

- mechanically control or assist patient breathing by delivering a predetermined percentage of oxygen in the breathing gas
6. Sterilization services for any device as defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act and sterilizers as defined in 21 CFR 880.6860, 880.6870, and 880.6880, including devices that already have FDA marketing authorization and those that do not have FDA marketing authorization but are intended for the same uses
 7. Disinfecting devices intended to kill pathogens and other kinds of microorganisms by chemical means or physical means, including those defined in 21 CFR 876.1500, 880.6992, and 892.1570 and other sanitizing and disinfecting products suitable for use in a clinical setting
 8. Medical gowns or apparel, *e.g.*, surgical gowns or isolation gowns
 9. Personal protective equipment (PPE) coveralls, *e.g.*, Tyvek Suits
 10. PPE face masks, including any masks that cover the user's nose and mouth and may or may not meet fluid barrier or filtration efficiency levels
 11. PPE surgical masks, including masks that covers the user's nose and mouth and provides a physical barrier to fluids and particulate materials
 12. PPE face shields, including those defined at 21 CFR 878.4040 and those intended for the same purpose
 13. PPE gloves or surgical gloves, including those defined at 21 CFR 880.6250 (exam gloves) and 878.4460 (surgical gloves) and such gloves intended for the same purposes
 14. Ventilators, anesthesia gas machines modified for use as ventilators, and positive pressure breathing devices modified for use as ventilators (collectively referred to as "ventilators"), ventilator tubing connectors, and ventilator accessories as those terms are described in FDA's March 2020 Enforcement Policy for Ventilators and Accessories and Other Respiratory Devices During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency located at <https://www.fda.gov/media/136318/download>
 15. Laboratory reagents and materials used for isolation of viral genetic material and testing, such as transport media, collection swabs, test kits and reagents specific to those kits, and consumables such as plastic pipette tips and plastic tubes
 16. Drug products currently recommended by the NIH COVID-19 Treatment Guidelines Panel, including (as of July 23, 2020) remdesivir and dexamethasone

17. Alcohol-based hand sanitizer and rubs

Authority

The authority for this Notice is Executive Order 13910 and section 102 of the Defense Production Act of 1950, 50 U.S.C. 4512, as amended.

Dated: July 23, 2020.

Ann C. Agnew,

Executive Secretary, Department of Health and Human Services.

[FR Doc. 2020-16458 Filed 7-27-20; 4:15 pm]

BILLING CODE 4150-03-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria

AGENCY: Office of the Secretary, Office of the Assistant Secretary for Health, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: As stipulated by the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) is hereby giving notice that a meeting is scheduled to be held for the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria (PACCARB). The meeting will be open to the public via webex and teleconference; a pre-registered public comment session will be held during the meeting. Pre-registration is required for members of the public who wish to attend the meeting via webex/teleconference. Individuals who wish to send in their pre-recorded or written public comments should send an email to CARB@hhs.gov. Registration information is available on the website <http://www.hhs.gov/paccarb> and must be completed by September 2, 2020. Additional information about registering for the meeting and providing public comment can be obtained at <http://www.hhs.gov/paccarb> on the Meetings page.

DATES: The meeting is scheduled to be held on September 9, 2020, from 12:00 p.m. to 3:30 p.m. and September 10, 2020, from 12:00 p.m. to 3:30 p.m. ET (times are tentative and subject to change). The confirmed times and agenda items for the meeting will be posted on the website for the PACCARB at <http://www.hhs.gov/paccarb> when this information becomes available. Pre-registration for attending the meeting is required to be completed no later than September 2, 2020.

ADDRESSES: Instructions regarding attending this meeting virtually will be posted one week prior to the meeting at: <http://www.hhs.gov/paccarb>.

FOR FURTHER INFORMATION CONTACT:

Jomana Musmar, M.S., Ph.D., Designated Federal Officer, Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria, Office of the Assistant Secretary for Health, U.S. Department of Health and Human Services, Room L616, Switzer Building, 330 C. St. SW, Washington, DC 20201. Phone: 202-746-1512; Email: CARB@hhs.gov.

SUPPLEMENTARY INFORMATION: The Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria (PACCARB), established by Executive Order 13676, is continued by Section 505 of Public Law 116-22, the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019 (PAHPAIA). Activities and duties of the Advisory Council are governed by the provisions of the Federal Advisory Committee Act (FACA), Public Law 92-463, as amended (5 U.S.C. App.), which sets forth standards for the formation and use of federal advisory committees.

The PACCARB shall advise and provide information and recommendations to the Secretary regarding programs and policies intended to reduce or combat antibiotic-resistant bacteria that may present a public health threat and improve capabilities to prevent, diagnose, mitigate, or treat such resistance. The PACCARB shall function solely for advisory purposes.

Such advice, information, and recommendations may be related to improving: The effectiveness of antibiotics; research and advanced research on, and the development of, improved and innovative methods for combating or reducing antibiotic resistance, including new treatments, rapid point-of-care diagnostics, alternatives to antibiotics, including alternatives to animal antibiotics, and antimicrobial stewardship activities; surveillance of antibiotic-resistant bacterial infections, including publicly available and up-to-date information on resistance to antibiotics; education for health care providers and the public with respect to up-to-date information on antibiotic resistance and ways to reduce or combat such resistance to antibiotics related to humans and animals; methods to prevent or reduce the transmission of antibiotic-resistant bacterial infections; including stewardship programs; and coordination with respect to international efforts in

order to inform and advance the United States capabilities to combat antibiotic resistance.

