

Silver Spring, MD 20993–0002, 240–762–8729, email: [DSaRM@fda.hhs.gov](mailto:DSaRM@fda.hhs.gov), or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check FDA's website at <https://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

#### **SUPPLEMENTARY INFORMATION:**

**Agenda:** The meeting presentations will be heard, viewed, captioned, and recorded through an online teleconferencing platform. The committees will discuss proposed changes to the iPLEDGE Risk Evaluation and Mitigation Strategy requirements to minimize burden on patients, pharmacies, and prescribers while maintaining safe use of isotretinoin oral capsules for patients.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available on FDA's website at the time of the advisory committee meeting. Background material and the link to the online teleconference meeting room will be available at <https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee meeting link. The meeting will include slide presentations with audio components to allow the presentation of materials in a manner that most closely resembles an in-person advisory committee meeting.

**Procedure:** Interested persons may present data, information, or views, orally or in writing, on issues pending before the committees. All electronic and written submissions submitted to the Docket (see **ADDRESSES**) on or before March 14, 2023, will be provided to the committees. Oral presentations from the public will be scheduled between approximately 10:30 a.m. and 12 p.m. Eastern Time on March 29, 2023. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of

proposed participants, and an indication of the approximate time requested to make their presentation on or before March 6, 2023. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by March 7, 2023.

For press inquiries, please contact the Office of Media Affairs at [fdaoma@fda.hhs.gov](mailto:fdaoma@fda.hhs.gov) or 301–796–4540.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Philip Bautista (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: January 11, 2023.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2023–00795 Filed 1–17–23; 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; The National Health Service Corps Loan Repayment Programs**

**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 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. OMB may act on HRSA's ICR only after the 30-day comment period for this notice has closed.

**DATES:** Comments on this Information Collection Request must be received no later than February 17, 2023.

**ADDRESSES:** Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to [www.reginfo.gov/public/do/PRAMain](http://www.reginfo.gov/public/do/PRAMain). Find this particular information collection by selecting “Currently under Review—Open for Public Comments” or by using the search function.

**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 Samantha Miller, the acting HRSA Information Collection Clearance Officer at 301–594–4394.

#### **SUPPLEMENTARY INFORMATION:**

**Information Collection Request Title:** The National Health Service Corps Loan Repayment Programs OMB No. 0915–0127—Revision.

**Abstract:** The National Health Service Corps (NHSC) Loan Repayment Program (LRP) was established to assure an adequate supply of trained primary care health professionals to provide services in Health Professional Shortage Areas (HPSAs) of the United States with the greatest need. The NHSC Substance Use Disorder Workforce LRP and the NHSC Rural Community LRP were established to recruit and retain a health professional workforce with specific training and credentials to provide evidence-based substance use disorder treatment in HPSAs. Under these programs, the Department of Health and Human Services agrees to repay the qualifying educational loans of selected primary care health professionals. In return, the health professionals agree to serve for a specified period of time in an NHSC-approved site located in a federally-designated HPSA approved by the Secretary of Health and Human Services for LRP participants.

The forms used by each LRP include the following: (1) the NHSC LRP Application, (2) the Authorization for Disclosure of Loan Information Form, (3) the Privacy Act Release Authorization Form, and, if applicable, (4) the Verification of Disadvantaged Background Form, and (5) the Private Practice Option Form. The first four of the aforementioned NHSC LRP Forms collect information that is needed for

selecting participants and repaying qualifying educational loans. The last referenced form, the Private Practice Option Form, is needed to collect information for all participants who have applied for that service option.

NHSC-approved sites are health care facilities that provide comprehensive outpatient, ambulatory, primary health care services to populations residing in HPSAs. Related in-patient services may be provided by NHSC-approved Critical Access Hospitals and Indian Health Service hospitals. In order to become an NHSC-approved site, new sites must submit a Site Application for review and approval. Existing NHSC-approved sites are required to complete a Site Recertification Application every 3 years in order to maintain their NHSC-approved status. Both the NHSC Site Application and Site Recertification Application request information on the clinical service site, sponsoring agency, recruitment contact, staffing levels, service users, charges for services, employment policies, and fiscal management capabilities. Assistance in completing these applications may be obtained through the appropriate State Primary Care Offices and the NHSC. The information collected on the applications is used for determining the eligibility of sites for the assignment of NHSC health professionals and to verify the need for NHSC clinicians. NHSC service site approval is valid for 3 years.

