DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0002]

Risk Communication Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Risk Communication Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on May 5, 2011, from 8 a.m. to 5 p.m.

Location: Food and Drug Administration, 5630 Fishers Lane, Conference Room, rm. 1066, Rockville, MD 20857.

Contact Person: Lee L. Zwanziger, Office of Policy, Planning and Budget, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 3278, Silver Spring, MD 20993–0002, 301–796–9151, FAX: 301–847–8611, e-mail: *RCAC@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), and follow the prompts to the desired center or product area. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: On May 5, 2011, the committee will hear and discuss developments in FDA's ongoing communications programs. The discussion will focus on the use of different channels for information dissemination, tracking how information is gathered and spread, and thoughts on reaching less accessible target audiences.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before April 29, 2011. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. on May 5, 2011. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before April 21, 2011. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by April 22, 2011.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Lee L. Zwanziger at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: March 17, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–6788 Filed 3–22–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Memorandum of Agreement Between the Indian Health Service and the Department of Interior; Bureau of Indian Affairs and Bureau of Indian Education

AGENCY: Indian Health Service, HHS.

ACTION: Notice.

SUMMARY: The Indian Health Service (IHS) is providing notice of a Memorandum of Agreement (MOA) between the IHS and the Department of the Interior (DOI), signed in 2009, and has developed an amendment to that MOA that includes language consistent with Section 703 of the Indian Health Care Improvement Act (IHCIA), Public Law 94–437, as amended. The purpose of the MOA and the amendment is to advance our partnership with Tribes and Federal stakeholders on alcohol and substance abuse prevention and treatment. The Patient Protection and Affordable Care Act's, Public Law 111–148, permanent authorization of the Indian Health Care Improvement Act (IHCIA) establishes timelines and requirements for coordinated actions by the Department of Interior (DOI), the Department of Health and Human Services (HHS), Tribes and Tribal organizations. Specifically, Section 703 of the IHCIA provides new authorities that permit the DOI and HHS, acting through the Indian Health Service (IHS), to develop and enter into a Memorandum of Agreement (MOA), or review and update any existing memoranda of agreement, as required by Section 4205 of the Indian Alcohol and Substance Abuse Prevention and Treatment Act of 1986 (25 U.S.C.2411). DOI and IHS signed an MOA on this topic in 2009, and have developed an amendment to that MOA that includes language consistent with the new IHCIA provision. In accordance with Section 703 of the IHCIA, which states that the MOA between the IHS and DOI shall be published in the **Federal Register**, the agency is publishing notice of this MOA and the amendment to this MOA.

DATES: The original MOA was effective on December 12, 2009. The amendment is effective March 1, 2011.

FOR FURTHER INFORMATION CONTACT: Dr. Rose Weahkee, Director, Division of Behavioral Health, Office of Clinical and Preventive Services, Indian Health Service, 801 Thompson Avenue, Rockville, MD 20852, (301) 443–2038.

SUPPLEMENTARY INFORMATION: In accordance with Section 703 of the Indian Health Care Improvement Act (IHCIA), Public Law No. 94–437, as amended, which states that the MOA between the IHS and DOI shall be published in the **Federal Register**, the agency is publishing notice of this MOA and the amendment to this MOA.

Dated: March 17, 2011.

Yvette Roubideaux,

Director, Indian Health Service.

3–CPS–10–0011

OCTOBER 2009

MEMORANDUM OF AGREEMENT

BETWEEN

DEPARTMENT OF HEALTH AND HUMAN SERVICES

INDIAN HEALTH SERVICE

AND

DEPARTMENT OF THE INTERIOR

BUREAU OF INDIAN AFFAIRS

AND

BUREAU OF INDIAN EDUCATION

ON

INDIAN ALCOHOL AND SUBSTANCE ABUSE PREVENTION

I. *PURPOSE*

The Memorandum of Agreement (MOA) emphasizes assisting tribal governments in their efforts to address substance abuse. It affirms the importance of a systematic approach to enhance the quality of life. This MOA shall include coordination of data collection, resources, and programs of the Indian Health Service (IHS), the Bureau of Indian Affairs (BIA), and the Bureau of Indian Education (BIE).

The Department of Health and Human Services (DHHS) and the Department of the Interior (DOI) shall coordinate and collaborate pursuant to this MOA. Special acknowledgment is given to the rights of tribes in accordance with Indian Self-Determination and Education Assistance Act (25 U.S.C. 450, et seq.) and local control in accordance with Section 1130 of the Education Amendments of 1978 (25 U.S.C. 2010).

The tribes, in conjunction with Federal and state entities, will identify the need for services and their best applications.

