

evaluating whether the available scientific data, information, and methods establish that a substance is

safe under the conditions of its intended use in food.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

Activity; 21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
GRAS notification procedure for human food; 170.210–170.280 (part 170, subpart E)	100	1	100	170	17,000
GRAS notification procedure for animal food and animal feed; 570.210–570.280 (part 570, subpart E)	12	1	12	170	2,040
Total	125	19,040

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

In row 2 of table 1, we are decreasing our estimate for the number of respondents submitting GRAS notices

for animal food and animal feed from 25 to 12, which results in a decrease of 2,210 burden hours (4,250 hours minus

2,040 hours). This estimate is based on the number of submissions we received over the last 3 years.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN ¹

Activity; guidance document section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Maintaining written GRAS panel policy; V. Recommendations	696	1	696	2	1,392
Application of written GRAS panel policy to GRAS panel members; V. Recommendations	94	6	564	16	9,024
Total	1,260	10,416

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Row 1 of table 2 reflects a decrease of the average burden per recordkeeping as compared to the corresponding estimate under OMB control number 0910–0911, which decreased from 40 hours to 2

hours per recordkeeping. When we issued the guidance for convening a GRAS panel, we estimated that a proponent would take 40 hours to create and establish a written GRAS panel

policy. We presume that proponents will have now established their written GRAS panel policy and only needs to maintain it, which we estimate will take 2 hours for each proponent.

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN ¹

Activity; guidance document section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Potential GRAS panel members provide information to the proponents of GRAS conclusions; V. Recommendations	564	1	564	4	2,256

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

We are revising the information collection to include related activities associated with the guidance for convening a GRAS panel, currently approved under OMB control number 0910–0911, “Substances Generally Recognized as Safe: Best Practices for Convening a GRAS Panel.” The revision will add 10,462 hours and 1,824 responses. This estimate is based on our experience with this information collection and the number of notifications received in the past 3 years.

Dated: June 24, 2025.
Grace R. Graham,
Deputy Commissioner for Policy, Legislation, and International Affairs.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Notice of Purchased/Referred Care Delivery Area Re-Designation for the Chippewa Cree Tribe of the Rocky Boy's Reservation

AGENCY: Indian Health Service, Department of Health and Human Services.

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 Chippewa Cree Tribe of the Rocky Boy's Reservation ("Chippewa Cree Tribe" or "Tribe") to include the Montana County of Cascade. The final PRCDA for the Chippewa Cree Tribe now includes the Montana counties of Cascade, Choteau, Hill and Liberty. The sole purpose of this expansion is to authorize additional Chippewa Cree Tribal members and beneficiaries to receive Purchased/Referred Care (PRC) services.

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

ADDRESSES: This notice can be found at <https://www.federalregister.gov>. Written requests for information should be delivered to: CDR Tracy Sanchez, Acting Director, Office of Resource Access and Partnerships, Indian Health Service, 5600 Fishers Lane, Mail Stop 10E85C, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: CDR Tracy Sanchez, Acting Director, Office of Resource Access and Partnerships by email at Tracy.Sanchez@ihs.gov, or by phone at (301) 443-3216 (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 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 notice of proposed redesignation and requested public comments on December 17, 2024 (89 FR 102150). The IHS did not receive any comments in response to the notice of proposed redesignation.

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

1. By expanding the PRCDA to include Cascade County in the State of Montana, the Chippewa Cree Tribe's PRC-eligible population will increase by an estimated 251 Tribal members.

2. As part of their expansion request, the Chippewa Cree Tribe submitted a resolution from the Tribe's governing body. The resolution explains that the expansion is intended to serve their members living in Cascade County, Montana, and it describes those members as being socially and economically tied to the Tribe's reservation. The IHS therefore finds that the Tribal members within the proposed, expanded PRCDA are socially and economically affiliated with the Chippewa Cree Tribe.

3. The expanded PRCDA county forms a contiguous area with the existing PRCDA. Members of the Chippewa Cree Tribe reside in the county proposed for inclusion in the expanded PRCDA. Through their expansion request, the Tribe described how close Cascade County, Montana is to their reservation and explained that it is close enough for their members residing there to return frequently to the Tribe's reservation for ceremony and participation in Tribal elections. For these reasons, the IHS has determined the additional county proposed for inclusion herein to be geographically proximate, meaning "on or near," to the Tribe's reservation.

4. Through the Chippewa Cree Tribe's request to expand its PRCDA, the Tribe has indicated that the PRC program can continue providing the same level of care to the PRC eligible population if the PRCDA is expanded as proposed, without requiring additional funding from the IHS or reduction of the current medical priority level.

An updated listing of the PRCDA's for all federally recognized Tribes may be accessed via a link on the IHS PRCDA Expansion website (<https://www.ihs.gov/prc/prcda-expansion>).

Public Comments: The IHS did not receive any comments in response to the notice of proposed expansion.

P. Benjamin Smith,

Acting Director, Indian Health Service.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Notice of Purchased/Referred Care Delivery Area Redesignation for the Iowa Tribe of Kansas and Nebraska

AGENCY: Indian Health Service, Department of Health and Human Services.

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 Iowa Tribe of Kansas and Nebraska (Iowa Tribe or Tribe) to include the counties of Jackson in the State of Kansas, and Holt in the State of Missouri. The final PRCDA for the Iowa Tribe now includes the following counties: Brown, Doniphan, and Jackson in the State of Kansas; Holt in the State of Missouri; and Richardson in the State of Nebraska. The sole purpose of this expansion is to authorize additional Iowa Tribal members and beneficiaries to receive Purchased/Referred Care (PRC) services.

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

ADDRESSES: This notice can be found at <https://www.federalregister.gov>. Written requests for information should be delivered to: CDR Tracy Sanchez, Acting Director, Office of Resource Access and Partnerships, Indian Health Service, 5600 Fishers Lane, Mail Stop 10E85C, Rockville, MD 20857.

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