

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Subcommittee for Dose Reconstruction Reviews (SDRR), Advisory Board on Radiation and Worker Health (ABRWH or the Advisory Board), National Institute for Occupational Safety and Health (NIOSH)

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease Control and Prevention (CDC), announces the following meeting for the aforementioned subcommittee:

Time and Date: 9 a.m.–5 p.m., September 29, 2011.

Place: Cincinnati Airport Marriott, 2395 Progress Drive, Hebron, Kentucky 41018, Telephone: (859) 334-4611, Fax: (859) 334-4619.

Status: Open to the public, but without a public comment period. To access by conference call dial the following information 1 (866) 659-0537, Participant Pass Code 9933701.

Background: The Advisory Board was established under the Energy Employees Occupational Illness Compensation Program Act of 2000 to advise the President on a variety of policy and technical functions required to implement and effectively manage the new compensation program. Key functions of the Advisory Board include providing advice on the development of probability of causation guidelines that have been promulgated by the Department of Health and Human Services (HHS) as a final rule; advice on methods of dose reconstruction, which have also been promulgated by HHS as a final rule; advice on the scientific validity and quality of dose estimation and reconstruction efforts being performed for purposes of the compensation program; and advice on petitions to add classes of workers to the Special Exposure Cohort (SEC).

In December 2000, the President delegated responsibility for funding, staffing, and operating the Advisory Board to HHS, which subsequently delegated this authority to CDC. NIOSH implements this responsibility for CDC. The charter was issued on August 3, 2001, renewed at appropriate intervals, and will expire on August 3, 2013.

Purpose: The Advisory Board is charged with (a) Providing advice to the Secretary, HHS, on the development of guidelines under Executive Order 13179; (b) providing advice to the Secretary, HHS, on the scientific validity and quality of dose reconstruction efforts performed for this program; and (c) upon request by the Secretary, HHS, advise the Secretary on whether there is a class of employees at any Department of Energy facility who were exposed to radiation but for whom it is not feasible to estimate their radiation dose, and on whether there is reasonable likelihood

that such radiation doses may have endangered the health of members of this class. The Subcommittee for Dose Reconstruction Reviews was established to aid the Advisory Board in carrying out its duty to advise the Secretary, HHS, on dose reconstruction.

Matters To Be Discussed: The agenda for the Subcommittee meeting includes: Discussion of dose reconstruction cases under review (sets 7–10); DCAS dose reconstruction quality management and assurance activities.

The agenda is subject to change as priorities dictate.

In the event an individual wishes to provide comments, written comments may be submitted. Any written comments received will be provided at the meeting and should be submitted to the contact person below well in advance of the meeting.

Contact Person for More Information: Theodore Katz, Executive Secretary, NIOSH, CDC, 1600 Clifton Road, Mailstop E-20, Atlanta, Georgia 30333, Telephone: (513) 533-6800, Toll Free: 1 (800) CDC-INFO, E-mail: ocas@cdc.gov.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention, and the Agency for Toxic Substances and Disease Registry.

Dated: August 29, 2011.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2011-22934 Filed 9-7-11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Advisory Committee to the Director (ACD), Centers for Disease Control and Prevention (CDC)—Ethics Subcommittee (ES)

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease Control and Prevention (CDC) announces the following meeting of the aforementioned subcommittee:

Time and Date: 1 p.m.–1:30 p.m., October 5, 2011.

Place: Teleconference.

Status: Open to the public, limited only by availability of telephone ports. The public is welcome to participate during the public comment period. A public comment period is tentatively scheduled for 3 p.m.–3:15 p.m. To participate in the teleconference, please dial (877) 928-1204 and enter code 4305992.

Purpose: The ES will provide counsel to the ACD, CDC, regarding a broad range of

public health ethics questions and issues arising from programs, scientists and practitioners.

Matter To Be Discussed: The ES will review workgroup progress on developing practical tools to assist state, tribal, local, and territorial health departments in their efforts to address public health ethics challenges.

The agenda is subject to change as priorities dictate.

Contact Person for More Information: Drue Barrett, PhD, Designated Federal Officer, ACD, CDC—ES, CDC, 1600 Clifton Road, NE., M/S D-50, Atlanta, Georgia 30333. Telephone (404) 639-4690. E-mail: d Barrett@cdc.gov.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: August 31, 2011.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2011-22931 Filed 9-7-11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Tribal Consultation Policy

AGENCY: Administration for Children and Families.

ACTION: Final policy issuance.

SUMMARY: This document contains the final Administration for Children and Families (ACF) Tribal Consultation Policy outlining the policy to engage in meaningful consultation with federally recognized tribes and the procedures and processes to be followed by tribes and the ACF bureaus and offices when the need for consultation is requested or required.

DATES: The effective date of this policy is the date of signature by the Acting Assistant Secretary for Children and Families.

ADDRESSES: You can download a copy of this policy at the following Internet address: <http://www.acf.hhs.gov/tribal/index.html>.

FOR FURTHER INFORMATION CONTACT: Lillian Sparks, Commissioner, Administration for Native Americans, 370 L'Enfant Promenade, SW., Washington, DC 20447. Telephone: 202-401-5590.

SUPPLEMENTARY INFORMATION:

Background

On November 5, 2009, President Obama signed the Memorandum for the Heads of Executive Departments and Agencies titled "Tribal Consultations." The President stated that his Administration is committed to regular and meaningful consultation and collaboration with tribal officials in policy decisions that have tribal implications including, as an initial step, through complete and consistent implementation of Executive Order 13175. Accordingly, President Obama directed each agency head to submit to the Director of the Office of Management and Budget (OMB) within 90 days after the date of the memorandum, a detailed plan of actions the agency will take to implement the policies and directives of Executive Order 13175.

The Department of Health and Human Services (HHS) has taken its responsibility to comply with Executive Order 13175 very seriously over the past decade, including the initial implementation of a Department-wide policy on tribal consultation and coordination in 1997, and through multiple evaluations and revisions of that policy. The most recent version of the HHS Tribal Consultation Policy was signed by Secretary Kathleen Sebelius on December 14, 2010. As a result of the commitment to tribal consultation by President Obama and Secretary Sebelius, the Administration for Children and Families (ACF) convened a Tribal Federal Workgroup (TFWG) to develop a draft Tribal Consultation Policy for ACF. Below is a timeline of activities leading to the final ACF Tribal Consultation Policy that is published with this report.

- June 22, 2010, Principal Deputy Assistant Secretary David A. Hansell, on behalf of the Assistant Secretary for Children and Families Carmen R. Nazario, established the Native American Affairs Advisory Committee.

- July 23, 2010, Acting Assistant Secretary David A. Hansell sent a letter to all tribal leaders requesting nominations from each of the ten ACF regions to participate in an ACF TFWG.

- August 23–24, 2010, the TFWG met for the first time in Washington, DC, to develop the first draft of the ACF Tribal Consultation Policy.

- August 24, 2010, Acting Assistant Secretary David A. Hansell sent a letter to all tribal leaders announcing the 2010 ACF Tribal Consultation Session to be held in Washington, DC, to discuss the draft policy and ACF programs.

- September 2, 2010, ACF published a **Federal Register** (FR) notice formally

announcing the 2010 ACF Tribal Consultation Session. 75 FR 53975 (Sep. 2, 2010).

- September 16–17, 2010, the TFWG held a second workgroup meeting in Minneapolis, Minnesota, to continue development of the draft ACF Tribal Consultation Policy.

- September 28, 2010, ACF held a Tribal Resource Day in Washington, DC. This session focused on the interoperability of ACF's various programs. This event was attended by 150 registered participants.

- September 29, 2010, ACF held a Tribal Consultation Session in Washington, DC. This session focused on the draft ACF Tribal Consultation Policy and ACF program issues. This event was attended by 150 registered participants.

