- Submitting under § 314.50(d)(1)(i) chemistry, manufacturing, and controls information, including the drug substance, for the content and format of an NDA for rare diseases; and
- Submitting under § 314.50(d)(5) and (d)(5)(iv) clinical data of a drug, including a description of any other data information relevant to an evaluation of the safety and effectiveness of a drug.
- Submissions under 21 CFR part 314, subpart H, to grant accelerated approval of new drugs for serious or life-threatening illnesses.
- Submissions under §§ 312.47 and 312.82 for requesting meetings with FDA about drug development programs.

The following collections of information in the final guidance have been approved under OMB control number 0910–0014:

- Submitting under 21 CFR 312.23(a)(6)(i) (§ 312.23(a)(6)(i)) a protocol for the duration of a trial and the criteria to enter a trial and under § 312.23(a)(6)(i), (a)(6)(iii)(d) and (g) a description of an estimate of patients that will be involved in a trial, including a description of the safety exclusions and a description of clinical procedures, laboratory, or other methods.
- Submitting under § 312.23(a)(3)(i) a brief introductory statement and general investigational plan, including the route of administration of a drug;
- Submitting under § 312.23(a)(7) and (a)(7)(iv)(a) chemistry, manufacturing, and controls information for the content and format of an investigational new drug application (IND) and the safety and effectiveness of such information;
- Submitting under § 312.23(a)(8) and (a)(8)(i) pharmacology, toxicology, and drug disposition information for rare diseases;
- Submitting under 312.23(a)(10)(iii) plans for assessing pediatric safety and effectiveness;
- Submitting under § 312.32(c)(1) IND safety reports;
- Submissions under §§ 312.305(b) and 312.310(b) for expanded access uses and treatment of an individual patient.

The collections of information in 21 CFR part 316 for submitting the content and format of NDAs for orphan drugs have been approved under OMB control number 0910–0167. The collections of information pertaining to postmarketing adverse drug experience reporting have been approved under OMB control number 0910–0230. The collections of information pertaining to expedited review programs for serious conditions, accelerated approval, breakthrough therapy-designation, and fast-track designation, have been approved under OMB control number 0910–0765. The collections of information in 21 CFR part 58 pertaining to good laboratory practices have been approved under OMB control number 0910–0119. The collection of information pertaining to current good manufacturing practices have been approved under OMB control number 0910–0139.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: December 18, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–28310 Filed 12–22–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–0990–30D]

Agency Information Collection Request. 30-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before January 25, 2024.

ADDRESSES: Submit your comments to *Sherrette.Funn@hhs.gov* or by calling (202) 264–0041 and *PRA@HHS.GOV*

FOR FURTHER INFORMATION CONTACT: When submitting comments or requesting information, please include the document identifier 0990–0313 and project title for reference, to Sherrette A. Funn, email: *Sherrette.Funn@hhs.gov, PRA@HHS.GOV* or call (202) 264–0041 the Reports Clearance Officer.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (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.

Title of the Collection: National Blood Collection & Utilization Survey (NBCUS)

Type of Collection: Revision

OMB No. 0990–30D–0313 Office of the Assistant Secretary for Health/HHS

Abstract

The Office of the Assistant Secretary for Health (OASH) is requesting approval for a three-year revised information collection request (ICR) titled ''National Blood Collection & Utilization Survey (NBCUS).'' The NBCUS is a biennial survey that includes a core of standard questions on blood collection, processing, and utilization practices. Questions on transfusion-transmitted infections, transfusion associated circulatory overload, acute hemolysis, delayed hemolysis, and severe allergic reactions are also included in the survey. The rapidly changing environment in blood supply and demand makes it important to have regular, periodic data describing the state of U.S. blood collections and transfusions for understanding the dynamics of blood safety and availability. In 2023, two sections were removed from the survey related to the impact of the COVID–19 pandemic on the blood supply during the course of 2020.