II. *GOAL*

To promote tribal communities that are safe, healthy, and productive by the following means:

- Increase collaboration and coordination among the BIA, BIE, IHS, and tribes.
- Facilitate resource sharing (funding, personnel, information, knowledge, and skills) among the BIA, the BIE, IHS, and tribes.
- Support and assist local BIA agencies, schools, BIE line offices, and IHS area and service units in working with tribes in developing and implementing joint programs and services.

III. *BACKGROUND*

Substance abuse, including alcohol, illegal drugs, and controlled substances, impact the whole community. Probable consequences include depression, domestic violence, child neglect and abuse, elderly abuse, property damage, gang activity, and violent crime. It increases the burden on communities and on those Federal, state, and tribal governments attempting to assist these communities.

The production, distribution, and use of substances such as methamphetamine (meth) are not a new problem. Substance abuse threatens not only the user but threatens the well-being of the community. Related illicit acts encourage gang activities as well as organized crime on Indian lands. The production of meth results in toxic by-products that are left in buildings, fields, and waterways. Some of these chemicals can cause disfigurement, illness, or death.

American Indian youth, ages 12–17, have the highest percentage rate for illegal drug use according to the Substance Abuse and Mental Health Services Administration (SAMHSA). Prevention efforts targeting youth and young adults are the most cost-effective in addressing this problem. It has been clearly demonstrated that the younger an individual is when he/she encounters a prevention message, the better the outcome.

Illegal drugs and controlled substances present a special challenge to agencies and organizations. Supply reduction, in combination with demand reduction, must be undertaken through a comprehensive and multi-disciplinary approach if they are to be successful. The illegal production, distribution, and use of controlled substances within Indian Country is at an epidemic level. These challenges necessitate a comprehensive evaluation by the BIA, BIE, and IHS in order to address these issues.

IV. *STATEMENT OF PURPOSE*

A. Coordination Efforts

1. Juvenile and Adult Detention Centers

The IHS and BIA will collaborate to expand substance abuse resources for detoxification, treatment, and post-detention community re-entry and aftercare planning.

2. Youth Regional Treatment Centers (YRTC)

The IHS will continue to provide funding support for the operation of existing centers and to advocate for additional resources. The IHS will include BIE in the planning and identification of educational resources (curriculum, libraries, recreational facilities, computers, funds for teachers, etc.) for IHS-operated YRTC's. The BIE will be active in considering the needs of tribally-operated YRTC's. The BIE and IHS will collaborate regarding the most suitable placement to meet the needs of the individuals.

3. Residential Schools

The IHS, BIA and BIE will coordinate delivery of healthcare and wellness support services to boarding school residents and their families. The agencies will support efforts to align policies such that residents have appropriate access to healthcare services including a range of behavioral health services on-site. Such services will, where possible, be part of an integrated, holistic approach to student support that includes appropriate recognition and targeting of interventions to both general student populations and high risk students.

4. Community Based Adult Services

The IHS, BIA, and BIE will collaborate with tribes to enhance program coordination, planning, and implementation of community based prevention, referral, enforcement, treatment (both individual and family), recovery models, and implementation of programs with linkages to adjunct community services. These efforts will be implemented at the BIA agency, BIE line office, and IHS service unit levels jointly with the affected tribes.

5. Child Protection and Child Welfare

The BIA will include the BIE, IHS, and tribes in planning and implementation activities. These shall include defining the scope of services appropriate to tribal area needs and identifying resources to address the continuum of

care for American Indian children at risk for abuse and/or neglect.

The BIA, BIE, and the IHS will obtain input from local tribes on planning initiatives. This will strengthen the coordinated interagency multidisciplinary response for the protection of children and the prevention of child abuse and neglect in American Indian and Alaska Native communities, especially for drug endangered children. These agencies will continually reaffirm the need for coordinated approaches to prevent child abuse and neglect and its long-term social and economic consequences (poor academic performance, substance use, multiple disorders, suicides, etc.) and promote a full range of effective services for abused American Indian and Alaska Native children and their families.

6. Data Collection, Analysis, and Sharing

The BIA, BIE, and IHS will consult with the tribes to determine the need for sharing information, data collection systems that are compatible with current systems in use, and data resources on substance abuse and collaboration and coordination on information collection and reporting will be encouraged. Linkages will be forged with other Federal, state, and local entities. This will facilitate appropriate recommendations and decisions about programs and initiatives.

7. Joint Multi-Disciplinary Meetings

The BIA and BIE Central Offices and IHS Headquarters staff, including participation by regional, line, and area office staff, will jointly conduct multidisciplinary meetings to discuss coordination and collaboration issues and identify barriers to the implementation of this MOA. These meetings will occur not less than every 6 months.

In addition, an annual, multidisciplinary meeting will be planned and coordinated that focuses on local BIA agency superintendents and BIE line officers (including superintendents or education specialists, IHS service unit chief executive officers, and tribal health directors and facility directors). It will address organizational coordination and effective responses to the impact of substance abuse in Indian Country.