- September 30, 2010, the ACF TFWG met in Washington, DC, to discuss and incorporate, where possible, suggestions to the draft Consultation Policy that were presented during the ACF Tribal Consultation Session.

- December 16, 2010, the revised ACF Tribal Consultation Policy was published in the FR seeking comments for 45 days. 75 FR 78709 (Dec. 16, 2010). The comment period closed on January 31, 2011.

- March 7–8, 2011, the ACF TFWG met for a fourth and final time in Washington, DC, to review and incorporate, where possible, the recommendations to the ACF Tribal Consultation Policy.

Explanation and Summary of Comments: Fourteen written comments were received from tribal leaders and tribal organizations in response to the FR notice published on December 16, 2010, requesting public comment on the draft ACF Tribal Consultation Policy.

General comments on the policy included the following: (1) The draft policy should include urban Indian representation; (2) HHS and ACF must develop a self-governance compacting pilot program for tribes; (3) ACF should apply the HHS Tribal Consultation Policy by simply substituting "ACF" for "HHS" throughout the document; and (4) it is difficult to determine if the terms "ACF" and "ACF program offices" are meant to be used interchangeably. ACF's response to these comments are: (1) We will refer to the HHS policy that states government-to-government as the basis for consultation; (2) the Department as a whole is looking at ways to expand self-governance and ACF is also looking closely at this issue; (3) there are directives under the HHS policy for each operating division to further refine their process and ACF is taking this

opportunity to create a division-wide policy for all ACF programs; and (4) "ACF" and "ACF program offices" are interchangeable and a definition for ACF was added to the policy that specifically states this.

1. Introduction

It was suggested that the first paragraph of the policy under the introduction section should be exchanged with the second paragraph, and the opening statement regarding President Obama's Executive Memorandum be moved to either the Background section or some sort of History section. ACF did not accept this comment as the Workgroup wanted to acknowledge the current directive by the current Administration as the impetus for the development of this consultation policy.

2. Purpose

One comment suggested that the *Purpose* section might be an appropriate place to state clearly that this policy applies to all offices of ACF. This comment was accepted and the policy was revised accordingly in this section.

Two comments recommended that a statement be added to the policy that ACF shall also abide by the HHS Consultation policy. This comment was accepted and the policy was revised accordingly in this section.

A third comment stated that the policy needed to contain specific language requiring that consultation be more than a request for comments. This comment is addressed in *Section 6. Consultation Principles*, which addresses the meaning of consultation.

3. Background

One comment stated that the language in the original HHS Tribal Consultation Policy was more respectful and protective of Indian sovereignty than the ACF language and recommended a change to use the language in the HHS policy. This comment was accepted and the language was incorporated in the policy under *Section 3. Background*.

4. Tribal Sovereignty

One comment stated that under the Federal Trust Doctrine, the United States and its individual agencies of the Federal Government owe a duty of protection and a fiduciary duty to tribes. It was suggested that ACF address in its policy how it plans to meet its trust responsibility to protect tribal resources and treaty rights "to the fullest extent possible." ACF added language that the policy does not diminish any rights and is using language consistent with the HHS Tribal Consultation Policy. The

Workgroup felt that the language “to the fullest extent possible” might be seen as limiting ACF’s responsibility to tribes and therefore declined to accept the suggestion.

5. Background on ACF

A comment suggested adding language that clearly binds ACF to follow the HHS Consultation Policy. This comment was accepted and is addressed under *Section 2. Purpose*; the ACF Tribal Consultation Policy will comply with the overall HHS Tribal Consultation Policy.

Another comment suggested that the Native American Affairs Advisory Council (NAAAC) would be better served if there were a tribal component to it to advise ACF of specific priorities, the effect ACF programs have on the priorities, and to more effectively focus limited resources to respond to local tribal needs and priorities. ACF’s response was the NAAAC serves as an internal working group to provide better coordination, collaboration and promote interoperability within ACF. ACF will continue to utilize TFWGs that incorporate tribal leadership to inform ACF leadership and develop ACF-wide policies, including the Tribal Consultation Policy.

6. Consultation Principles

Again, a comment suggested adding language that clearly binds ACF to follow the HHS Tribal Consultation Policy to supplement and not repeat HHS policy. ACF’s response to this comment was that ACF policy will comply with HHS policy and language has been added to *Section 8. Consultation Process*, to further clarify the steps necessary by either ACF or tribe(s) to initiate consultation. There is also a process to resolve an impasse in *Section 11. ACF-Tribal Conflict Resolution*. A similar comment recommended that a substantive, stand-alone paragraph be inserted stating: “ACF is bound by the HHS Tribal Consultation Policy in full. Nothing in the ACF Tribal Consultation Policy shall be construed as diminishing any of the obligations imposed on ACF by the HHS Tribal Consultation Policy. When any provision of the ACF Tribal Consultation Policy conflicts with the HHS Tribal Consultation Policy, the HHS Tribal Consultation Policy controls.” ACF’s response to this comment was the Workgroup added a stand-alone paragraph to *Section 2. Purpose*.

Another comment requested clarification on the meaning of an “enhanced form of communication” because “enhanced communication”

may be interpreted as simply requiring ACF to send a letter to a tribal official offering to initiate consultation without additional follow through or communication on actions that affect tribal interests. This ACF policy clarifies that either the U.S. Government or an Indian Tribe can initiate consultation, and the steps and timeline for an ACF response, as well as a reporting of outcomes is included in this policy.

Another comment felt that the definition of “consultation” was too vague. It was recommended that the definition should incorporate more of the intergovernmental concepts of Executive Order 13175. ACF would like to refer the commenter to *Section 7. Consultation Parties* of the policy, wherein ACF outlines the parties to the consultation process and the government-to-government nature of the process.

Another comment recommended that the ACF policy contain a clear statement, similar to the HHS policy, that consultation shall take place with *Indian tribes*. In the HHS Tribal Consultation Policy, *Section 7. Consultation Participants and Roles*, it states for Indian tribes, “The government-to-government relationship between the U.S. and Federally recognized Indian Tribes dictates that the principle focus for HHS consultation is Indian tribes * * *” This comment is addressed in the ACF policy under *Section 2. Purpose*.

Several comments were received regarding the scope and duration of consultation. There was a recommendation to restore the foundational language from the HHS Tribal Consultation Policy as the core policy statement in the ACF Tribal Consultation Policy. ACF’s response to the above comments is ACF will follow HHS policy that institutes a protocol for tribal officials (elected or designated authorized representatives). ACF also modified paragraph 2 of this section to further address these comments.

7. Consultation Parties

A comment to this section stated that meaningful consultation requires consultation between tribal leaders and decision makers within ACF—both the administrative agency decision makers and the regional staff with decision-making authority over day-to-day issues. ACF’s response to this comment was that ACF Regional Administrators will play a facilitative role and assist with resolving programmatic issues. Their responsibilities do not extend to policy making.

8. Consultation Process

One comment to this section asked that ACF ensure the policy includes a spirit of interactive dialogue, concluded by a consensus of the decision between the tribe and agency representative to be implemented. ACF’s response to this comment was that this is the intent of the policy and is included in the definition of consultation.

Other comments centered on the possible limitation of actions (legislative proposal, new rule adoption, and other policy changes) that cause ACF to consult with the tribes. ACF’s response to these comments was that the concerns have been addressed in this policy and have expanded the description of the process in this section. In addition, a definition of “action” has been added to *Section 13. Definitions*.

Two comments addressed the parties who can initiate consultation and recommended that consultation can be initiated by either the tribe(s) or the agency, and appropriate information be provided to the other party(ies) when consultation is requested. ACF agreed with these comments and expanded the description of the process in this section.

Another comment addressed the ACF definition of a tribe’s representative for consultation and stated that this is a departure from the HHS Tribal Consultation Policy which makes designation of the tribal representative the tribe’s choice. ACF points out that consultation parties are addressed in *Section 7. Consultation Parties* of the policy and includes elected or appointed leaders and authorized representatives as appropriate tribal representatives.