The September 9–10 public meeting will be dedicated to the welcoming of eight new liaison members, and acknowledging the dedication of retiring liaisons. The remainder of the two-day public meeting will include antimicrobial (AMR)-focused panel presentations and council discussions focused on the impact of COVID–19, with topics ranging from: COVID–19 mortality rate due to secondary acquired infections, antibiotic stewardship practices during a pandemic, disruptions in the agricultural industry due to COVID–19 and the intersection of AMR and emergency preparedness. The meeting agenda will be posted on the PACCARB website at <http://www.hhs.gov/paccarb> when it has been finalized. All agenda items are tentative and subject to change.

Instructions regarding attending this meeting virtually will be posted one week prior to the meeting at: <http://www.hhs.gov/paccarb>.

Members of the public will have the opportunity to provide comments prior to the public meeting by emailing CARB@hhs.gov. Public comments should be sent in by midnight September 2, 2020 and should be limited to no more than one page, or a two-minute pre-recorded message to be played live during the meeting. All public comments received prior to September 2, 2019, will be provided to Advisory Council members and will be acknowledged during the public teleconference.

Dated: July 27, 2020.

Jomana F. Musmar,

Designated Federal Officer, Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria, Office of the Assistant Secretary for Health.

[FR Doc. 2020–16547 Filed 7–29–20; 8:45 am]

BILLING CODE 4150–44–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Tribal Self-Governance Negotiation Cooperative Agreement

Announcement Type: New.

Funding Announcement Number: HHS–2020–IHS–TSGN–0001.

Assistance Listing (Catalog of Federal Domestic Assistance or CFDA) Number: 93.444.

Key Dates

Application Deadline Date: October 28, 2020.

Earliest Anticipated Start Date: November 12, 2020.

I. Funding Opportunity Description

Statutory Authority

The Indian Health Service (IHS) Office of Tribal Self-Governance (OTSG) is accepting applications for Negotiation Cooperative Agreements for the Tribal Self-Governance Program (TSGP). This program is authorized under Title V of the Indian Self-Determination and Education Assistance Act (ISDEAA), 25 U.S.C. 5383(e). This program is described in the Assistance Listings located at <https://beta.sam.gov> (formerly known as Catalog of Federal Domestic Assistance) under 93.444.

Background

The TSGP is more than an IHS program; it is an expression of the government-to-government relationship between the United States (U.S.) and Indian Tribes. Through the TSGP, Tribes negotiate with the IHS to assume Programs, Services, Functions, and Activities (PSFAs), or portions thereof, which gives Tribes the authority to manage and tailor health care programs in a manner that best fits the needs of their communities.

Participation in the TSGP affords Tribes the most flexibility to tailor their health care needs by choosing one of three ways to obtain health care from the Federal government for their citizens. Specifically, Tribes can choose to: (1) Receive health care services directly from the IHS; (2) contract with the IHS to administer individual programs and services the IHS would otherwise provide (referred to as Title I Self-Determination Contracting); and (3) compact with the IHS to assume control over health care programs the IHS would otherwise provide (referred to as Title V Self-Governance Compacting or the TSGP). These options are not exclusive and Tribes may choose to combine options based on their individual needs and circumstances.

The TSGP is a Tribally-driven initiative and strong Federal-Tribal partnerships are essential to the program's success. The IHS established the OTSG to implement the Tribal Self-Governance authorities under the ISDEAA. The primary OTSG functions are to: (1) Serve as the primary liaison and advocate for Tribes participating in the TSGP; (2) develop, direct, and implement TSGP policies and procedures; (3) provide information and technical assistance to Self-Governance Tribes; and (4) advise the IHS Director on compliance with TSGP policies, regulations, and guidelines. Each IHS

Area has an Agency Lead Negotiator (ALN), designated by the IHS Director to act on his or her behalf, who has authority to negotiate Self-Governance Compacts and Funding Agreements (FA). Tribes interested in participating in the TSGP should contact their respective ALN to begin the Self-Governance planning and negotiation process. Tribes currently participating in the TSGP, which are interested in expanding existing or adding new PSFAs, should also contact their respective ALN to discuss the best methods for expanding or adding new PSFAs.

Purpose

The purpose of this Negotiation Cooperative Agreement is to provide Tribes with resources to help defray the costs associated with preparing for and engaging in TSGP negotiations. TSGP negotiations are a dynamic, evolving, and Tribally-driven process that requires careful planning, preparation and sharing of precise, up-to-date information by both Tribal and Federal parties. Because each Tribal situation is unique, a Tribe's successful transition into the TSGP, or expansion of their current program, requires focused discussions between the Federal and Tribal negotiation teams about the Tribe's specific health care concerns and plans. One of the hallmarks of the TSGP is the collaborative nature of the negotiations process, which is designed to: (1) Enable a Tribe to set its own priorities when assuming responsibility for IHS PSFAs; (2) observe and respect the government-to-government relationship between the U.S. and each Tribe; and (3) involve the active participation of both Tribal and IHS representatives, including the OTSG. Negotiations are a method of determining and agreeing upon the terms and provisions of a Tribe's Compact and FA, the implementation documents required for the Tribe to enter into the TSGP. The Compact sets forth the general terms of the government-to-government relationship between the Tribe and the Secretary of the U.S. Department of Health and Human Services (HHS). The FA: (1) Describes the length of the agreement (whether it will be annual or multi-year); (2) identifies the PSFAs, or portions thereof, the Tribe will assume; (3) specifies the amount of funding associated with the Tribal assumption; and (4) includes terms required by Federal statutes and other terms agreed to by the parties. Both documents are required to participate in the TSGP and they are mutually negotiated agreements that become legally binding and