Survey respondents will consist of blood collection centers and hospitals that perform blood transfusions, except those reporting fewer than 100 inpatient surgeries per year. For the purposes of this ICR, federal burden is only being placed on facilities located within the fifty states and the District of Columbia. The total estimated burden is 5,106 hours.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Number of respondents	Number responses per respondent	Average burden per response (in hours)	Total burden hours
Transfusing Hospitals	2754	1	1 hour, 46 min	4,865
Hospital Blood Banks	83	1	1 hour, 46 min	147
Community-based blood center	53	1	1 hour, 46 min	94
Total	2,890			5,106

James Berger,

Senior Advisor for Blood and Tissue Safety, Office of the Assistant Secretary for Health.

[FR Doc. 2023–28412 Filed 12–22–23; 8:45 am]

BILLING CODE 4150–41–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Notice of Purchased/Referred Care Delivery Area Redesignation for the Spokane Tribe of Indians in the State of Washington

AGENCY: Indian Health Service, HHS.

ACTION: Notice.

SUMMARY: Notice is hereby given that the Indian Health Service (IHS) has decided to expand the geographic boundaries of the Purchased/Referred Care Delivery Area (PRCDA) for the Spokane Tribe to include the counties of Spokane and Whitman in the State of Washington. The final PRCDA for the Spokane Tribe now includes the Washington counties of Ferry, Lincoln, Spokane, Stevens, and Whitman. The sole purpose of this expansion is to authorize additional Spokane Tribal members and beneficiaries to receive Purchased/Referred Care (PRC) services.

DATES: This expansion is effective as of the publication date of this notice.

ADDRESSES: This notice can be found at *https://www.federalregister.gov.* Written requests for information should be delivered to: CAPT John Rael, Director, Office of Resource Access and Partnerships, Indian Health Service, 5600 Fishers Lane, Mail Stop 10E85C, Rockville, MD 20857, or by phone at (301) 443–0969 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION: 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 relative medical priority of the services to be provided, 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. 42 CFR 136.22(b). 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). 42 CFR 136.22(c). In compliance with this requirement, the IHS published a proposed notice of redesignation and requested public comments on August 9, 2023 (88 FR 53899). The IHS did not receive any comments to the notice of the proposed expansion.

Two other Tribes currently have PRCDAs which include one or both of the counties to be included in the Spokane Tribe's expanded PRCDA—the Coeur d'Alene Tribe (both Spokane and Whitman Counties) and the Kalispel Tribe of Indians (Spokane County only). On December 10, 2021, the Portland Area Director notified both Tribes of the Spokane Tribe's request to expand their PRCDA, and requested any comments in response. The Kalispel Tribe of Indians did not provide any comments. The Coeur d'Alene Tribe responded with objections to the proposed expansion. The Portland Area IHS engaged in further conversations and correspondence with the Coeur d'Alene Tribe throughout 2021 and 2022.

Through letters from the Spokane Tribe, dated May 31, 2022 and August 8, 2022, the Tribe expressed its support for the expansion, described the geographic proximity of Spokane and Whitman counties to the Tribe's reservation, and explained that the Tribe's reservation expanded into Spokane County in 2001 and that some of the Tribe's members reside in Whitman County.

In support of this expansion, the IHS adopts the following findings:

1. By expanding the PRCDA to include Spokane County and Whitman County, the Spokane Tribe's eligible population will be increased by an estimated 480 Tribal members. Although the Coeur d'Alene Tribe has a PRCDA which includes these two counties, the Coeur d'Alene Tribe does not provide PRC services to Spokane Tribal members residing in those counties. Expansion of the Spokane Tribe's PRCDA to include Spokane and Whitman Counties will therefore increase access to care for those individuals.

2. The IHS finds that the Tribal members within the expanded PRCDA are socially and economically affiliated with the Spokane based on letters from the Spokane Tribe, dated May 31, 2022 and August 8, 2022, which noted that the Spokane Tribal Council had