

Dated: July 18, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012-18232 Filed 7-25-12; 8:45 am]

BILLING CODE 4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0001]

Food and Drug Administration Pediatric Medical Devices Workshop; Notice of Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

The Food and Drug Administration's (FDA) Office of Orphan Products Development is announcing the following workshop: FDA Pediatric Medical Devices Workshop. This meeting is intended to focus on challenges in pediatric device development—namely, business planning and funding concerns; and how sponsors can most effectively interact with the FDA. The goal of this meeting is to engage and educate pediatric innovators and device industry sponsors.

This educational meeting will consist of live presentations provided by FDA experts from various Centers and Offices, as well as from outside experts. The interactive meeting will also include a “mock” FDA pre-submission meeting for a “mock” pediatric medical device, to illustrate how such encounters may transpire. In addition, attendees will have an opportunity during lunch to engage with Pediatric Device Consortia Grant Program leaders. The meeting will be recorded for subsequent posting on the FDA Web site.

Date and Time: The meeting will be held on September 24, 2012, from 8 a.m. to 5:30 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993-0002. For participants who cannot attend the live meeting, a recorded Web cast will be made available after the meeting.

Contact: Linda Ulrich, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5206, Silver Spring, MD 20993-0002, 301-796-8686, FAX: 301-847-8621, email: megan.mcnamee@icfi.com.

Registration: Interested participants may register for this meeting at the following Web site: [https://events-](https://events-support.com/events/FDA_OOPD_Pediatric_Medical_Devices_Workshop)

[support.com/events/FDA_OOPD_Pediatric_Medical_Devices_Workshop](https://events-support.com/events/FDA_OOPD_Pediatric_Medical_Devices_Workshop). Please note that registration for the live meeting will be limited based on available seating.

If you need sign language interpretation during this meeting, please contact Linda Ulrich at: Linda.Ulrich@fda.hhs.gov by August 24, 2012.

The FDA Pediatric Medical Devices Workshop is supported by FDA's Office of Orphan Product Development and will include participants from the FDA's Center for Devices and Radiologic Health.

(FDA has verified the Web site addresses throughout this document, but we are not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

Dated: July 17, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012-18231 Filed 7-25-12; 8:45 am]

BILLING CODE 4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Draft Policy on Conferring With Urban Indian Organizations

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

ACTION: Notice, with a 45-day comment period.

SUMMARY: This Notice sets forth the Indian Health Service policy for conferring with urban Indian organizations and invites comments within 45 days. In March 2010, the Indian Health Care Improvement Act was reauthorized and amended as part of the Patient Protection and Affordable Care Act, Public Law 111-148, as amended by the Health Care and Education Reconciliation Act (together, the Affordable Care Act), Public Law 111-152. One of the changes made to the IHCA was to create a new requirement that the IHS “confer” with UIOs, to the maximum extent practicable, in carrying out the Act as defined by the Indian Health Care Improvement Reauthorization and Extension Act, as enacted and amended by the Affordable Care Act.

DATES: We will consider all comments received by September 10, 2012.

ADDRESSES: Submit comments by email to Betty.Gould@ihs.gov; or by US mail to: Ms. Betty Gould, Regulations Officer,

Indian Health Service, 801 Thompson Avenue, TMP Suite 450, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Ms. Phyllis Wolfe, Director, Office of Urban Indian Health Programs, Indian Health Service, 801 Thompson Avenue, Suite 200, Rockville, Maryland 20852. Telephone 301/443-4680 (This is not a toll free number).

Policy on Conferring With Urban Indian Organizations

5-26.1 Introduction

A. Purpose. Congress has specifically declared that it is the policy of the Nation “to ensure the highest possible health status for Indians and urban Indians.” 25 U.S.C. 1602(1). The U. S. Department of Health and Human Services (HHS) is committed to working with Indian and urban Indian communities to meet this policy. This policy applies to the Indian Health Service (IHS).

This Notice establishes the IHS policy and procedures for conferring with urban Indian organizations (UIOs). The IHS will use this conferring policy to ensure that the health care needs of the urban Indian population are considered at the local, Area, and national levels, when implementing and carrying out the Indian Health Care Improvement Act (IHCA).