A 60-day notice was published in the **Federal Register** on October 31, 2022, vol. 87, No. 209; pp. 65598–00. There were no public comments.

**Need and Proposed Use of the Information:** The need and proposed use of this information collection is to assess an LRP applicant's eligibility and qualifications for the LRP, and to obtain

information for NHSC site applicants. The NHSC LRP application asks for personal, professional, and financial/loan information.

The proposed revisions in this ICR include asking applicants to provide their educational information on the completion of postgraduate training. The NHSC will use this information to identify graduates or completers of the following HRSA-funded programs: the Primary Care Training and Enhancement: Training Primary Care Champions Program, the Addiction Medicine Fellowship Program, the Teaching Health Center Graduate Medical Education Program, the Advanced Nursing Education Nurse Practitioner Residency Program, and the Advanced Nursing Education Nurse Practitioner Residency Integration Program. To identify the graduates or completers of these HRSA-funded programs, the NHSC will require applicants to respond to the following additional questions:

(1) Have you completed a postgraduate training?

(2) Applicants who selected "yes" to the question above are required to submit the National Practitioner Identifier number.

(3) Further, if applicable, applicants are asked to enter the residency identification number and their residency completion certificate, if available.

NHSC policy requires behavioral health providers to practice in a community-based setting that provides access to comprehensive behavioral health services. Accordingly, for those sites seeking to be assigned behavioral health NHSC participants, additional site information will be collected from an NHSC Comprehensive Behavioral

Health Services Checklist. NHSC sites that do not directly offer all required behavioral health services must demonstrate a formal affiliation with a comprehensive, community-based primary behavioral health setting or facility to provide these services.

**Likely Respondents:** Likely respondents include (1) licensed primary care medical, dental, and behavioral health providers who are employed or seeking employment, and are interested in serving underserved populations; (2) health care facilities interested in participating in the NHSC and becoming an NHSC-approved service site; and (3) NHSC sites providing behavioral health care services directly, or through a formal affiliation with a comprehensive community-based primary behavioral health setting or facility providing comprehensive behavioral health services.

**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 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
NHSC LRP Application .....	9,020	1	9,020	1.00	9,020
Authorization for Disclosure of Loan Information Form .....	7,150	1	7,150	.10	715
Privacy Act Release Authorization Form .....	303	1	303	.10	30
Verification of .....					
Disadvantaged Background Form .....	660	1	660	.50	330
Private Practice Option Form .....	330	1	330	.10	33
NHSC Comprehensive Behavioral Health Services Checklist .....	4,400	1	4,400	.13	572
NHSC Site Application .....					
(including recertification) .....	4,070	1	4,070	.5	2,035
Total .....	25,933	.....	25,933	.....	12,735

**Maria G. Button,**

*Director, Executive Secretariat.*

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**BILLING CODE 4165-15-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Indian Health Service

#### Notice of Purchased/Referred Care Delivery Area Redesignation for the Hoh Tribe in the State of Washington

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

**ACTION:** Notice.

**SUMMARY:** This Notice advises the public that the Indian Health Service (IHS) proposes to expand the geographic boundaries of the Purchased/Referred Care Delivery Area (PRCDA) for the Hoh Tribe in the State of Washington to include the county of Clallam in the State of Washington. The current PRCDA for the Hoh Tribe includes the Washington county of Jefferson. Hoh Tribe members residing outside of the PRCDA are eligible for direct care services, however, they are not eligible for Purchased/Referred Care (PRC) services. The sole purpose of this expansion would be to authorize additional Hoh Tribe members and beneficiaries to receive PRC services.

**DATES:** Comments must be submitted February 17, 2023.

**ADDRESSES:** Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission. You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to <http://www.regulations.gov>. Follow the "Submit a Comment" instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Carl Mitchell, Director, Division of Regulatory and Policy Coordination Indian Health Service, 5600 Fishers Lane, Mail Stop: 09E70, Rockville, Maryland 20857.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the above address.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to the address above.