One comment addressed the proper notification of consultation and method of consultation “as determined by ACF” as being restrictive to open dialogue. ACF removed “as determined by ACF” to meet the concern that ACF is the only determinant of need for or method of tribal consultation.

Two comments addressed the need to provide sufficient notice for consultation to ensure meaningful consultation. ACF has addressed this concern and has committed to providing no less than a 30 day notice of subject, date, time, and location of meeting.

Two comments addressed the methods of consultation “as determined by the parties.” It was recommended that ACF identify examples for the method of consultation. ACF accepted the comments and addressed them by revising the section to include examples of methods of consultation.

Two other comments addressed meetings as acceptable methods of consultation and asked ACF to clarify by specifically identifying the meetings as consultation meetings. ACF accepted the comments and addressed this accordingly in the policy.

One comment addressed using correspondence as an appropriate method of consultation and asked for further clarification to state that consultation may occur in the form of written communications. ACF accepted this comment and revised this section accordingly.

Another comment regarding correspondence recommended language on how ACF should respond to tribes when using correspondence as the method of consultation. ACF felt this comment was directed more towards individual Bureau/Office required consultations which is addressed in *Section 9. ACF Consultation and Communication Responsibilities, C.* of the policy.

Two comments were received on the use of the FR as an appropriate method of consultation and asked that this method be removed from the policy. ACF's response to this recommendation was tribal and Federal budgets may at times preclude face-to-face or teleconference meetings; therefore, a FR notice remains a method to communicate and receive input on issues. Also the FR is a useful tool for soliciting input for broad-based issues. However, the FR should be used in conjunction with other methods. The policy was revised accordingly to include language stating, "The **Federal Register** will not be used as a sole method of communication for consultation."

Two comments were received on the "Reporting of Outcome" asking ACF to develop a process to report back to tribes on actions taken or to be taken to resolve issues/concerns such as sending out an email alert informing tribes that reports are available and specifically where they can be obtained on the Web site. ACF will widely distribute reports using all available methods of communication, including emailing and web hosting of documents. This issue is also addressed in *Section 9. ACF Consultation and Communication Responsibilities, C., 4., 5., and 8.* of the policy.

One comment addressed the issue of State compliance with ACF program requirements while serving Indian populations. The commenter recommended ACF provide an opportunity for nonbinding mediation between State and tribal officials. The commenter went on to state, "If

mediation results in an impasse, ACF should take tangible, constructive and/or disciplinary steps to enforce accountability." ACF's response was that the policy for noncompliance of States is outside the purview of this Tribal Consultation Policy.

One comment was received about the provision at *Section 8., J. Meaningful Outcomes*, which was added after the September 29, 2010, consultation session. The commenter advised ACF that it believed the provision opposes the true objectives of tribal consultation. The commenter recommended that language from the HHS Tribal Consultation Policy be used in lieu of the ACF language in this section. ACF disagreed with this comment and advised that this section reflects that all parties have engaged in a meaningful dialogue regarding ACF policies.

Comments were received regarding ACF facilitating consultations and outcomes between tribe(s) and States administering ACF programs. ACF accepted the comments and the revisions are reflected in this section, in *Section 9. ACF Consultation and Communication Responsibilities, C. Individual Consultation Responsibilities*. The TFWG also noted that the Office of Intergovernmental Affairs has the authority to facilitate consultations between States and HHS programs.

A comment regarding waivers in this section recommended that the policy make it clear that this section applies to all agencies under ACF. ACF added language in *Section 2. Purpose*, to emphasize that this policy (including this section) applies to all ACF offices.

A comment that the ACF policy omits "consistent with the applicable Federal policy objectives" (as included in E.O. 13175) and replaces it with, "to achieve established ACF program objectives" substantially diminishes tribal flexibility. ACF policy complies with HHS policy and is intended to supplement that policy and not repeat the HHS Tribal Consultation Policy verbatim. ACF is willing to provide waivers in compliance with Executive Order 13175, *Consultation and Coordination With Indian Tribal Governments*, and Executive Order 13272, *Proper Consideration of Small Entities in Agency Rulemaking*. However, ACF did not accept a recommendation to remove the language "to the extent practicable and permitted by law." ACF believes this language ensures that ACF will not commit itself to consultation in situations where consultation is not practicable (e.g., in an emergency or disaster situation

where human services needs must be expediently assessed).

One comment stated that it is unclear under the current draft which party would bear the burden of proof when there is a dispute over a consultation outcome. The commenter strongly believes the program office should do so as it has the duty, in accordance with its trust responsibility to tribal nations, to ensure that its policies and programs meet the needs of tribal communities. A similar comment stated that the ACF policy places the "elevation of issues" under the waiver section and "limits sovereign prerogatives" that are recognized in the HHS Tribal Consultation Policy. The commenter recommended that the elevation of issues appear with the conflict resolution section and include the following statement from the HHS policy: "Indian tribes may elevate an issue of importance to a higher or separate decision-making authority." ACF agreed with both of the comments and has outlined the process to elevate an issue for conflict resolution in the policy.

9. ACF Consultation and Communication Responsibilities

One comment asked ACF to clarify how the States and Regional Offices will be woven into the consultation policies. ACF would like to point the commenter to the revisions to *Section 9., C. Individual Program Consultation Responsibilities, 7.*

Another comment asked ACF to set the annual date for an Annual Tribal Consultation session in a manner that provides plenty of notice to tribes for planning purposes. ACF accepted this comment and states there will be a minimum of 30 days notice for tribal consultation meetings.

A comment regarding "Individual Program Consultation Responsibilities" asked ACF to provide regional consultations to afford as many affected tribes the opportunity to attend by directing Regional Office principals to arrange and initiate consultation. ACF's response was that ACF participates in the HHS Regional Consultations and encourages tribes to attend these events to address ACF issues.

One comment asked ACF to provide a single point of contact (SPOC) for information to tribes and keep it current. ACF agreed with this comment and advises that this information will be kept current on the ACF Web site.

One comment asked that all internal manuals, procedures, protocols, guidelines, and forms that set forth the processes by which HHS takes actions that affect tribes be amended to integrate

the tribal consultation requirements. ACF stated that the ACF consultation policy is a supplemental document that should be read in conjunction with ACF manuals and procedures. ACF will provide a briefing for staff on the ACF Tribal Consultation Policy once it is completed and reference the HHS Tribal Consultation Policy.

One comment urged ACF to consider holding regional consultation sessions in addition to the agency-wide annual consultation sessions proposed by the consultation policy. The commenter believes that by conducting regional consultation sessions, ACF can develop priorities for the national meeting, as well as foresee the specific types of agency actions that will require tribal consultation in the future. ACF's response was that due to fiscal constraints, ACF will continue to participate in the HHS regional consultation meetings and encourage tribes to participate in these sessions to address ACF policy. In addition, tribes can request consultation following the process outlined in *Section 8. Consultation Process*.

10. ACF Performance and Accountability

One comment supported the proposed use of ACF's Annual Performance Plan and suggested the creation of ACF TFWGs that "will develop and discuss agency-wide policies that impact Indian tribes" to gauge the efficacy of the policy. In addition to providing meetings with representatives from tribal organizations and forums for tribal viewpoints, the commenter proposed that these workgroups should also convene to monitor the success of the consultation policy. Further, as another means to ensure accountability, it is recommended that ACF strengthen its communication and coordination with HHS. For example, the commenter suggested that when ACF proposes legislation, new or amended regulations, or other policy initiatives, it should report to the Secretary about what the tribal implications may be and what consultation preceded the proposal. It was also recommended that in order to foster consistency within the Department, ACF should report to HHS its training activities and other programs intended to raise awareness of the unique situations faced by tribes. ACF agreed with these comments and will continue to put forth efforts in this regard.