B. Background. Urban Indian organizations are a major provider of health care to urban American Indians and Alaska Natives (AI/AN) across the country. When the IHCA was enacted into law in 1976, it identified the authorities, responsibilities, and functions of the IHS, the primary Federal Agency charged with providing health care to AI/AN. The IHCA included the authority for the IHS to “establish programs in urban centers to make health services more accessible to urban Indians” [Indian Health Care Improvement Act, Title V, section 501, Pub. L. 94-437, 90 Statute (Stat.) 1400, 1410 (1976), codified at 25 United States Code (U.S.C.) 1651]. The IHS carries out this authority through contracts with and grants to UIOs. In March 2010, as part of the Affordable Care Act, Congress reauthorized and amended the IHCA. The reauthorization of the IHCA included a requirement that the IHS “confer,” to the maximum extent practicable, with UIOs in carrying out the IHCA.

C. Policy. It is IHS policy to confer with UIOs, to the maximum extent practicable, whenever a “critical event or issue,” as defined in this Notice, arises in implementing or carrying out the IHCA.

D. *Requirement.* The IHClA, as amended, includes four provisions that require the IHS to confer with UIOs.

(1) Indian Health Care Improvement Act, 25 U.S.C. 1660d(b). “The Secretary shall ensure that the Service confers, to the maximum extent practicable, with urban Indian organizations in carrying out this [Act].”

(2) Indian Health Care Improvement Act, 25 U.S.C. 1602(5). “Congress declares * * * that all actions under this [Act] shall be carried out with * * * conference with urban Indian organizations, to implement this [Act]. * * *”

(3) Indian Health Care Improvement Act, 25 U.S.C. 1631(f). “The Secretary shall * * * confer with urban Indian organizations, in developing innovative approaches to address all or part of the total unmet need for construction of health facilities. * * *”

(4) Indian Health Care Improvement Act, 25 U.S.C. 1665k(a)(2)(A)(vii). “Funding provided pursuant to [25 U.S.C. 1665k “fetal alcohol spectrum disorders programs”] shall be used * * * to develop and implement * * * in conferring with urban Indian organizations, culturally sensitive assessment and diagnostic tools including * * * multidisciplinary fetal alcohol spectrum disorder clinics for use in Indian communities and urban centers.”

E. *Authorities.*

(1) Indian Health Care Improvement Reauthorization and Extension Act, as enacted and amended by the Patient Protection and Affordable Care Act, Public Law 111–148, § 10221, 124 Stat. 119, 935 (2010).

(2) Indian Health Care Improvement Act, 25 U.S.C. 1601–1683, as amended, including, §§ 1602(1), 1603(29), 1651, 1653(a).

(3) Office of Management and Budget Circular A–19.

F. *Definitions.*

(1) *Confer.* The term “confer” means to engage in an open and free exchange of information and opinions that:

- a. leads to mutual understanding and comprehension, and
- b. emphasizes trust, respect, and shared responsibility.

(2) *Conferring Activities.* The term “conferring activities” means implementing confer mechanisms, such as face-to-face meetings, teleconferences, and mailings, to solicit comments and discuss critical events or issues.

(3) *Critical Event or Issue.* A “critical event or issue,” as used in this policy, is an event or issue that significantly affects one or more UIOs. Critical events or issues are complex, have significant

implications, and are time sensitive. Examples of critical events or issues include developing program regulations, formulating the budget, allocating new resources, and changing policy, as well as public health or environmental events. When necessary, it is within the discretion of the Director, IHS, to make the final determination as to whether or not a specific event or issue qualifies as a “critical event or issue,” as defined in this policy.

(4) *IHS Confer with UIOs Report.* The term “IHS Confer with UIOs Report” means an annual report to the Secretary, HHS, describing “critical events or issues” to UIOs arising in implementing or carrying out the IHClA.

(5) *Urban Indian Organization.* The term “urban Indian organization” means a nonprofit corporate body situated in an urban center, governed by an urban Indian controlled board of directors, and providing for the maximum participation of all interested Indian groups and individuals, which body is capable of legally cooperating with other public and private entities for the purpose of performing the activities described in [25 U.S.C. 1653(a)]. 25 U.S.C. 1603(29).

5–26.2 Objectives

A. To formalize the IHS approach to conferring with UIOs to ensure that urban Indian health priorities and goals are considered.

B. To establish a minimum set of requirements and expectations with respect to conferring for the three levels of IHS management: Headquarters, Area Offices, and Service Units.

C. To identify “critical events or issues” arising in implementing or carrying out the IHClA for which conferring with UIOs will be required for the three levels of IHS management: Headquarters, Area Offices, and Service Units.

