

limit rather than the AI limit recommended in this guidance based on predicted carcinogenic potency. In general, FDA would expect manufacturers and applicants to control impurities within the recommended AI limit. Additionally, manufacturers and applicants should continue to pursue mitigation efforts to reduce or remove NDSRIs in their drug products.

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 "Recommended Acceptable Intake Limits for Nitrosamine Drug Substance-Related Impurities (NDSRIs)." 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. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in 21 CFR parts 210 and 211 pertaining to current good manufacturing practice have been approved under OMB control number 0910–0139. The collections of information in 21 CFR part 312 pertaining to investigational new drug applications have been approved under OMB control number 0910–0014. The collections of information in 21 CFR part 314 pertaining to NDAs and ANDAs have been approved under OMB control number 0910–0001. The collections of information in 21 CFR part 601 pertaining to BLAs have been approved under OMB control number 0910–0338. The collections of information in 21 CFR part 201 pertaining to OTC monograph drug products have been approved under OMB control number 0910–0340.

III. Electronic Access

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

Dated: August 2, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Notice of Purchased/Referred Care Delivery Area Redesignation for the Confederated Tribes of Grand Ronde in the State of Oregon

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 Confederated Tribes of Grand Ronde (CTGR) in the State of Oregon to include the county of Clackamas in the State of Oregon. The current PRCDA for the CTGR includes the Oregon counties of Washington, Polk, Yamhill, Marion, Multnomah, and Tillamook. The CTGR 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 CTGR members and beneficiaries to receive PRC services.

DATES: Comments must be submitted September 6, 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, 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 is publishing this Notice and requesting public comments.

The CTGR is located in Grand Ronde, Oregon, which is located in Western Oregon where it has an 11,500-acre reservation in Yamhill County. The Tribe has requested to add Clackamas County to their PRCDA which is currently comprised of Washington, Polk, Yamhill, Marion, Multnomah, and Tillamook Counties in Oregon. Multnomah and Marion Counties are contiguous to the requested expansion into Clackamas County, and part of ceded lands from the Willamette Valley Treaty.

The CTGR's PRC Program is operated under a long standing Title V agreement. The Portland Area IHS estimates there are currently 179 Tribal members who live within Clackamas County and would become PRC eligible through this proposed expansion. The Tribe states that many of these members routinely travel to Portland, or to the Tribal facilities in Grand Ronde, to seek care as they are not currently eligible for PRC. They are also active members of the community and routinely participate in Tribal elections, General Council meetings, and Tribal events. The Tribe would like to recognize them as eligible for PRC. Accordingly, the IHS proposes to expand the PRCDA of the CTGR to include the Oregon county of Clackamas.

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 PRCDA to include Clackamas County, the CTGR's eligible population will be increased by an estimated 179 Tribal members residing in Clackamas County.

2. The IHS finds that the Tribal members within the expanded PRCDA are socially and economically affiliated with CTGR based on a letter from the CTGR, dated May 19, 2021, which noted that the CTGR members residing in Clackamas County are active members of the community and routinely participate in Tribal elections, General Council meetings, and Tribal events.

3. Clackamas County in the State of Oregon is "on or near" the reservation, as it maintains a common boundary with the current PRCDA consisting of the counties of Washington, Polk, Yamhill, Marion, Multnomah, and Tillamook in the State of Oregon.

4. The CTGR administers the PRC program and will use its existing Federal allocation for PRC, along with Tribal resources, to provide services to the expanded population. The Tribe acknowledged that no additional financial resources will be allocated by the IHS to the Portland Area IHS to provide services to CTGR members residing in Clackamas County in the State of Oregon.

This Notice does not contain reporting or recordkeeping requirements subject to prior approval by the Office of Management and Budget under the Paperwork Reduction Act of 1995.

Roselyn Tso,

Director, Indian Health Service.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Request for Public Comment: 30-Day Information Collection: Indian Self-Determination and Education Assistance Act Contracts

AGENCY: Indian Health Service, HHS.

ACTION: Notice and request for comments; request for extension of approval.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the Indian Health Service (IHS) invites the general public to comment on the information collection titled, "Indian Self-Determination and Education Assistance Act Contracts," Office of Management and Budget (OMB) Control Number 0917-0037. The IHS is requesting OMB to approve an extension for this collection, which expires on August 31, 2023.

DATES:

Comment Due Date: September 6, 2023. Your comments regarding this

information collection are best assured of having full effect if received within 30 days of the date of this publication.

ADDRESSES:

Direct Your Comments to OMB: Send your comments and suggestions regarding the proposed information collection contained in this notice, especially regarding the estimated public burden and associated response time to: Office of Management and Budget, Office of Regulatory Affairs, New Executive Office Building, Room 10235, Washington, DC 20503, Attention: Desk Officer for IHS.

FOR FURTHER INFORMATION CONTACT: To request additional information, please contact Evonne Bennett, Information Collection Clearance Officer at: *Evonne.Bennett@ihs.gov* or 240-472-1996.

SUPPLEMENTARY INFORMATION: This notice announces our intent to seek an extension of the collection already approved by OMB, and to solicit comments on specific aspects of the information collection. There were two public comments received in response to the notice. The purpose of this notice is to allow 30 days for public comment to be submitted to OMB. A copy of the supporting statement is available at www.regulations.gov (see Docket ID IHS-2023-0001).

Comments: Both comments did not pertain to the collection, or the IHS.

Response to Comment: The Agency does not have a response to the comments.

Information Collection Title: Indian Self-Determination and Education Assistance Act Contracts, 25 CFR part 900, 0917-0037.

Type of Information Collection Request: Extension of currently approved collection.

Form Numbers: 0917-0037.

Need and Use of Information Collection: In 1975, Congress enacted the Indian Self-Determination and Education Assistance Act (ISDEAA) to authorize Tribes and Tribal organizations (T/TO) to assume control of certain Federal programs, e.g., health care programs that certain Federal agencies would otherwise provide to American Indians and Alaska Natives.

The T/TO that intend to establish a new or expanded Title I self-determination contract with the IHS are required to provide proposal information identified at 25 CFR 900.8, which describes what a contract proposal must contain. This information is used by the IHS to determine applicant eligibility, evaluate applicant capabilities, protect the service