A comment was received to define "various partners" or remove it from paragraph of this section because it is unclear as to who the partners are. ACF agrees to remove the words because we

are unable to clearly define who the partners may be.

Another comment on this section was to elaborate in greater detail its compliance with *Section 6. Objectives*, of the HHS Tribal Consultation Policy on accountability—there should be more attention paid to outlining the process for determining whether compliance is happening. The commenter suggested if ACF program offices "design indicators to ensure accountability * * *," that this be a topic specifically discussed with the tribes for ideas on how to measure performance. ACF would like to direct the commenter to *Section 10. ACF Performance and Accountability, D.*, of the policy where the formulation of indicators is discussed.

One comment referred to the HHS Tribal Consultation Policy, *Section 13. Evaluation, Recording of Meetings and Reporting*, regarding measuring the level of satisfaction of the Indian tribes on an annual basis and noted that this language is missing from the ACF Tribal Consultation Policy. Although the ACF policy is meant to supplement the HHS policy, the commenter believed this language should be included in the ACF policy as well. ACF's response was that ACF works with the HHS Office of Intergovernmental Affairs (IGA) and will comply with HHS Tribal Consultation Policy, *Section 13*.

One comment recommended that the ACF policy be enhanced by including a requirement for ACF to conduct at a minimum an annual satisfaction survey of the tribes to achieve the objectives of President Obama's memorandum of November 9, 2010. ACF's response was that ACF will be a part of the HHS Consultation Progress Report to the Office of Management and Budget.

Another comment recommended that a mechanism be adopted for the tribes to report on agency compliance, including sanctions for non-compliance or poor performance. ACF disagreed with this comment and stated that it is not feasible at this time.

11. ACF-Tribal Conflict Resolution

One comment recommended that effective tribal liaisons be hired within key ACF program divisions to advocate for tribes. ACF's response to this recommendation is the creation of new positions and subsequent hiring is a matter of budget/resources. ACF already has designated individuals within each program office who represent their office on an internal workgroup. A listing of the designated individuals can be found on the ACF Tribal webpage at <http://www.acf.hhs.gov/tribal/index.html>.

One comment recommended that the policy include a Conflict Resolution section, and should discuss what process can be used to address any issues. ACF accepted this recommendation and this section has been expanded to detail the conflict resolution process.

Another comment recommended that the policy include a stay of a proposed action until that consultation process has been completed in compliance with the policy. ACF's response was that *Section 8. Consultation Process*, requires consultation to occur prior to any action that will significantly impact a tribe or tribes. *Section 11* also incorporates the stay of a proposed action until the resolution of the conflict resolution process as well.

12. Workgroups and Advisory Committees

One comment recommended a change to "ACF may convene Tribal/Federal Workgroups" to "ACF will convene Tribal/Federal Workgroups." The commenter also recommended adding a section stating ACF understands the workgroups and advisory committees do not take the place of formal tribal consultation. ACF accepted this recommendation and modified the wording in this section and also added that the convention of workgroups is subject to available funding.

Another comment on this section asked that ACF seek input from the tribe(s) when the need to convene a TFWG is indicated. ACF accepted this recommendation and ACF will seek tribal nominations when convening a TFWG.

One comment suggested that TFWGs be required to participate in any ACF new hire orientation training that addresses the government-to-government relationship with tribes, with particular attention to the differences between American Indian tribes and Alaska Native tribes' structure of governance, land jurisdictions, and tribal-State relations. ACF stated that it will encourage all TFWG members to participate in the online training available at <http://tribal.golearnportal.org/>.

Another comment addressed the language used to define tribal official. ACF removed language to clarify that ACF TFWG will comply with HHS and the Federal Advisory Committee Act (FACA).

One comment wanted clarification on whether or not the need to include retaining ACF's "right to meet with various representatives of organizations on an individual basis" is necessary. The commenter asked that ACF clarify

this requirement by including language such as, “ACF understands that organizations cannot and do not represent all tribes.” A similar comment advised that these meetings have been construed by some ACF program offices as tribal consultation. This section should clearly state that ACF meetings with various associations, organizations, or committees are not to be construed as tribal consultation. ACF’s response to all the above comments was that meetings in groups as described in this section, A–E, will not be construed as tribal consultation and a statement to that effect is added in *Section 12. Workgroups and Advisory Committees, F.*

One comment asked ACF to emphasize the importance of holding States accountable for their actions when implementing ACF programs. ACF’s response is that ACF will work to ensure States are fully compliant with ACF programs and serve all populations the State included in their application, see *Section 9. ACF Consultation and Communication Responsibilities, C. Individual Program Consultation Responsibilities, 7.*

13. Definitions

In response to a comment regarding the possible limitation of the definition for “action,” a new definition for “action” has been added to this section. Also in response to the comment regarding “ACF” and “ACF program office” and their interchangeability, a definition for the “Administration for Children and Families (ACF)” has been added to clarify that the terms are interchangeable throughout the document.

One comment asked ACF to delete the definition for “consortia of tribes” as it is not used in the body of the ACF policy. In response to this comment, ACF believes it is important for ACF to acknowledge that several tribes operate programs in consortia and have retained the definition.

One comment recommended that ACF delete the definition of “Indian Organization,” stating this is a completely different definition from the one appearing in the HHS policy, it is not used in the body of the ACF policy, and the HHS definition makes an important point about their role that is omitted here: “The government does not participate in government-to-government consultation with these entities; rather these organizations represent the interests of tribes when authorized by those tribes.” ACF did not accept the recommendation to delete the definition; rather, it expanded the

definition by adopting the HHS Tribal Consultation Policy definition.

One commenter supported the inclusion of the definition of “Indian tribe” as articulated in Public Law 93–638 (25 U.S.C. 450b). They urged that the policy continue to utilize the definition of “Indian tribe” as articulated in Public Law 93–638 (25 U.S.C. 450b(e)) rather than the Federally Recognized Tribe List Act of 1994, (25 U.S.C. 479a). ACF accepted the suggestion to keep the definition from 25 U.S.C. 450b(e) in the ACF Tribal Consultation Policy. Regarding the definition of “Indian,” one commenter mentioned that the definition of Indian as a member of a federally recognized tribe rather than a member of an Indian tribe, as defined under the Self-Determination Act definition, excludes many Alaska Native people who are not members of tribes, but who are shareholders in Alaska Native corporations. ACF agreed and has used the broadest definition for Indian and the concern is satisfied with using 25 U.S.C. 450b(d).

A definition for “Joint Tribal Federal Workgroups and/or Task Forces” has been added to clarify that working with these workgroups does not constitute tribal consultation.

One comment recommended the deletion of the term and definition of “Inter-Tribal Organization” because it is not used in the body of the ACF policy, nor does it appear in the HHS policy. ACF accepted this recommendation and deleted the term and definition.

One comment recommended the deletion of the term and definition of “Non-Recognized Tribe” because it is not used in the body of the ACF policy, nor does it appear in the HHS policy. ACF accepted this recommendation and deleted the term and definition.

One comment recommended the deletion of the term and definition of “Reservation” because it is not used in the body of the ACF policy, nor does it appear in the HHS policy. ACF accepted this recommendation and deleted the term and definition.

One comment recommended the deletion of the term and definition of “Self Government” because it is not used in the body of the ACF policy, nor does it appear in the HHS policy. ACF accepted this recommendation and deleted the term and definition.

One comment recommended the deletion of the term and definition of “Tribal Resolution” because it is not used in the body of the ACF policy, nor does it appear in the HHS policy. ACF accepted this recommendation and deleted the term and definition.

One comment recommended the deletion of the term and definition of “Tribal Self-Governance” because it is not used in the body of the ACF policy, nor does it appear in the HHS policy. ACF accepted this recommendation and deleted the term and definition.

