

during the meeting for public oral comments, which will be limited to 1 minute for each individual and a total of 3 minutes per organization.

#### VIII. Meeting Attendance

The meeting is open to the public; however, attendance is limited to space available. Attendance will be determined on a first-come, first-served basis.

Persons wishing to attend this meeting, which is located on Federal property, must e-mail the DFO to register in advance no later than 5 p.m. (e.s.t.), Wednesday, February 23, 2011. A confirmation will be sent to the requester(s) by return e-mail.

The following personal information must be e-mailed to the DFO by the date and time above:

- Name(s) of attendee(s).
- Title(s).
- Organization.
- E-mail address(es).
- Telephone number(s).

#### IX. Security, Building, and Parking Guidelines

The following are the security, building, and parking guidelines:

- Persons attending the meeting including presenters must be registered and on the attendance list by the prescribed date.
- Individuals who are not registered in advance will not be permitted to enter the building and will be unable to attend the meeting.
- Attendees must present photographic identification to the Federal Protective Service or Guard Service personnel before entering the building.
- Security measures include inspection of vehicles, inside and out, at the entrance to the grounds.
- All persons entering the building must pass through a metal detector.
- All items brought into CMS including personal items, such as laptops, cell phones, and palm pilots, are subject to physical inspection.
- The public may enter the building 30 to 45 minutes before the meeting convenes each day.
- All visitors must be escorted in areas other than the lower and first-floor levels in the Central Building.
- The main-entrance guards will issue parking permits and instructions upon arrival at the building.

#### X. Special Accommodations

Individuals requiring sign-language interpretation or other special accommodations must send a request for these services to the DFO by 5 p.m. (e.s.t.), Wednesday, February 23, 2011.

#### XI. Panel Recommendations and Discussions

The Panel's recommendations at any APC Panel meeting generally are not final until they have been reviewed and approved by the Panel on the last day prior to final adjournment.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: December 2, 2010.

**Donald M. Berwick,**

*Administrator, Centers for Medicare & Medicaid Services.*

[FR Doc. 2010–31542 Filed 12–15–10; 8:45 am]

**BILLING CODE 4120–01–P**

#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

##### Administration for Children and Families

##### Public Comment on the Draft Tribal Consultation Policy

**AGENCY:** Administration for Children and Families, HHS.

**ACTION:** Notice.

**SUMMARY:** On November 5, 2009, President Obama signed the “Memorandum for the Heads of Executive Departments and Agencies on Tribal Consultation.” 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.

The United States has a unique legal and political relationship with Indian tribal governments, established through and confirmed by the Constitution of the United States, treaties, statutes, executive orders, and judicial decisions. In recognition of that special relationship, pursuant to Executive Order 13175 of November 6, 2000, executive departments and agencies are charged with engaging in regular and meaningful consultation and collaboration with tribal officials in the development of Federal policies that have tribal implications, and are responsible for strengthening the government-to-government relationship between the United States and Indian Tribes.

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, most recently in 2008. Many HHS agencies have already developed their own agency-specific consultation policies that complement the Department-wide efforts.

Since 2005, the Administration for Children and Families (ACF) has been working under the guidance of the HHS policy issued in 2005, and updated in 2008. Due to the various programs administered by ACF and the many requests from Tribes for consultation for specific programs, as well as specific program mandates for tribal consultation, ACF has decided to create an ACF Tribal Consultation Policy to help ACF program and regional offices better engage Federally recognized Indian Tribes in the development or revision of policies, regulations, and proposed legislation that impact American Indians. ACF firmly believes that to create a good policy, ACF needs input from Tribes to ensure that ACF is meeting tribal needs and to establish a partnership that can carry into the future. ACF solicited membership for an ACF Tribal/Federal Workgroup to develop the initial draft policy. The Workgroup met August 23 and 24, 2010, in Washington, DC, and again in Minneapolis, Minnesota, on September 16 and 17, 2010. The draft was reviewed by tribal leaders attending the ACF Tribal Consultation Session held in Washington, DC on September 29, 2010, and the Workgroup met again to address the comments heard at the Tribal Consultation Session. ACF will convene the Tribal/Federal Workgroup again to review and address the comments received from this publication.

**DATES:** The deadline for receipt of comments is January 31, 2011.

**ADDRESSES:** Comments made in response to this notice should be addressed to Lillian Sparks, Commissioner, Administration for Native Americans, 370 L'Enfant Promenade, SW., Mail Stop: Aerospace 2—West, Washington, DC 20447. Delays may occur in mail delivery to Federal offices; therefore, a copy of comments should be faxed to (202) 690–7441. Comments will be available for inspection by members of the public at the Administration for Native Americans, 901 D Street, SW., Washington, DC 20447.