If you intend to deliver your comments to the Rockville address, please call telephone number (301) 443-

1116 in advance to schedule your arrival with a staff member.

#### FOR FURTHER INFORMATION CONTACT:

CAPT John Rael, Director, Office of Resource Access and Partnerships, Indian Health Service, 5600 Fishers Lane, Mail Stop: 10E85C, Rockville, Maryland 20857. Telephone (301) 443-0969 (This is not a toll-free number).

**SUPPLEMENTARY INFORMATION:** *Inspection of Public Comments:* All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment.

*Background:* The IHS provides services under regulations in effect as of September 15, 1987, and republished at 42 CFR part 136, subparts A-C. Subpart C defines a Contract Health Service Delivery Area (CHSDA), now referred to as a PRCDA, as the geographic area within which PRC will be made available by the IHS to members of an identified Indian community who reside in the PRCDA. Residence within a PRCDA by a person who is within the scope of the Indian health program, as set forth in 42 CFR 136.12, creates no legal entitlement to PRC but only potential eligibility for services. Services needed, but not available at an IHS/Tribal facility, are provided under the PRC program depending on the availability of funds, the person's relative medical priority, and the actual availability and accessibility of alternate resources in accordance with the regulations.

The regulations at 42 CFR part 136, subpart C provide that, unless otherwise designated, a PRCDA shall consist of a county which includes all or part of a reservation and any county or counties which have a common boundary with the reservation. 42 CFR 136.22(a)(6). The regulations also provide that after consultation with the Tribal governing body or bodies on those reservations included within the PRCDA, the Secretary may from time to time, redesignate areas within the United States for inclusion in or exclusion from a PRCDA. The regulations require that certain criteria must be considered before any redesignation is made. The criteria are as follows:

(1) The number of Indians residing in the area proposed to be so included or excluded;

(2) Whether the Tribal governing body has determined that Indians residing in the area near the reservation are socially and economically affiliated with the Tribe;

(3) The geographic proximity to the reservation of the area whose inclusion or exclusion is being considered; and  
(4) The level of funding which would be available for the provision of PRC.

Additionally, the regulations require that any redesignation of a PRCDA must be made in accordance with the procedures of the Administrative Procedure Act (5 U.S.C. 553). In compliance with this requirement, IHS is publishing this Notice and requesting public comments.

The Hoh Indian Tribe (Tribe) is located in the upper Northwest Peninsula of Washington State. The Tribe is located on a small reservation of just over 470 acres in Jefferson County which is the only county in their established PRCDA. The Tribal offices, as well as a large portion of the Tribal members, live in the nearest town of Forks, WA which is in Clallam County. The Tribe has expressed the desire to add Clallam County to ensure a large portion of their members can be PRC eligible, which is important because the Tribe does not currently operate any primary care services. Clallam County is not currently part of the Hoh Tribe's designated PRCDA. Accordingly, IHS proposes to expand the Hoh Tribe's PRCDA to include the Washington county of Clallam.

Under 42 CFR 136.23, those otherwise eligible Indians who do not reside on a reservation, but reside within a PRCDA, must be either members of the Tribe or other IHS beneficiaries who maintain close economic and social ties with the Tribe. In this case, applying the aforementioned PRCDA redesignation criteria required by operative regulations codified at 42 CFR part 136, subpart C, the following findings are made:

1. By expanding, the Hoh Tribe estimates the current eligible population will be increased by 41 for a total eligible population of 73.

2. IHS is construing the letter from the Tribe, dated July 28, 2021, to mean that the tribal members within the new PRCDA are socially and economically affiliated with the Hoh Tribe.

3. The expanded area including Clallam County in the State of Washington maintains a common boundary with the current PRCDA consisting of Jefferson County in the State of Washington.

4. The Portland Area IHS administers the PRC program for the Hoh Tribe and will use its existing Federal allocation for PRC funds to provide services to the expanded population. No additional financial resources will be allocated by IHS to the Portland Area IHS to provide services to Hoh Tribe members residing