

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN <sup>1</sup>—Continued

21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours <sup>3</sup>
1271.265(e) .....	1,561	1,324.08	2,066,890	.083 (5 minutes) .....	171,552
1271.270(a) .....	1,561	1,324.08	2,066,890	.25 (15 minutes) .....	516,723
1271.270(e) .....	1,774	2	3,548	.5 (30 minutes) .....	1,774
1271.290(d) and (e) .....	1,561	66.25	103,419	.25 (15 minutes) .....	25,855
1271.320(b) .....	1,249	5	6,245	1 .....	6,245
Total .....					2,066,060

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

<sup>2</sup> Sections 1271.47(a), 1271.85(b)(2), 1271.160(b)(2) and (d)(1), 1271.180(a), 1271.190(d)(1), 1271.200(b), 1271.200(c), 1271.230(a), 1271.250(a), 1271.265(e), 1271.265(f), 1271.270(b) and (d), 1271.290(b)(1), and 1271.320(a).

<sup>3</sup> Rounded to the nearest whole number.

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN <sup>1</sup>

21 CFR section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
1271.55(a) .....	1,551	1,422.88	2,206,890	.5 (30 minutes) .....	1,103,445
1271.60(c) and (d)(2) .....	1,375	416	572,000	.5 (30 minutes) .....	286,000
1271.290(c) .....	1,561	1,324.08	2,066,890	.083 (5 minutes) .....	171,552
1271.290(f) .....	1,561	1	1,561	1 .....	1,561
1271.370(b) and (c) .....	1,561	1,324.08	2,066,890	.25 (15 minutes) .....	516,723
Total .....					2,079,281

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

Dated: March 28, 2017.

**Anna K. Abram,**

*Deputy Commissioner for Policy, Planning, Legislation, and Analysis.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2017-N-0001]

**Roadmap for Engaging With the Food and Drug Administration’s Center for Drug Evaluation and Research; Public Workshop**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of public workshop.

**SUMMARY:** The Food and Drug Administration’s (FDA’s) Center for Drug Evaluation and Research (CDER), is announcing the following public workshop entitled “Roadmap for Engaging with FDA’s Center for Drug Evaluation and Research (CDER).” The purpose of this workshop is to help the public learn how to successfully engage with CDER.

**DATES:** The public workshop will be held on May 12, 2017, from 9 a.m. to 3 p.m.

**ADDRESSES:** The public workshop will be held at FDA’s White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20903-0002. Entrance for the public workshop participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to <https://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm>.

**FOR FURTHER INFORMATION CONTACT:** Chris Melton, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-7381, [NAV-CDER@fda.hhs.gov](mailto:NAV-CDER@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Background**

FDA is announcing a public workshop entitled “Roadmap for Engaging with FDA’s Center for Drug Evaluation and Research (CDER).” This workshop is intended to help the public learn the most effective ways to successfully engage with CDER. There will be presentations on learning about the drug approval process, as well as the

opportunity for questions and answers following each presentation.

**II. Participating in the Public Workshop**

**Registration:** Persons interested in attending this workshop must register online at [https://www.eventbrite.com/e/fda-public-workshop-roadmap-for-engaging-with-fdas-center-for-drug-evaluation-and-research-cder-tickets-28608664285?utm\\_source=eb\\_email&utm\\_medium=email&utm\\_campaign=new\\_event\\_email&utm\\_term=viewmyevent\\_button](https://www.eventbrite.com/e/fda-public-workshop-roadmap-for-engaging-with-fdas-center-for-drug-evaluation-and-research-cder-tickets-28608664285?utm_source=eb_email&utm_medium=email&utm_campaign=new_event_email&utm_term=viewmyevent_button). Please provide complete contact information for each attendee, including name, title, affiliation, address, email and telephone.

Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending this public workshop must register by May 5, 2016, 6 p.m. EST. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. If time and space permit, onsite registration on the day of the public workshop will be provided beginning at 8 a.m. We will let registrants know if registration closes before the day of the public workshop.

If you need special accommodations due to a disability, please contact Chris Melton no later than May 1, 2017.