**FOR FURTHER INFORMATION CONTACT:** Lillian Sparks, Commissioner, Administration for Native Americans, (877) 922–9262.

**SUPPLEMENTARY INFORMATION:** The draft Tribal Consultation Policy is provided below.

Dated: December 7, 2010.

**David A. Hansell,**

*Acting Assistant Secretary for Children and Families.*

## U.S. Department of Health and Human Services

### Administration for Children and Families

#### *Tribal Consultation Policy*

#### 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, as an Operating Division within the Department of Health and Human Services, hereby establishes a consultation policy with Federally recognized Indian Tribes in accordance with the HHS consultation policy. 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.

This ACF Tribal Consultation Policy document was developed based upon:

- Executive Order 13175, reaffirmed in 2009;
- HHS Tribal Consultation Policy (established in 2005, and amended in 2010);
- Input from an ACF Tribal/Federal Workgroup convened to develop the ACF Draft Consultation Policy;
- Input from Tribes to ensure a consultation policy that reflects the goals of all partners involved; and

- Input of all of the programs and regions within ACF, many of which already consult with American Indians and Alaska Natives (AI/ANs).

#### 3. Background

Since the formation of the Union, the United States (U.S.) has recognized Indian Tribes as sovereign nations. A unique nation-to-nation relationship exists between AI/AN Indian Tribes and the Federal Government. This relationship is grounded in the U.S. Constitution, numerous treaties, statutes, and executive orders, as well as political, legal, moral, and ethical principles. This relationship is derived from the political relationship that Tribes have with the Federal Government and is not based upon race. The Federal Government has enacted numerous regulations that establish and define a trust relationship with Indian Tribes.

An integral element of this government-to-government relationship is that consultation occurs with Indian Tribes. This policy applies to all offices of ACF. Offices shall provide an opportunity for meaningful consultation between Tribes and ACF in policy development, as set forth in this policy. Executive Memorandum entitled "Government-to-Government Relationship with Tribal Governments" 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 (PPACA), 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 Memorandum, Government-to-Government Relationship with Tribal Governments, September 23, 2004 and November 5, 2009.

#### 4. Tribal Sovereignty

This policy does not waive 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)
- Administration on Developmental Disabilities (ADD)
- 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)
- 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.

In June 2010, ACF established the Native American Affairs Advisory Council (NAAAC). This Council will function as an internal agency work group 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 the Council is to facilitate the development of the ACF Tribal Consultation Policy, in conjunction with the Office of the Assistant Secretary for Children and Families.

The members of the Council 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 opinion 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.

The ACF policy is to conduct timely communication and meaningful consultation with Tribes wherein elected officials and other authorized representatives of the Tribal Governments have an opportunity to provide meaningful and timely input prior to a legislative proposal, new rule adoption, or other policy change that ACF determines may significantly affect Indian Tribes, or where one or more

Tribes has communicated that such action will significantly affect one or more Indian Tribes. An action is considered to significantly affect Tribes if it has 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.

#### 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. Consultation is initiated when either the ACF or a Tribe(s) makes a written request for a consultation to discuss issue(s) concerning a legislative proposal, new rule adoption, or other policy change that ACF determines may significantly affect the Tribe(s).

B. A consultation request by a Tribe 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).

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

C. Proper notice of the tribal consultation and the level of consultation, as determined by ACF, 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, **Federal Register** (FR), and other outlets.

D. The following are Levels of Consultation: Consultation will occur through a combination of one or more levels of consultation, defined below, and will include additional actions and participants as determined by the parties.

1. Meeting(s): One or more meetings 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 ACF determines 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 or by teleconference call.

2. Correspondence: Written communications exchanged between ACF and the Indian Tribe(s) that 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:** When one or more meetings are not practicable, notices in the **Federal Register** will represent the level of consultation to solicit comment from Tribes about concerns, potential impacts, proposed alternatives or flexibilities. Such notices will include clear and explicit instructions for the submission of comments that provide adequate time for tribal responses.

E. 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 forty-five (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.

F. 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, 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.

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 providing program services and funding on an equitable basis to tribal members.

ACF shall facilitate meaningful consultations and outcomes between Tribe(s) and one or more States administering ACF programs, shall measure State performance in serving tribal populations, 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.

G. Waivers and Elevation of Issue(s): The intent of this policy is to provide increased ability to address issues impacting Indian Tribes. ACF will, to the extent 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.

In cases where a Tribe(s) is not satisfied with the resolution of an issue or issues after consultation with the program office, a Tribe(s), consistent with the government-to-government relationship, may elevate an issue of importance to the Assistant Secretary of ACF. If the Tribe is still not satisfied with the resolution of an issue after consultation with the Assistant Secretary of ACF, a Tribe(s), consistent with the government-to-government relationship, may elevate an issue of importance to the Department, through the Office of Intergovernmental Affairs (IGA), for decision.

