

TABLE 1—NEW DRAFT PRODUCT—
Continued
SPECIFIC GUIDANCES FOR DRUG
PRODUCTS

Active Ingredient(s)
Lotilaner
Nalmefene hydrochloride
Omaveloxolone
Oxazepam
Pegcetacoplan
Perfluorohexyloctane
Pirtobrutinib
Rezafungin acetate
Sodium oxybate
Sparsentan
Tasimelteon
Tobramycin
Zavegepant hydrochloride

III. Drug Products for Which Revised Draft Product-Specific Guidances Are Available

FDA is announcing the availability of revised draft product-specific guidances for industry for drug products containing the following active ingredients:

TABLE 2—REVISED DRAFT PRODUCT-SPECIFIC GUIDANCES FOR DRUG PRODUCTS

Active Ingredient(s)
Benzoyl peroxide; Erythromycin (multiple reference listed drugs)
Fluticasone furoate
Fluticasone furoate; Vilanterol trifrenatate
Nitrofurantoin
Tretinoin

For a complete history of previously published **Federal Register** notices related to product-specific guidances, go to <https://www.regulations.gov> and enter Docket No. FDA-2007-D-0369.

These draft guidances are being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). These draft guidances, when finalized, will represent the current thinking of FDA on, among other things, the product-specific design of BE studies to support ANDAs. They do not establish any rights for any person and are not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

IV. Paperwork Reduction Act of 1995

FDA tentatively concludes that these draft guidances contain no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

V. Electronic Access

Persons with access to the internet may obtain the draft guidance at 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: May 14, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Notice of Proposed Purchased/ Referred Care Delivery Area Re-Designation for the Pokagon Band of Potawatomi Indians of Michigan and Indiana

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 Purchased/Referred Care Delivery Area (PRCDA) for the Pokagon Band of Potawatomi Indians of Michigan and Indiana to include the counties of Kalamazoo, Kent, and Ottawa in the State of Michigan. The sole purpose of this expansion would be to authorize additional Pokagon Band of Potawatomi Indians of Michigan and Indiana citizens and other PRC-eligible individuals to receive PRC services.

DATES: Comments must be submitted by June 17, 2024.

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 regulation 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 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, re-designate 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

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 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 re-designation 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 Pokagon Band of Potawatomi Indians of Michigan and Indiana (Pokagon Band, or Tribe) is located in Dowagiac, Michigan, and operates their PRC program as a Tribal Health Program. The IHS established the Pokagon Band's current PRCDA consistent with the language of the Act of September 21, 1994, restoring Federal recognition to the Pokagon Band. Public Law 103-323 (108 Stat. 2152); *see also* 72 FR 34262 (June 21, 2007). Although the IHS has historically established PRCDA in accordance with Congressional intent, the IHS has also preserved regulatory flexibility to re-designate areas as appropriate for inclusion in or exclusion from a PRCDA under PRC regulations. *See* 81 FR 20388 (April 7, 2016).

The current PRCDA for the Pokagon Band of Potawatomi Indians of Michigan and Indiana currently consists of 10 counties in Southwestern Michigan and Northwestern Indiana. *See* 72 FR 34262 (June 21, 2007). These counties are Allegan, Berrien, Cass, and Van Buren Counties in Michigan; and Elkhart, Kosciusko, La Porte, Marshall, St. Joseph, and Starke Counties in Indiana. Pokagon Band of Potawatomi Indians of Michigan and Indiana citizens residing outside of the PRCDA are eligible for direct care services; however, they are not eligible for Purchased/Referred Care (PRC) services.

The Pokagon Band estimates that approximately 537 Pokagon citizens reside in Kalamazoo, Kent, and Ottawa Counties in Michigan and would become PRC eligible through the proposed re-designation and expansion of the Tribe's PRCDA. The Pokagon Band states that these citizens, "by virtue of their citizenship with the Pokagon Band are socially and

economically affiliated with the Pokagon Band and belong to the Pokagon Band community served by the [Health] Center . . ." The Tribe also considers certain other PRC-eligible individuals to be socially and economically affiliated with the Pokagon Band and to belong to the Pokagon Band community, including non-Indian women pregnant with a Pokagon Band citizen's child, and children of Pokagon Band citizens as detailed in the Tribe's PRCDA re-designation request. The Pokagon Band would like to recognize these persons as eligible for PRC services. The IHS confirmed that there are Pokagon Band citizens residing in each of the proposed expansion counties. Accordingly, the IHS proposes to expand the PRCDA of the Pokagon Band of Potawatomi Indians of Michigan and Indiana to include the Michigan counties of Kalamazoo, Kent, and Ottawa.

If the Pokagon Band's PRCDA re-designation and expansion is finalized as proposed, the Tribe's expanded PRCDA would overlap the existing PRCDA of three other Tribes: the Nottawaseppi Band of Huron Potawatomi (Kalamazoo, Kent, and Ottawa Counties); the Match-E-Be-Nash-She-Wish Band of Pottawatomi Indians of Michigan (Kalamazoo, Kent, and Ottawa Counties); and Little River Band of Ottawa Indians (Kent and Ottawa Counties). The IHS has consulted with each of the overlapping Tribes regarding the proposed expansion of the Pokagon Band's PRCDA, and none of the overlapping Tribes has expressed a current concern regarding the proposed re-designation and expansion.

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 re-designation 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 Kalamazoo, Kent, and Ottawa Counties in Michigan, the Pokagon Band of Potawatomi Indians of Michigan and Indiana's PRC eligible population will increase by an estimated 537 Tribal citizens.

2. The IHS finds that the Tribal citizens and other PRC-eligible individuals within the expanded PRCDA are socially and economically affiliated with the Pokagon Band based on a Tribal resolution in which the Pokagon Band Tribal Council identified

its intent to expand the PRCDA to include Kalamazoo, Kent, and Ottawa Counties in Michigan, and stated that the Tribal citizens and certain other individuals residing in such areas are socially and economically affiliated with the Pokagon Band.

3. The expanded PRCDA counties form a contiguous area with the existing PRCDA, and Pokagon Band citizens reside in each of the counties proposed for inclusion in the expanded PRCDA. For these reasons, the IHS has determined the additional counties proposed for inclusion herein to be geographically proximate, meaning "on or near," to the existing PRCDA.

4. The Pokagon Band has indicated that its 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 or reduction of the current medical priority level.

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 1980.

Roselyn Tso,

Director, Indian Health Service.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Cancer Institute Initial Review Group; Transition to Independence Study Section (I), June 5, 2024, 8 a.m. to June 6, 2024, 1 p.m., Cambria Hotel Rockville, 1 Helen Heneghan Way, Rockville, Maryland 20850 which was published in the **Federal Register** on May 10, 2024, FR Doc 2024-10229, 89 FR 40496. This notice is being amended to change the meeting format from in-person to virtual and the meeting time from 8 a.m. to 1 p.m. to 11 a.m. to 4 p.m. The meeting will now be held virtually, June 5, 2024, 11 a.m. to June 6, 2024, 4 p.m., National Cancer Institute Shady Grove, 9609 Medical Center Drive, Room 7W238, Rockville, Maryland 20850. The meeting is closed to the public.