D. To identify “critical events or issues” arising in implementing or carrying out the IHClA where partnerships and the inclusion of UIOs would complement consultation with Indian Tribes.

E. To require conferring with UIOs on proposed, new, and existing health policies and programs that qualify as “critical events or issues” arising in implementing or carrying out the IHClA.

F. To promote and develop innovative methods of involving UIOs in IHS policy development and in the decision-making processes of the IHS.

G. To coordinate with the HHS Divisions or Regional Offices; State Agencies; to assist UIOs in communicating their priorities.

H. To charge and hold responsible all levels of management within the IHS for the implementation of this policy.

5–26.3 Roles

A. *Headquarters.* The Director, IHS, is responsible for providing overall guidance and direction to the Office of Urban Indian Health Programs (OUIHP) and ensuring that the IHS confers, to the maximum extent practicable, with UIOs in accordance with this policy.

The IHS has the responsibility to engage in an open and free exchange of information and opinions with UIOs that leads to mutual understanding and comprehension; and emphasizes trust, respect, and shared responsibility whenever a “critical event or issue,” as defined in this policy, arises in implementing or carrying out the IHClA. When necessary, it is within the discretion of the Director, IHS, to make the final determination as to whether or not a specific event or issue qualifies as a “critical event or issue,” as defined in this policy.

The Director, OUIHP, is responsible for monitoring compliance with this policy, including submissions to the OUIHP conferring email address: urbanconfer@ihs.gov. The Director, OUIHP, will ensure that all levels of the IHS conduct regular official conferring sessions that are publicized through correspondence or, when necessary, **Federal Register** Notices (FRN), and receive conferring reports. The Director, OUIHP, will also receive and acknowledge receipt of written correspondence from UIOs describing potential “critical events or issues” arising in implementing or carrying out the IHClA, the affected UIO(s), and the proposed conferring activity. Where applicable, OUIHP will notify all affected UIOs through a “Dear Urban Indian Health Organization Director Letter” and broadcast emails, and, if necessary, through the **Federal Register**, if the IHS will undertake any conferring activity. The notice will identify the issue, the method for conferring, and the timeline for the conferring activity. The Director, OUIHP, is responsible for preparing and submitting the annual IHS Confer with UIOs Report.

All IHS Headquarters Office Directors will provide leadership to identify potential “critical events or issues” arising in implementing or carrying out the IHClA for which conferring with UIOs will be recommended to the Director, OUIHP, and assist the OUIHP in completion of the annual IHS Confer with UIOs Report, when necessary.

B. *Area Offices.* The Area Director is responsible for regional administration, management, evaluation, contract and

grant monitoring, and funding responsibilities for the IHCA Title V-funded UIOs located in their Areas. The Area Director will provide the support and assistance to ensure that IHS confers, in accordance with this policy, with UIOs at the Area level. The Area Director will conduct regular official conferring sessions through bi-annual meetings and other conferring activities with UIOs. The Area Director will ensure that the Director, OUIHP, is informed of the Area conferring activities and outcomes for inclusion in the Annual IHS Confer with UIOs Report.

C. *Service Units.* The Service Unit Chief Executive Officer (CEO) is responsible for ensuring compliance with this policy by conferring with UIOs that are located in the Service Unit. The CEO shall provide the Service Unit conferring activities and results or outcomes through the Area Urban Coordinator, to the Area Director, who will report them to the OUIHP.

5-26.4 Confer Management

A. *Identification of Conferring Activities.* A potential “critical event or issue” arising in implementing or carrying out the IHCA may be identified by either the IHS and/or UIOs.

(1) If a potential “critical event or issue” is identified by a UIO, written correspondence must be submitted to the Director, OUIHP, (with a copy to the appropriate Area Director) describing the event or issue, the affected UIO(s), and the proposed conferring activity. The Director, OUIHP, shall acknowledge receipt of the request within 15 business days. IHS will consider whether or not to confer with affected/potentially affected UIOs in response to this request.

(2) The Director, OUIHP, shall determine whether or not a specific event or issue arising in implementing or carrying out the IHCA qualifies as a “critical event or issue,” as defined in this policy. The Director, OUIHP, shall provide an official response indicating the reason(s) why conferring will or will not be conducted. If the Director, OUIHP, determines that a “critical event or issue” has arisen in implementing or carrying out the IHCA, the Director, OUIHP, shall, in the official response, identify the conferring activity that has been selected and the timeline for the activity. In addition, if the Director, OUIHP, determines that a “critical event or issue” has arisen in implementing or carrying out the IHCA, the IHS will issue notices to all affected/potentially affected UIOs through correspondence such as a “Dear Urban Indian Health

Organization Director Letter” and broadcast emails, as well as through a FRN, if applicable. Communication will identify the “critical events or issues” to be discussed, as well as the mechanism for conferring. When necessary, it is within the discretion of the Director, IHS, to make the final determination as to whether or not a specific event or issue qualifies as a “critical event or issue,” as defined in this policy.