16. Retention of Executive Branch Authorities

One comment regarding Section 16 discussed the absence of mechanisms to enforce agency compliance with this policy. Another comment was concerned by the lack of any right to enforce this consultation duty in court. ACF’s response to both comments was that in the absence of statutory authority, there is no right of action against the Federal Government.

Drafting information: The principal authors of this policy are Lillian Sparks, Commissioner, Administration for Native Americans, and the ACF Tribal Federal Workgroup composed of representatives from the 10 Regional Offices and at-large Indian organizations. Other members of ACF, HHS, and federally recognized Indian tribes also participated in its development.

SUPPLEMENTARY INFORMATION: The final ACF Tribal Consultation Policy is provided below.

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1. Introduction

On November 5, 2009, President Obama signed an Executive Memorandum reaffirming the government-to-government relationship between Indian tribes and the Federal Government, and directing each executive department and agency to consult with tribal governments prior to taking actions that affect this population. The importance of consultation with Indian tribes was affirmed through Presidential Memoranda in 1994, 2004, and 2009, and Executive Order 13175 in 2000.

The U.S. Department of Health and Human Services (HHS) and Indian tribes share the goal of eliminating health and human service disparities of American Indians and Alaska Natives (AI/AN) and ensuring that access to critical health and human services is maximized.

2. Purpose

The Administration for Children and Families (ACF), as an Operating Division within HHS, hereby establishes a consultation policy with federally recognized Indian tribes. The purpose of the ACF Tribal Consultation Policy is to build meaningful relationships with federally recognized tribes by engaging in open, continuous, and meaningful consultation. True consultation leads to information exchange, mutual understanding, and informed decision-making.

ACF is bound by the HHS Tribal Consultation Policy in full. Nothing in the ACF Tribal Consultation Policy shall be construed as diminishing or waiving the HHS Tribal Consultation Policy. The ACF Tribal Consultation Policy shall not conflict with the HHS Tribal Consultation Policy and applies to all offices of ACF.

This ACF Tribal Consultation Policy document was developed based upon:

1. Executive Memorandum "Tribal Consultation," November 5, 2009;
2. Executive Order 13175, reaffirmed in 2009;
3. HHS Tribal Consultation Policy (established in 2005, and amended in 2010);
4. Input from an ACF Tribal Federal Workgroup (TFWG) convened to develop the draft ACF Consultation Policy;
5. Input from tribes to ensure a consultation policy that reflects the goals of all partners involved; and
6. Input of all of the programs and regions within ACF, many of which already consult with AI/ANs.

3. Background

Since the formation of the Union, the United States (U.S.) has recognized Indian tribes as sovereign nations. A unique government-to-government relationship exists between AI/AN Indian tribes and the Federal Government. This relationship is grounded in the U.S. Constitution, numerous treaties, statutes, Federal case law, regulations and executive orders, as well as political, legal, moral, and ethical principles. This relationship is derived from the political relationship that Indian tribes have with the Federal Government.

An integral element of this government-to-government relationship is that consultation occurs with Indian tribes. ACF program offices shall provide an opportunity for meaningful consultation between tribes and ACF in policy development, as set forth in this policy. The Executive Memorandum titled "Tribal Consultation" reaffirmed this government-to-government relationship with Indian tribes on November 5, 2009. The implementation of this policy is in recognition of this special relationship.

This special relationship is affirmed in statutes and various Presidential Executive Orders including, but not limited to:

- Older Americans Act, Public Law 89-73, as amended (42 U.S.C. 3001 *et seq.*);
- Indian Self-Determination and Education Assistance Act, Public Law 93-638, as amended (25 U.S.C. 450 *et seq.*);
- Native American Programs Act, Public Law 93-644, as amended (42 U.S.C. 2991 *et seq.*);
- Indian Health Care Improvement Act, Public Law 94-437, as amended (25 U.S.C. 1601 *et seq.*);
- Personal Responsibility and Work Opportunity Reconciliation Act of 1996, Public Law 104-193 (42 U.S.C. 1305 *et seq.*);
- Head Start for School Readiness Act of 2007, Public Law 110-134, as amended (42 U.S.C. 9801 *et seq.*);
- Patient Protection and Affordable Care Act (ACA), Public Law 111-148 (42 U.S.C. 18001 *et seq.*);
- Fostering Connections to Success and Increasing Adoptions Act of 2008, Public Law 110-351 (42 U.S.C. 1305 *et seq.*);
- Presidential Executive Memorandum to the Heads of Executive Departments dated April 29, 1994;
- Presidential Executive Order 13175, Consultation and Coordination With Indian Tribal Governments, November 6, 2000; and
- Presidential Memoranda, Government-to-Government Relationship with Tribal Governments, September 23, 2004; and Tribal Consultation, November 5, 2009.

4. Tribal Sovereignty

This policy does not waive or diminish any tribal governmental rights, including treaty rights, sovereign immunities, or jurisdiction. Additionally, this policy does not diminish any rights or protections afforded other ai/an persons or entities under federal law.

Our nation, under the law of the u.s. And in accordance with treaties,

statutes, executive orders, and judicial decisions, has recognized the right of indian tribes to self-government and self-determination. Indian tribes exercise inherent sovereign powers over their members and territory. The u.s. Continues to work with indian tribes on a government-to-government basis to address issues concerning tribal self-government, tribal trust resources, tribal treaties, and other rights.

The constitutional relationship among sovereign governments is inherent in the very structure of the constitution, and is formalized in and protected by article i, section 8. Self-determination and meaningful involvement for indian tribes in federal decision-making through consultation in matters that affect indian tribes have been shown to result in improved program performance and positive outcomes for tribal communities. The involvement of indian tribes in the development of public health and human services policy allows for locally relevant and culturally appropriate approaches to public issues.

Tribal self-government has been demonstrated to improve and perpetuate the government-to-government relationship and strengthen tribal control over federal funding that it receives, and its internal program management.

5. Background on ACF

Acf provides national leadership and direction to plan, manage, and coordinate the nationwide administration of comprehensive and supportive programs for vulnerable and at-risk children and families. Acf oversees and finances a broad range of programs for children and families, including native americans, persons with developmental disabilities, refugees, and legal immigrants, to help them develop and grow toward a more independent, self-reliant life. These programs, carried out by state, county, city, and tribal governments, and public and private local agencies, are designed to promote stability, economic security, responsibility, and self-sufficiency.

Acf coordinates development and implementation of family-centered strategies, policies, and linkages among its programs, and with other federal, tribal, and state programs serving children and families. Acf's programs assist families in financial crisis, emphasizing short-term financial assistance, and education, training, and employment for the long term. Its programs for children and youth focus on those children and youth with special problems, including children of low-income families, abused and

neglected children, those in institutions or requiring adoption or foster family services, runaway youth, children with disabilities, migrant children, and native american children. ACF promotes the development of comprehensive and integrated community and home-based modes of service delivery where possible. The following offices are located in acf:

- Administration on children, youth and families (ACYF).
 - Children's bureau (CB).
 - Family and youth services bureau (FYSB).
- Office of the deputy assistant secretary for early childhood development.
- Administration on developmental disabilities (ADD):
 - President's committee for people with intellectual disabilities (PCPID), an advisory committee to the president of the united states and health and human services secretary.
- Administration for native americans (ANA).
- Office of administration.
- Office of community services (OCS).
- Office of child care (OCC).
- Office of child support enforcement (OCSE).
- Office of family assistance (OFA):
 - Temporary assistance for needy families bureau (TANF).
- Office of head start (OHS).
- Office of human services emergency preparedness and response (OHSEPR).
- Office of legislative affairs and budget (OLAB).
- Office of planning, research and evaluation (opre).
- Office of refugee resettlement (ORR).
- Office of regional operations (ORO).

