 2025.

ADDRESSES: Submit your comments to paperwork@hrsa.gov or mail the HRSA Information Collection Clearance

Officer, Room 14NWH04, 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 HRSA Information Collection Clearance Officer, at (301) 443-3983.

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

Information Collection Request Title: Shortage Designation Management System OMB No. 0906-0029—Extension.

Abstract: HRSA 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. The Department of Health and Human Services 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 health, 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. MUP designations are limited to a 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 Bureau of Health Workforce’s cooperative agreement with the state primary care offices (PCOs), the state PCOs conduct needs assessments 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. 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 HPSA and MUA/P applications 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 state’s governor, primary care association, and professional

associations are notified of each designation request submitted via SDMS for their comments and recommendations.

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 of Health and Human Services. HPSAs are statutorily required to be annually reviewed and revised as necessary after initial designation to reflect current data. HPSA scores, therefore, may and do change from time to time. 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/>) so that interested parties can access the information.

Need and Proposed Use of the Information: The information obtained from the SDMS applications is used to determine which areas, populations, and facilities have critical shortages of health professionals per PCO application submission. The SDMS HPSA and MUA/P applications are used for these designation determinations.

Applicants must have a SDMS application submitted to HRSA to obtain a federal shortage designation. In addition, the application must contain detailed information explaining how the area, population, or facility faces a critical shortage of health professionals.

Likely Respondents: State primary care offices and or site point of contacts interested in obtaining a primary care, dental health, or mental health 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 | 20,736 |
| SDMS Application | 54 | 83 | 4,482 | 4 | 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.

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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: HRSA Ryan White HIV/AIDS Program Part F National AIDS Education and Training Center Program Activities, OMB No. 0906–XXXX New

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 July 18, 2025.

ADDRESSES: Submit your comments to paperwork@hrsa.gov or mail the HRSA Information Collection Clearance Officer, Room 14NWH04, 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 Joella Roland, the HRSA