*Transcripts:* Please be advised that as soon as a transcript of the public workshop is available, it will be assessable at <https://www.regulations.gov>. It may be viewed at the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. A transcript will also be available in either hardcopy or on CD-ROM, after submission of a Freedom of Information request. The Freedom of Information office address is available on the Agency's Web site at <https://www.fda.gov>.

Dated: March 27, 2017.

**Anna K. Abram,**

*Deputy Commissioner for Policy, Planning, Legislation, and Analysis.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Indian Health Service

#### Notice To Propose the Re-Designation of the Service Delivery Area for the Tolowa Dee-ni' Nation (Smith River Rancheria)

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

**ACTION:** Notice.

**SUMMARY:** This notice advises the public that the Indian Health Service (IHS) proposes to expand the geographic boundaries of the Service Delivery Area for the Tolowa Dee-ni' Nation (Tribe) previously known as the Smith River Rancheria of Smith River, California. The Tolowa Dee-ni's Tribal Headquarters is located three miles south of the California-Oregon border in Northern California.

The entire State of California, excluding the counties of Alameda, Contra Costa, Los Angeles, Marin, Orange, Sacramento, San Francisco, San Mateo, Santa Clara, Kern, Merced, Monterey, Napa, San Benito, San Joaquin, San Luis Obispo, Santa Cruz, Solano, Stanislaus, and Ventura, are designated a Purchased/Referred Care (PRC) Service Delivery Area, formerly referred to as a Contract Health Service Delivery Area, by statute. The current Service Delivery Area for the Tolowa Dee-ni' Nation Tribal members is the statutorily established California PRC Service Delivery Area. The expanded PRC Service Delivery Area for the Tolowa Dee-ni' Nation includes the statutorily established California PRC

Service Delivery Area and Curry County in the State of Oregon.

**DATES:** Comments must be submitted May 1, 2017.

**ADDRESSES:** In commenting, please refer to the title of this notice. 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: Evonne Bennett-Barnes, Indian Health Service, 5600 Fishers Lane, Mailstop: 09E70, Rockville, Maryland 20852.

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.

Comments will be made available for public inspection at the Rockville address from 8:30 a.m. to 5:00 p.m., Monday-Friday, two weeks after publication of this notice.

**FOR FURTHER INFORMATION CONTACT:** Terri Schmidt, Acting Director, Office of Resource Access and Partnerships, Indian Health Service, 5600 Fishers Lane, Mailstop: 10E85C, Rockville, Maryland 20852. Telephone 301/443-2694 (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 currently provides services under regulations codified at 42 CFR part 136, subparts A through C. Subpart C defines a Contract Health Service Delivery Area, now known as PRC Service Delivery Area, 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 Service Delivery Area. Potential eligibility for

services alone, or residence in a PRC Service Delivery Area by a person who is within the scope of the Indian health program, as set forth in 42 CFR 136.12, does not create a legal entitlement to PRC. 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.

As applicable to the Tribes, these regulations provide that, unless otherwise designated, a PRC Service Delivery Area 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) (2016). The regulations also provide that after consultation with the Tribal governing body or bodies on those reservations included within the PRC Service Delivery Area, the Secretary may from time to time, re-designate areas within the United States for inclusion in or exclusion from a PRC Service Delivery Area. The regulations require that certain criteria must be considered before any re-designation 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 Tribes;

(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 re-designation of a PRC Service Delivery Area must be made in accordance with the Administrative Procedures Act (5 U.S.C. 553). In compliance with this requirement, we are publishing this proposal and requesting public comments.

Congress designated the entire state of California as a PRC Service Delivery Area, excluding certain counties, under section 810 of the Indian Healthcare Improvement Act, Public Law 94-437, as amended (25 U.S.C. 1680). IHS has utilized the congressionally established PRC Service Delivery Area for the purposes of administering PRC benefits to members of the Tribe. Thus, members of the Tribe who reside outside of the statutorily established California PRC Service Delivery Area do not reside within the Tolowa Dee-ni's current PRC