In June 2010, ACF established the native american affairs advisory council (NAAAC). This council will function as an internal agency workgroup to support the assistant secretary for children and families, the commissioner of ana, and all acf program and regional offices that provide services to native americans. On behalf of the assistant secretary, administration for children and families, the commissioner of ANA is the chair of the NAAAC and ANA is the lead office to coordinate the activities.

One of the responsibilities of NAAAC is to facilitate the development of the acf tribal consultation policy, in conjunction with the office of the assistant secretary for children and families and in consultation with tribes.

The members of NAAAC are the acf program and regional offices that have

native american constituents or work with native american communities. These offices include the administration on children, youth and families (children's bureau, and the family and youth services bureau); the administration on developmental disabilities; the administration for native americans; the office of child care; the office of child support enforcement; the office of community services; the office of family assistance (tribal temporary assistance for needy families (tribal tanf)); the office of head start; the office of planning, research and evaluation; and the office of regional operations. The following regions will be represented: region i, region ii, region iv, region v, region vi, region vii, region viii, region ix, and region x.

6. Consultation Principles

Consultation is an enhanced form of communication that emphasizes trust, respect, and shared responsibility. It is an open and free exchange of information and opinions among parties, which leads to mutual understanding and comprehension. Consultation is integral to a deliberative process that results in effective collaboration and informed decision-making with the ultimate goal of reaching consensus on issues. ACF will consult, as defined in this document and as practicable and permitted by law, with indian tribes before taking action that will significantly affect indian tribes.

The acf policy is to conduct timely, respectful, meaningful, and effective two-way communication and consultation with tribes wherein elected officials and other authorized representatives of the tribal governments provide input prior to any action that either acf or one or more tribes determines has or may have significantly affected one or more indian tribes, and before any such action or further action is taken. An action that triggers consultation is any legislative proposal, new rule adoption, or other policy change that either acf or a tribe determines may significantly affect indian tribes. ACF or a tribe may determine that an action may significantly affect one or more indian tribes and by appropriate communication initiate tribal consultation. An action is considered to significantly affect tribes if there exists a reasonable presumption that it has or may have substantial direct effects on one or more indian tribes, on the relationship between the federal government and indian tribes, on the amount or duration of acf program

funding, on the delivery of acf program services to one or more tribes, or on the distribution of power and responsibilities between the federal government and indian tribes.

7. Consultation Parties

Consultation parties are:

A. The ACF assistant secretary, acf deputy assistant secretaries, ACF central office principals, or their designee; and

B. Tribal president, tribal chair or tribal governor, or an elected or appointed tribal leader, or their authorized representative(s).

Each party will identify their authorized representatives with delegated authorities to negotiate on their behalf.

8. Consultation Process

A. A consultation is initiated:

1. When either acf or one or more tribes makes a written request for a consultation.

a. Either acf or a tribe may determine an action significantly affects or may affect one or more indian tribes.

b. An action that triggers consultation is any legislative proposal, new rule adoption, or policy change that either acf or a tribe determines may significantly affect indian tribes.

2. An action is considered to significantly affect tribes if there exists a reasonable presumption that it has or may have substantial direct effects on:

a. One or more indian tribes;

b. The amount or duration of acf program funding for one or more tribes;

c. The delivery of acf program services to one or more tribes;

d. The relationship between the federal government and indian tribes; or the distribution of power and responsibilities between the federal government and indian tribes.

B. A consultation request by acf or tribe(s) should:

1. Identify the subject issue(s) for resolution.

2. Identify the applicable program(s), policy, rule, regulation, statute, and authorizing legislation.

3. Identify the related concerns such as state-tribal relations, related programs, complexity, time constraints, funding and budget implications.

4. Identify the affected and potentially affected indian tribe(s).

C. ACF will acknowledge receipt of the tribal consultation request within 14 calendar days after receipt of the request.

D. ACF shall have an accountable process to ensure meaningful and timely input by tribal officials in the development of policies that have tribal implications.

E. To the extent practicable and permitted by law, acf shall not promulgate any regulation that has tribal implications, that imposes substantial direct compliance costs on indian tribes, or that is not required by statute, unless:

1. Funds necessary to pay the direct costs incurred by the indian tribe in complying with the action are provided by the federal government; or

2. Acf, prior to the formal promulgation of the regulation,

a. Consulted with tribal officials early and throughout the process of developing the proposed regulation;

b. Provided a tribal summary impact statement in a separately identified portion of the preamble to the regulation as it is to be issued in the **Federal Register** (FR), which consists of a description of the extent of acf's prior consultation with tribal officials, a summary of the nature of their concerns and ACF's position supporting the need to issue the regulation, and a statement of the extent to which the concerns of tribal officials have been met; and

c. Made available to the assistant secretary any written communications submitted to acf by tribal officials.

F. To the extent practicable and permitted by law, ACF shall not promulgate any regulation that has tribal implications and that preempts tribal law unless ACF, prior to the formal promulgation of the regulation:

1. Consulted with tribal officials early and throughout the process of developing the proposed regulation;

2. Provided a tribal summary impact statement in a separately identified portion of the preamble to the regulation as it is to be issued in the fr, which consists of a description of the extent of acf's prior consultation with tribal officials, a summary of the nature of their concerns and acf's position supporting the need to issue the regulation, and a statement of the extent to which the concerns of tribal officials have been met; and

3. Made available to the assistant secretary any written communications submitted to acf by tribal officials.

G. Proper notice of the tribal consultation and the level of consultation shall be communicated to all affected and all potentially affected indian tribes within 45 calendar days after receipt of the tribal request. Appropriate forms of notice include a "dear tribal leader letter" signed by the assistant secretary, broadcast e-mail, fr, and other outlets. The notice will provide at least 30 days notice of subject, location, date, and time.

H. Consultation will occur through a combination of one or more methods,

and will include additional actions and participants as determined by the parties. The following are examples of methods of consultation:

1. Meeting(s): one or more meetings for consultation with affected and potentially affected indian tribes to discuss all pertinent issues related to the legislative proposal, new rule adoption, or other policy change that may significantly affect the tribe(s) using a single purpose meeting, or a national or regional forum, if appropriate, when the consultation is determined to include all tribes. Meetings can be face-to-face, by teleconference call, and other forms of new technologies.

2. Correspondence: written communications for consultation exchanged between acf and the indian tribe(s) provide affected and potentially affected indian tribes an opportunity to identify concerns, potential impacts, proposed alternatives or flexibilities, and provide acf with the opportunity to identify resources and other considerations relevant to the issue(s) raised. All correspondence will identify the manner in which tribal comments will be solicited.

3. **Federal Register** (FR): when one or more meetings are not practicable, notices in the fr may be used as the method of consultation to solicit comment from tribes about broad-based issues including concerns, potential impacts, proposed alternatives or flexibilities. Such notices will include clear and explicit instructions for the submission of comments that provide adequate time, a minimum of 45 days, for tribal responses. The fr will not be used as a sole method of communication for consultation.

I. *Reporting of outcome*: all national and regional consultation meetings and recommended actions shall be recorded and made available to indian tribes.

ACF program offices will provide a detailed report on their consultation sessions, which summarizes the discussions, specific recommendations, and responses, and solicits tribal feedback on the consultation process, within 45 calendar days of the conclusion of the consultation process. The acf report will be available on the program offices' Web sites.

Once the consultation process is complete and a proposed policy is approved and issued, the final policy must be broadly distributed to all Indian tribes and it will be independently posted on the ACF webpage and also linked to several appropriate tribal and inter-tribal organization Web sites.

J. *Meaningful Outcomes*: The consultation process and activities

conducted within the scope of the ACF policy should result in a meaningful outcome for both ACF and tribes. Before any final policy decisions are adopted that significantly affect Indian tribes, the proposed outcome of a consultation shall be widely publicized and circulated for review and comment to affected Indian tribes, inter-tribal organizations, and within HHS, when appropriate, practicable and permitted by law.