B. *Conferring Activity.* The IHS will conduct regular, official conferring sessions through bi-annual meetings. The bi-annual meetings shall be publicized, both through correspondence such as a “Dear Urban Indian Health Program Director Letter” and broadcast emails, and, if necessary, through a FRN. The notices will include information such as the dates and locations of the conferring sessions, the agenda, and any “critical events or issues” that will be discussed. In addition to the bi-annual meetings, other conferring activities may occur throughout the year. In the event that a confer activity will be conducted, the degree and extent of the conferring and the mechanism for conferring shall depend upon several factors, including:

- (1) the nature of the “critical event or issue,”
- (2) the number of potentially affected UIOs, and
- (3) the most cost effective and efficient conferring mechanism, based on the nature of the “critical event or issue” and the number of potentially affected UIOs.

C. *Confer Mechanisms.* The IHS will consider the following confer mechanisms as options that provide the opportunity for an open and free exchange of information and opinions that lead to mutual understanding and comprehension and emphasize trust, respect, and shared responsibility:

- (1) Mailings
- (2) Teleconferences
- (3) Regular or special program level conferring sessions
- (4) Annual meetings, such as the annual Spring Urban Indian Health Leadership Conference
- (5) Opportunities for comment, including submissions to urbanconfer@ihs.gov
- (6) Face-to-face meetings, including meetings conducted at the Area Office level or at the national-level Indian health system meetings that include the IHS, Tribes, and UIO(s).

D. *Contract- and Grant-Specific Issues.* A UIO may request to meet one-on-one with an IHS representative to confer on issues specific to that UIO and its contract and grant awards from the IHS.

E. *Unresolved Issues.* Upon the completion of any of the conferring activities in this section, the IHS will document and follow-up on any unresolved issue(s) that would benefit from the ongoing involvement of the affected UIO(s). Documentation of the conferring process and outcomes will be maintained by the OUIHP and the Area Office(s) in which the affected UIO(s) are located.

F. *Annual IHS Confer with UIOs Report to HHS.* As part of the annual IHS Confer with UIOs Report to the Secretary, HHS, the IHS shall prepare and submit an annual report describing “critical events or issues” arising in implementing or carrying out the IHCA, related conferring activities, and the results and outcomes of conferring with UIOs.

(1) The report shall address: Development of the urban Indian health program budget; development and implementation of urban Indian health program regulations and policies; and public health or environmental health critical events impacting UIOs.

(2) The report shall include a description of the “critical event or issue(s)” that was the subject of conferring, a description of the process that was used, a discussion of the recommendations that resulted from the conferring meeting(s), a list of any follow-up action items, a timeline for addressing these items, and a discussion of the level of satisfaction with the conferring process.

G. *Conflict Resolution.*

(1) The intent of this policy is to promote mutual understanding and comprehension, and to emphasize trust, respect, and shared responsibility between the IHS and UIOs.

(2) However, the IHS and UIOs may not always agree. Where such disagreement occurs, nothing in this policy creates a right of action against the IHS or the HHS for failure to comply with this policy.

5-26.5 Federal Advisory Committee Act

The Federal Advisory Committee Act (FACA) may apply to conferring activities. The FACA is implicated when an Agency establishes, manages, or controls a group that includes one or more participants who are not Federal employees for the purpose of obtaining the group’s advice or recommendations on Agency issues or policies. The FACA imposes several procedural requirements on Federal Agencies that convene advisory committees. Although FACA may not apply to groups consisting solely of Tribal leaders serving on the group in their official

capacities, UIOs do not meet the requirements of the "Tribal leader" exemption. Accordingly, any conferring activities that qualify as an advisory committee under the FACA will be required to comply with the procedures set out in FACA.

5–26.6 *Deliberative Process Privilege*

Nothing in this policy waives the Government's deliberative process privilege. Examples of the government's deliberative process privilege are as follows:

(1) When the Secretary, HHS, is specifically requested by a member or members of Congress to respond to or report on proposed legislation, the development of such responses and of related policy is a part of the Executive Branch's deliberative process privilege and should remain confidential.