B. Organizational Responsibility

1. Central Office/Headquarters

The BIA and BIE Central Office and IHS Headquarters are responsible for:

- Designing and delivering training and technical assistance;
- Identifying and advocating for financial resources; and
- Developing a biennial program plan, including specific objectives, performance improvement measures, benchmarks/milestones, and organizational responsibilities to be completed within 6 months of the last signature of this MOA.

2. BIA Regions, BIE Line Offices, and IHS Area Offices

The BIA regional directors, BIE line officers, and IHS area directors are responsible for encouraging the development of local MOA's between the IHS, BIA, and BIE in working with the local tribe(s) to increase collaboration and cooperation, facilitate resource sharing, and to develop joint programs/services to address substance abuse.

The BIA regional directors, BIE line officers, and IHS area directors are responsible for designating a staff member to attend the semi-annual organizational planning and implementation meetings (see item IV.A.7) and report activities (accomplished, ongoing, and unaccomplished) to BIA and BIE Central Offices and IHS Headquarters.

The BIA Central Office will compile a comprehensive list of Indian Country activities (accomplished, ongoing, and unaccomplished) semiannually for distribution to all BIA regions and agencies (through the Deputy Bureau Director for Field Operations), BIE line offices (through the BIE Deputy Director, School Operations), and IHS service unit chief executive officers (through the IHS Director).

V. *IDENTIFICATION OF STATUTORY AUTHORITIES*

1. Snyder Act of November 2, 1921 (42 Stat. 208; 25 U.S.C. 13)
2. Economy Act of September 13, 1982 (96 Stat. 933; 31 U.S.C. 1535)
3. Indian Self-Determination and Education Assistance Act of January 4, 1975 (88 Stat. 2203; 25 U.S.C. 450 et seq.)
4. Anti-Drug Abuse Act of 1988 (102 Stat. 4181; 21 U.S.C. 1501)
5. Indian Alcohol and Substance Abuse Prevention and Treatment Act of 1986 (100 Stat. 3207–137; 25 U.S.C. 2401)
6. Indian Health Care Improvement Act of September 30, 1976 (90 Stat. 1400; 25 U.S.C. 1600 et seq.)
7. Indian Child Protection and Family Violence Prevention Act of November 28, 1990 (104 Stat. 4544; 25 U.S.C. 3201)
8. No Child Left Behind Act of 2001 (115 Stat. 1425; 20 U.S.C. 6301)
9. Johnson-O'Malley Act of April 16, 1934, (48 Stat. 596; 25 U.S.C. 452 et seq.)
10. Victims of Child Abuse Act of November 29, 1990 (104 Stat. 4792; 42 U.S.C. 13001 et seq.)
11. Education Amendments of November 1, 1978 (92 Stat. 2143; 25 U.S.C. 2010 et seq.)

VI. *ADMINISTRATIVE PROVISIONS*

1. Nothing in this MOA may be construed to obligate BIA, BIE, IHS, or the United States to any current or future expenditures of resources in advance of the availability of appropriations from Congress. This MOA does not obligate BIA, BIE, IHS, or the United States to spend funds on any particular project or purpose, even if funds are available.
2. This MOA in no way restricts BIA, BIE, or IHS from participating in similar activities or arrangements with other public or private agencies, organizations, or individuals.
3. BIA, BIE, and IHS will comply with the Federal Advisory Committee Act to the extent it applies.
4. Upon the last signature, this MOA shall remain in effect, unless modified or terminated by the Assistant Secretary—Indian Affairs or the Director, Indian Health Service upon 60 days written notice. The Assistant Secretary—Indian Affairs, Director, BIA, Director, BIE, and Director, IHS shall review this MOA on a biennial basis.

VII. *SIGNATURES OF EACH PARTY*

Approved and accepted by:

/Larry Echohawk/ Assistant Secretary—Indian Affairs	10/13/09 Date
/Yvette Roubideaux/ Director, Indian Health Service	12/16/09 Date
/Spike Bighorn/ (Acting) Director, Bureau of Indian Education	10/15/09 Date
/Jerry Gidner/ Director, Bureau of Indian Affairs	10/20/09 Date

Amendment to Memorandum of Agreement

between

Department of Health and Human Services

Indian Health Service

and

The Department of the Interior

Bureau of Indian Affairs and Bureau of Indian Education

on

Indian Alcohol and Substance Abuse Prevention

PURPOSE

Pursuant to the Patient Protection and Affordable Care Act, Pub. L. No. 111–148, Title X, Subtitle B, Part III, § 10221(a), 124 Stat. 119, 935 (amending 25 U.S.C. §§ 1665, 1665a, and 2411), this amendment updates the "October 2009 Memorandum of Agreement (MOA) between the Department of Health and Human Services (DHHS) Indian Health Service (IHS) and the Department of the Interior (DOI) Bureau of Indian Affairs (BIA) and Bureau of Indian Education (BIE) on Indian Alcohol and Substance Abuse Prevention."