Good faith implementation of ACF programs and a cooperative working relationship with tribes in support of ACF programs is the primary meaningful outcome. ACF will work with States to emphasize the importance of working cooperatively with tribes.

ACF shall facilitate meaningful consultations and outcomes between tribe(s) and one or more States administering ACF programs, shall report the outcome of its efforts to affected tribes, and shall make a good faith effort to ensure all parties fully comply with ACF program requirements.

K. *Waivers*: The intent of this policy is to provide increased ability to address issues impacting Indian tribes. ACF will, consistent with HHS Tribal Consultation Policy and as practicable and permitted by law, utilize flexible approaches to enable tribes to achieve established ACF program objectives, including consideration of waivers of statutory and regulatory requirements and other alternatives that preserve the prerogatives and authority of Indian tribes.

L. *Elevation of Issues*: Indian tribes may elevate an issue of importance to a higher or separate decision-making authority, detailed in *Section 11. ACF-Tribal Conflict Resolution*.

9. ACF Consultation and Communication Responsibilities

ACF will conduct an annual agency-wide tribal consultation each year, in addition to the tribal consultations required by several ACF program offices. The following will guide ACF's coordination of the various sessions. NAAAC will work with the program offices to coordinate ACF required consultations, on required topics and in required regions, to maximize the time and resources of Indian tribes and program offices.

A. *ACF Annual Tribal Consultation Session*

1. ACF will hold, at a minimum, an agency-wide annual tribal consultation session to discuss ACF budget, programs and policies impacting tribal programs. ANA, working through

NAAAC, will be the lead agency to coordinate the annual tribal consultation session.

2. Every ACF program office Principal, or their designee, will be required to participate in the annual ACF tribal consultation.

3. NAAAC will coordinate with the program offices to prepare and disseminate a written report within 45 calendar days of the conclusion of the annual ACF tribal consultation.

4. ACF will post this report on its Web site within 7 days of the final report completion.

5. The annual ACF tribal consultation session will not supplant any tribal consultation sessions that are required by law to be conducted by ACF program offices.

B. Special Statutory Consultation Requirements

1. The following ACF Offices have programs that require consultation with Indian tribes in accordance with their authorizing statutes.

- Office of Head Start.
- Children's Bureau.
- Family and Youth Services Bureau.

2. ACF program offices will conduct tribal consultation sessions that are required by law, including in conjunction with the Annual ACF Tribal Consultation Session.

C. Individual Program Consultation Responsibilities

1. Each individual program office will meet with Indian tribes and AI/AN grantees regarding programmatic concerns at the request of the Indian tribe or AI/AN grantee.

2. An official staff contact will be designated as responsible for the initial coordination and facilitation of the program office interaction with tribes and Native American organizations and to serve as the program single point of contact for interaction with offices and workgroups within HHS on AI/AN issues. This contact will be kept current on the ACF Web site.

3. ACF program offices will acknowledge requests for consultation within 14 calendar days of receipt of the request.

4. ACF program offices will acknowledge and report on unresolved issues with the tribe in a timely manner. ACF program offices will acknowledge issues within 14 calendar days after the conclusion of the consultation.

5. Feedback will be provided by ACF program offices to tribes on the resolution of issues for which consultation has been requested within 45 calendar days of the conclusion of the consultation.

6. ACF program offices will ensure intra-agency coordination with Regional Offices to facilitate communication and outreach on consultations held in the Region. Regional Offices will facilitate State participation as appropriate.

7. ACF program offices and Regional Offices will provide assistance in efforts to resolve tribal-State issues.

8. ACF program offices will provide a written report on the consultations, which summarizes the discussions, recommendations, and responses, within 45 calendar days after the conclusion of the last consultation.

D. HHS Tribal Consultations

ACF will participate in the Annual Budget Consultation Session and Annual Regional Tribal Consultations.

10. ACF Performance and Accountability

A. Implementation of this policy shall be made part of the Annual Performance Plan for ACF Senior Management as a critical performance element in those offices where there are specific tribal activities.

B. ACF program offices will design indicators to ensure accountability among program managers, and central office and Regional Office staff in carrying out the HHS and ACF tribal consultation policies.

C. ACF will ensure that all personnel working with Indian tribes receive appropriate training on consultation, this policy, and working with tribal governments.

D. As part of the Department's annual measurement of the level of satisfaction of Indian tribes with the consultation process and the activities conducted under this policy, Indian tribes' satisfaction with ACF will be recorded and evaluated to determine whether the intended results were achieved and to solicit recommendations for improvement from tribes.

11. ACF-Tribal Conflict Resolution

A. Should an impasse arise between ACF and a tribe(s) concerning ACF compliance with the consultation policy or outcome of consultation, a tribe may invoke the conflict resolution process by filing a written notice of conflict resolution and any action that is the subject of an impasse will be stayed until the conflict resolution process with ACF is complete to the extent practicable and permitted by law. Authorized tribal representatives shall have the opportunity to meet with the Assistant Secretary for Children and Families, and/or a Deputy Assistant Secretary, and/or the Commissioner for the Administration for Native

Americans, and/or the ACF Regional Administrator(s) for the Regional Offices that provide services to the affected tribes. The goal is to accomplish the following:

1. Clarify all aspects of the issue(s) at an impasse;
2. Explore the alternative position(s) available to resolve the impasse;
3. Clearly state the issue(s) that the parties can accept on the record;
4. Form acceptance of recommended actions; and
5. Facilitate coordination of resolution(s) for parties.

B. In cases where a tribe(s) is not satisfied with the resolution of an issue or issues after consultation with ACF, a tribe(s), consistent with the government-to-government relationship, may elevate an issue of importance to the Secretary of the Department of Health and Human Services, through the Office of Intergovernmental Affairs (IGA), for decision.

12. Workgroups and Advisory Committees

A. To maximize the expertise and knowledge of individuals working in tribal communities, ACF will convene TFWGs, subject to available funding, to develop and discuss agency-wide policies that impact Indian tribes, prior to formal tribal consultation sessions on the policies.

The TFWG will work in accordance with the HHS policy on tribal workgroups and will follow procedures to ensure compliance with the Federal Advisory Committee Act (FACA). See the HHS Tribal Consultation Policy, Addendum 1, for further explanation of TFWG.

B. ACF has a standing internal working group made up of staff representatives from each ACF program office. This Native American Affairs Workgroup meets once a month to work on tribal issues at the program, ACF, and HHS level.

C. ACF retains the right to meet with various representatives of organizations on an individual basis.

D. For policies that impact more than federally recognized Indian tribes,¹ ACF will develop forums to provide opportunities for input and dialogue for State-recognized tribes; Native American organizations, including Native Hawaiians and Native American Pacific Islanders; urban Indian centers; tribally controlled community colleges

¹ These groups, while not federally recognized tribes, are eligible to receive funding under certain ACF programs in the same manner as federally recognized tribes. ACF will make every effort to seek the input of these groups when changes to policy impact these groups as well.

and universities; Alaska Region Corporations; and others as defined in program office guidance.

E. Program offices may still convene their individual working groups to work on program specific policies. Program offices will ensure that these working groups operate within the FACA guidelines and requirements.

F. ACF does not participate in government-to-government consultation with entities described in *Section 12., A-E*, and these meetings do not take the place of tribal consultation.

13. Definitions

A. Action—Any legislative proposal, new rule adoption, or policy change that either ACF or a tribe(s) determines may significantly affect an Indian tribe(s).

B. Agency—Any authority of the United States that is an “agency” under 44 U.S.C. 3502(1) other than those considered to be independent regulatory agencies, as defined in 44 U.S.C. 3502(5).

C. Administration for Children and Families (ACF)—All the offices that make up the organization of ACF. The acronyms “ACF” and “ACF program offices” are used interchangeably.