(2) In specified instances, when Congress requires the HHS to work with UIOs on the development of recommendations that may require legislation, such as reports, recommendations, or other products that are developed independent of a Department position, the development of which is governed by Office of Management and Budget Circular A–19.

Dated: July 20, 2012.

Yvette Roubideaux,
Director, Indian Health Service.

[FR Doc. 2012–18300 Filed 7–25–12; 8:45 am]

BILLING CODE 4165–16–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a conference call/Webinar meeting of the Interagency Autism Coordinating Committee (IACC).

The IACC Full Committee will be having an open meeting conference call/Webinar on Friday, July 27, 2012. The committee will discuss and vote on the establishment of subcommittees, as well as discuss future IACC activities and public comments that were received at the July 10, 2012 IACC meeting. The meeting will be accessible by Webinar and conference call.

Name of Committee: Interagency Autism Coordinating Committee (IACC).

Type of meeting: Open Meeting Conference Call and Webinar.

Date: July 27, 2012.

Time: 10:00 a.m. to 2:00 p.m. *Eastern Time*—Approximate end time.

Agenda: The committee will discuss and vote on the establishment of subcommittees, and discuss future IACC activities and public comments that were received at the July 10, 2012 IACC meeting.

Place: Webinar and conference call only; No in-person meeting.

Webinar Access: <https://www2.gotomeeting.com/register/732043378>.

Conference Call: Dial: 800–857–7423

Access code: 8875622.

Cost: The conference call and Webinar is free.

Contact Person: Ms. Lina Perez, Office of Autism Research Coordination, National Institute of Mental Health, NIH, 6001 Executive Boulevard, NSC, Room 6182A, Rockville, MD 20852. Phone: (301) 443–6040. Email: IACCPublicInquiries@mail.nih.gov.

Please Note: The meeting will be open to the public and accessible via Webinar and conference call. Members of the public who participate using the conference call phone number will be able to listen to the meeting but will not be heard. If you experience any technical problems with the conference call, please email IACCTechSupport@acclaroresearch.com or call the IACC Technical Support Help Line at 443–680–0098.

If you experience any technical problems with the Web presentation tool, please contact GoToWebinar at (800) 263–6317. To access the Web presentation tool on the Internet the following computer capabilities are required: (A) Internet Explorer 5.0 or later, Netscape Navigator 6.0 or later or Mozilla Firefox 1.0 or later; (B) Windows® 2000, XP Home, XP Pro, 2003 Server or Vista; (C) Stable 56k, cable modem, ISDN, DSL or better Internet connection; (D) Minimum of Pentium 400 with 256 MB of RAM (Recommended); (E) Java Virtual Machine enabled (Recommended).

Accommodations Statement

Individuals who participate by using this electronic service and who need special assistance such as captioning or other reasonable accommodations should submit a request to the Contact Person listed on this notice at least 1 day prior to the meeting.

This meeting is being published less than 15 days prior to the meeting due to the urgent need of the committee to discuss committee structure, upcoming activities and emerging issues in the autism community.

Schedule subject to change.

Information about the IACC and a registration link for this meeting are available on the Web site: www.iacc.hhs.gov

Dated: July 20, 2012.

Carolyn A. Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2012–18192 Filed 7–25–12; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Environmental Health Sciences Review Committee.

Date: August 22–23, 2012.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Garden Inn Durham Southpoint, 7007 Fayetteville Road, Durham, NC 27713.

Contact Person: Linda K Bass, Ph.D., Scientific Review Administrator, Scientific Review Branch, Division of Extramural Research and Training, Nat'l Institute of Environmental Health Sciences, P.O. Box 12233, MD EC–30, Research Triangle Park, NC 27709, (919) 541–1307.

(Catalogue of Federal Domestic Assistance Program Nos. 93.115, Biometry and Risk Estimation—Health Risks from Environmental Exposures; 93.142, NIEHS Hazardous Waste Worker Health and Safety Training; 93.143, NIEHS Superfund Hazardous Substances—Basic Research and Education; 93.894, Resources and Manpower Development in the Environmental Health Sciences; 93.113, Biological Response to Environmental Health Hazards; 93.114, Applied Toxicological Research and Testing, National Institutes of Health, HHS)

Dated: July 20, 2012.

Carolyn A. Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2012–18195 Filed 7–25–12; 8:45 am]

BILLING CODE 4140–01–P