AMENDMENTS

The October 2009 MOA is amended, as follows:

(1) The first sentence of **SECTION I** is amended to read:

I. *PURPOSE*

The Memorandum of Agreement (MOA) emphasizes assisting tribal governments in their efforts to address certain behavioral health issues among Indians, specifically mental illness and dysfunctional and self-destructive behavior, including substance abuse, child abuse, and family violence.

(2) **Section IV A.** is amended to read as follows:

2. Youth Regional Treatment Centers (YRTC)

The IHS will continue to provide funding support for the operation of existing centers and the implementation within the centers of alcohol and substance abuse treatment programs. IHS will also advocate for additional resources. The BIE will provide resources and funding for the education of the young people receiving treatment in the YRTCs (curriculum, libraries, recreational facilities, computers, funds for teachers, etc.), and will actively identify and seek funding and resources available from the states and other entities. IHS and BIE will work collaboratively to meet the needs of the YRTC residents.

(3) A new paragraph is added to **Section IV A. Coordination Efforts:**

8. Certain Behavioral Health Issues

IHS, BIA, and BIE will collaborate to:

(a) Assess the scope and nature of mental illness and dysfunctional and self-destructive behavior, including substance abuse, child abuse, and family violence, among Indians;

(b) Identify existing Federal, tribal, State, local, and private services, resources, and programs available to provide behavioral health services for Indians;

(c) Determine the unmet need for additional services, resources, and programs necessary to improve the mental and behavioral health of Indians;

(d) Support the right of Indians, as citizens of the United States and of the States in which they reside, to have access to behavioral health services to which all citizens have access;

(e) Delineate the responsibilities of IHS and BIA, including mental illness identification, prevention, education, referral, and treatment services (including services through multidisciplinary resource teams), at the central, area, and agency and service unit, service area, and headquarters levels;

(f) Develop a strategy for the comprehensive coordination of behavioral health services provided by IHS and BIA, including:

(i) the coordination of alcohol and substance abuse programs of IHS, BIA, and Indian tribes and tribal organizations developed under the Indian Alcohol and Substance Abuse Prevention and Treatment Act with behavioral health initiatives, particularly with respect to the referral and treatment of dually diagnosed individuals requiring behavioral health and substance abuse treatment, and;

(ii) ensuring that IHS and BIA programs and services (including multidisciplinary resource teams) addressing child abuse and family violence are coordinated with such non-Federal programs and services.

(g) Direct appropriate officials, particularly at the agency and service unit levels of BIA and IHS, to cooperate fully with tribal requests made pursuant to community behavioral health plans adopted under section 702(c) [25 U.S.C. § 1665a(c)] and section 4206 of the Indian Alcohol and Substance Abuse Prevention and Treatment Act.

(4) A new paragraph is added to **Section IV B. Organizational Responsibility:**

3. IHS shall assume responsibility for:

(a) the determination of the scope of the problem of alcohol and substance abuse among Indians, including the number of Indians within the jurisdiction of the Service who are directly or indirectly affected by alcohol and substance abuse and the financial and human cost;

(b) an assessment of the existing and needed resources necessary for the prevention of alcohol and substance abuse and the treatment of Indians affected by alcohol and substance abuse, and;

(c) an estimate of the funding necessary to adequately support a program of prevention of alcohol and substance abuse and treatment of Indians affected by alcohol and substance abuse.

(5) A new paragraph is added to **Section VI ADMINISTRATIVE PROVISIONS:**

5. The Secretaries of DHHS and DOI will conduct an annual review of this MOA which will be provided to Congress and Indian tribes and tribal organizations.

(6) Paragraph (4) in **Section VI** is amended to read:

4. Upon the last signature, this MOA shall remain in effect, unless modified or terminated by the Assistant Secretary—Indian Affairs or the Director, Indian Health Service or the Director, Bureau of Indian Education, or the Director, Bureau of Indian Affairs, upon 60 days' written notice.

(7) **Section V** is amended to read:

6. Indian Health Care Improvement Act of September 30, 1976 (90 Stat. 1400; 25 U.S.C. 1600 et seq.) as amended by Patient Protection and Affordable Care Act, Pub. L. No. 111–148, Title X, Subtitle B, Part III, § 10221(a), 124 Stat. 119, 935 (amending 25 U.S.C. §§ 1665, 1665a, 2411).

Signatures of Each Party

/Yvette Roubideaux/

Director, Indian Health Service
Department of Health and Human Services
Date: March 1, 2011

/Larry Echohawk/

Assistant Secretary—Indian Affairs
Department of the Interior
Date: March 1, 2011

[FR Doc. 2011–6826 Filed 3–22–11; 8:45 am]

BILLING CODE 4165–16–P