D. Communication—The exchange of ideas, messages, or information by speech, signals, writing, or other means.

E. Consortia of tribes—Two or more federally recognized Indian tribes.

F. Consultation—An enhanced form of communication, which emphasizes trust, respect, and shared responsibility. It is an open and free exchange of information and opinion among parties, which leads to mutual understanding and comprehension. Consultation is integral to a deliberative process, which results in effective collaboration and informed decision-making with the ultimate goal of reaching consensus on issues.

G. Coordination and Collaboration—Working and communicating together in a meaningful government-to-government effort to create a positive outcome.

H. Critical Event—Planned or unplanned event that has or may have a substantial impact on Indian tribe(s), e.g. issues, policies, or budgets which may come from any level within HHS.

I. Deliberative Process Privilege—Privilege exempting the government from disclosure of government-agency materials containing opinions, recommendations, and other communications that are part of the decision-making process within the agency.

J. Executive Order—An order issued by the government’s executive on the basis of authority specifically granted to

the Executive Branch (as by the U.S. Constitution or a Congressional Act).

K. Federally recognized tribal governments—Indian tribes with whom the Federal Government maintains an official government-to-government relationship, usually established by a Federal treaty, statute, executive order, court order, or a Federal Administrative Action. The Bureau of Indian Affairs (BIA) maintains and regularly publishes the list of federally recognized Indian tribes.

L. Indian—A person who is a member of an Indian tribe (25 U.S.C. 450b(d)). Throughout this policy, Indian is synonymous with American Indian/Alaska Native.

M. Indian Organization—(1) Those federally recognized, tribally constituted entities that have been designated by their governing body to facilitate HHS communications and consultation activities. (2) Any regional or national organizations whose board is comprised of federally recognized tribes and elected/appointed tribal leaders. The Government does not participate in government-to-government consultation with these entities; rather, these organizations represent the interests of tribes when authorized by those tribes.

N. Indian tribe—An Indian tribe, band, nation, or other organized group or community, including any Alaska Native village, or regional or village corporation, as defined in or established pursuant to the Alaska Native Claims Settlement Act (85 Stat. 688) (*43 U.S.C. 1601 et seq.*), which is recognized as eligible for the special programs and services provided by the United States to Indians because of their status as Indians (25 U.S.C. 450b(e)).

O. Joint Tribal Federal Workgroups and/or Task Forces—A group composed of individuals who are elected tribal officials, appointed by federally recognized tribal governments and/or Federal agencies to represent their interests while working on a particular policy, practice, issue, and/or concern.

P. Native American (NA)—Broadly describes the people considered indigenous to North America.

Q. Native American Affairs Advisory Council (NAAAC)—An internal agency work group established to support the Assistant Secretary for Children and Families, the Commissioner of the Administration for Native Americans, and all ACF program and Regional Offices that provide services to Native Americans.

R. Native Hawaiian—Any individual whose ancestors were natives of the area, which consists of the Hawaiian Islands prior to 1778 (42 U.S.C. 3057k).

S. Policies that have tribal implications—Refers to regulations, legislation, and other policy statements or actions that have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

T. Sovereignty—The ultimate source of political power from which all specific political powers are derived.

U. State recognized tribes—Tribes that maintain a special relationship with the State government and whose lands and rights are usually recognized by the State. State recognized tribes may or may not be federally recognized.

V. Substantial Direct Compliance Costs—Those costs incurred directly from implementation of changes necessary to meet the requirements of a Federal regulation. Because of the large variation in tribes, “substantial costs” is also variable by Indian tribe. Each Indian tribe and the Assistant Secretary shall mutually determine the level of costs that represent “substantial costs” in the context of the Indian tribe’s resource base.

W. To the Extent Practicable and Permitted by Law—Refers to situations where the opportunity for consultation is limited because of constraints of time, budget, legal authority, etc.

X. Treaty—A legally binding and written agreement that affirms the government-to-government relationship between two or more nations.

Y. Tribal Government—An American Indian or Alaska Native tribe, band, nation, pueblo, village, or community that the Secretary of the Interior acknowledges to exist as an Indian tribe pursuant to the Federally Recognized Indian Tribe List Act of 1994 (25 U.S.C. 479a).

Z. Tribal Officials—Elected or duly appointed officials of Indian tribes or authorized Indian organizations.

AA. Tribal Organization—The recognized governing body of any Indian tribe; any legally established organization of American Indians and Alaska Natives which is controlled, sanctioned, or chartered by such governing body or which is democratically elected by the adult members of the community to be served by such organization and which includes the maximum participation of Indian tribe members in all phases of its activities (25 U.S.C. 450b).

14. Acronyms

ACF Administration for Children and Families
AI/AN American Indian/Alaska Native

AI/AN/NA American Indian/Alaska Native/Native American
 ANA Administration for Native Americans
 BIA Bureau of Indian Affairs
 Division Staff Division and/or Operating Division
 EO Executive Order
 FACAA Federal Advisory Committee Act
 FR **Federal Register**
 HHS U.S. Department of Health and Human Services
 NAAAC Native American Affairs Advisory Council
 OPDIV Operating Divisions of HHS
 SPOC Single Point of Contact
 TFWG Tribal/Federal Workgroup
 U.S. United States
 U.S.C. United States Code

15. Policy Review

ACF shall review and, if necessary, revise its Tribal Consultation Policy no less than every 2 years. Should ACF determine that the policy requires revision, the TFWG will be convened to develop the revisions.

16. Retention of Executive Branch Authorities

Nothing in this policy waives the Government's deliberative process privilege, including when the Department is specifically requested by Members of Congress to respond to or report on proposed legislation. The development of such responses and related policy documents is a part of the deliberative process by the Executive Branch and should remain confidential.

Nothing in the Policy creates a right of action against the Department for failure to comply with this Policy nor creates any right, substantive or procedural, enforceable at law by a party against the United States, its agencies, or any individual.

17. Effective Date

This policy is effective on the date of signature by the Assistant Secretary for Children and Families and shall apply to all ACF program offices.

Dated: August 18, 2011.

George H. Sheldon,

Acting Assistant Secretary for Children and Families.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0002]

Endocrinologic and Metabolic Drugs 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: Endocrinologic and Metabolic Drugs 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 November 2, 2011, from 8 a.m. to 5 p.m.

Location: Hilton Washington DC/Silver Spring, The Ballrooms, 8727 Colesville Rd., Silver Spring, MD. The hotel telephone number is 301-589-5200.

Contact Person: Paul Tran, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, rm. 2417, Silver Spring, MD 20993-0002, 301-796-9001, Fax: 301-847-8533, e-mail: EMDAC@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 November 2, 2011, the committee will discuss supplemental new drug applications 21-687 and 21-445, VYTORIN (ezetimibe/simvastatin) and ZETIA (ezetimibe) tablets, respectively, MSP (Merck/Schering-Plough) Singapore Company, LLC. Simvastatin lowers lipids (fats that circulate in the bloodstream, including cholesterol) by inhibiting 3-hydroxy-3-methyl-glutaryl-CoA reductase, which is an enzyme involved in producing lipids

in the body, and ezetimibe lowers lipids by inhibiting the absorption of cholesterol from the intestine. The proposed indication (use) of ZETIA in combination with simvastatin or VYTORIN is to reduce major cardiovascular events in patients with chronic kidney disease based on the results of the Study of Heart and Renal Protection (SHARP). SHARP was a clinical trial that studied the effect of VYTORIN compared with placebo on the occurrence of major cardiovascular events in patients with chronic kidney disease who did not have a history of myocardial infarction or coronary revascularization (heart bypass surgery or opening heart vessels with a balloon or stents). The primary outcome of major cardiovascular events was defined as the first occurrence of either nonfatal myocardial infarction, cardiac death, stroke, or coronary or noncoronary revascularization (including nontraumatic amputation). The primary analysis demonstrated that assignment to VYTORIN significantly reduced the relative risk of a major cardiovascular event by 16% compared to placebo.

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 October 19, 2011. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. 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 October 11, 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