### 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. The 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 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 forty-five (45) calendar days of the annual ACF tribal consultation.

4. ACF will post this report on its Web site.

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.

3. Individual Program Consultation Responsibilities

(a) 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.

(b) 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.

(c) ACF program offices will acknowledge requests for consultation within fourteen (14) calendar days of receipt of the request.

(d) ACF program offices will acknowledge and report on unresolved issues with the Tribe in a timely manner. ACF program offices will acknowledge issues within fourteen (14) calendar days after the consultation.

(e) Feedback will be provided by ACF program offices to Tribes on the

resolution of issues for which consultation has been requested within forty-five (45) calendar days of the consultation.

(f) 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.

(g) ACF program offices will provide assistance to States in their efforts to develop policies and plans to ensure consultation with Indian Tribes.

(h) ACF program offices will provide a written report on the consultations, which summarizes the discussions, recommendations, and responses, within forty-five (45) calendar days of the last consultation.

#### 4. HHS Tribal Consultations

(a) 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, central office and regional offices staff, and various partners in carrying out the HHS and ACF tribal consultation policies.

C. ACF will ensure that all personnel working with 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

In compliance with the HHS Consultation Policy, each Operating Division shall develop a conflict resolution process. The following shall serve as the ACF tribal conflict resolution process until further defined. Should an impasse arise between ACF and a Tribe(s) concerning ACF compliance with consultation policy, a Tribe may invoke the conflict resolution process by filing a written notice of conflict resolution. Using the timelines under Section 8B, ACF will initiate the conflict resolution process. As

determined by the Assistant Secretary, authorized tribal representatives shall 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:

A. Clarify all aspects of the issue(s) at an impasse;

B. Explore the alternative position(s) available to resolve the impasse;

C. Establish language about the issue(s) that the parties can accept on the record;

D. Create acceptance of recommended actions; and

E. Facilitate coordination of resolution(s) for parties.

### 12. Workgroups and Advisory Committees

A. To maximize the expertise and knowledge of individuals working in tribal communities, ACF may convene Tribal/Federal Workgroups (TFWG) to develop and discuss agency-wide policies that impact Indian Tribes, prior to formal tribal consultation sessions on the policies.

B. 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). Groups with membership composed of Federal, State employees, or elected officials of a Federally recognized Indian Tribe are exempt from FACA.

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, 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 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.

### 13. Definitions

A. *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).

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

C. *Consortia of Tribes*—Two or more Federally recognized Indian Tribes.

D. *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.

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

F. *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.

G. *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).

H. *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.

I. *Indian Organization*—Any group, association, partnership, corporation, or legal entity owned or controlled by Indians, or a majority whose members are Indians.

J. *Indian Tribe*—Any 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. Sec 450b(e)].

K. *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.

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

M. *Native American Affairs Advisory Council (NAAAC)*—An internal agency work group 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.

N. *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).

O. *Inter-Tribal Organization*—A nongovernmental body organized and operated to represent the interests of a group of individuals considered indigenous to North American countries. Organizations that represent the interests of individuals do not fall under the intergovernmental committee exemption to FACA found in 2 U.S.C. Sec 1534. Therefore, the Department is required to adhere to FACA if representatives of those organizations are included on advisory committees or workgroups.

P. *Non-Recognized Tribe*—Any Tribe with whom the Federal Government does not maintain a government-to-government relationship, and to which the Federal Government does not recognize a trust responsibility.

Q. *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.

R. *Public Participation*—When the public is notified of a proposed or actual action, and is provided meaningful opportunities to participate in the policy development process.

S. *Reservation*—Lands reserved with the Federal Government for tribal use and are usually held in trust by the Federal Government or within certain defined boundaries.

T. *Self Government*—Government in which the people who are most directly affected by the decisions make decisions.

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

V. *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.

W. *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 Secretary shall mutually determine the level of costs that represent “substantial costs” in the context of the Indian Tribe’s resource base.

X. *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.

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

Z. *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).

AA. *Tribal Officials*—Elected or duly appointed officials of Indian Tribes or authorized inter-tribal organizations.

BB. *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).

CC. *Tribal Resolution*—A formal expression of the opinion or will of an official tribal governing body which is adopted by vote of the tribal governing body.

DD. *Tribal Self-Governance*—The governmental actions of Tribes exercising self-government and self-determination.

#### 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  
 FACA 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 Tribal/Federal Workgroup 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.

[FR Doc. 2010–31465 Filed 12–15–10; 8:45 am]

BILLING CODE 4184–34–P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2001–E–0027]

#### Determination of Regulatory Review Period for Purposes of Patent Extension; ANGIOMAX

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) has determined the regulatory review period for ANGIOMAX and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the