

U.S.C. 9601 *et seq.*] amended the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA or Superfund) [42 U.S.C. 9601 *et seq.*] by establishing certain requirements for ATSDR and the U.S. Environmental Protection Agency (EPA) regarding hazardous substances that are most commonly found at facilities on the CERCLA National Priorities List (NPL). Among these statutory requirements is a mandate for the Administrator of ATSDR to prepare toxicological profiles for each substance included on the priority list of hazardous substances [also called the Substance Priority List (SPL)]. This list identifies 275 hazardous substances that ATSDR and EPA have determined pose the most significant potential threat to human health. The SPL is available online at [www.atsdr.cdc.gov/spl](http://www.atsdr.cdc.gov/spl).

In addition, CERCLA provides ATSDR with the authority to prepare toxicological profiles for substances not found on the SPL. CERCLA authorizes ATSDR to establish and maintain an inventory of literature, research, and studies on the health effects of toxic substances (CERCLA Section 104(i)(1)(B); 42 U.S.C. 9604(i)(1)(B)); to respond to requests for health consultations (CERCLA Section 104(i)(4); 42 U.S.C. 9604(i)(4)); and to support the site-specific response actions conducted by the agency.

#### Availability

These Draft Toxicological Profiles will be available online at <http://www.atsdr.cdc.gov/ToxProfiles> and at [www.regulations.gov](http://www.regulations.gov), Docket No. ATSDR-2019-0006.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Community Living

#### Statement of Organization, Functions, and Delegations of Authority

Part B of the Statement of Organization, Functions, and Delegations of Authority of the Department of Health and Human Services (HHS), as last amended at 79 FR 80 FR 31389-31402, dated June 2, 2015, is amended to reflect the reorganization of the Administration on Community Living (ACL). This reorganization is being undertaken to

improve efficiency and effectiveness of the organization; strengthen infrastructure; and improve the connections between the organization and its stakeholder, grantees and consumers at the national, state and local levels. It changes the Office of Elder Justice and Adult Protective Services functions to include carrying out the Long-Term Care Ombudsman functions established in Section 201(d)(1) of the Older Americans Act (OAA) and the Deputy Assistant Secretary for Aging will meet the responsibilities of the Director of the Office of Long-Term Care Ombudsman Programs. It renames the Independent Living Administration to the Office of Independent Living Programs, which will continue to serve as the Independent Living Administration as specified in Section 701A of the Rehabilitation Act, and renames the Administration on Intellectual and Developmental Disabilities to the Office of Intellectual and Developmental Disabilities Programs. The Commissioner for the Administration on Disabilities (AoD) will also serve as the Director of the Independent Living Administration. It retitles the Center for Integrated Programs to the Center for Innovation and Partnership, the Office of Consumer Access and Self-Determination to the Office of Network Advancement, and the Office of Integrated Care Innovations to the Office of Interagency Innovation. It retitles the National Institute of Disability, Independent Living and Rehabilitation Research's Office of Research Evaluation and Administration to the Office of Research Administration. It retitles the Office of Regional Operations to the Center for Regional Operations. The changes are as follows:

I. Under Section B10, Organization, delete Center for Integrated Programs (BD) and replace with Center for Innovation and Partnership (BD).

II. Delete Section B20, Functions, in its entirety and replace with the following:

B.20 Functions. ACL is the principal agency in the department designated to lead aging and disability programs. More specifically, the provisions of the Older Americans Act (OAA) of 1965 are carried out by its subcomponent, the Administration on Aging (AoA); the provisions of the Developmental Disabilities Assistance and Bill of Rights Act (DD Act) of 2000 and Title VII of the Rehabilitation Act of 1973 are carried out by its subcomponent, the Administration on Disabilities (AoD); and the provisions of Title II of the Rehabilitation Act of 1973 are carried out by its subcomponent, the National Institute of Disability, Independent Living, and Rehabilitation Research. ACL also administers programs

authorized under Title III and Title XXIX of the Public Health Service Act (PHSA), section 262 and 292 of the Help America Vote Act (HAVA), section 119 of the Medicare Improvements for Patients and Providers Act (MIPPA) of 2008, section 6021(d) of the Deficit Reduction Act (DRA) of 2005, section 4360 of the Omnibus Budget Reconciliation Act (OBRA) of 1990, the Elder Justice Act (EJA) of 2010 (Subtitle B of Title XX of the Social Security Act), the Assistive Technology Act of 1998, and the Traumatic Brain Injury Program Reauthorization Act of 2018. In addition, ACL provides continuing support for the administration of the President's Committee for People with Intellectual Disabilities pursuant to E.O. 13652.

Specifically, ACL: Develops, recommends and issues regulations, policies, procedures, standards and guidelines to provide direction for the programs it administers. Approves or disapproves plans and funding applications for national programs providing community-based long-term services and supports. Administers programs for training, research, demonstration, evaluation and information dissemination. Administers programs related to advocacy, systems change and capacity building. Administers national centers for service development and provides technical assistance to states, tribal organizations, local communities and service providers. Serves as the lead federal agency for adult protective services.

Assists the Secretary in all matters pertaining to opportunities and challenges of persons with disabilities, older Americans, and Americans of all ages about their current and potential future need for information and access to long-term services and supports. Advocates for the needs of these constituencies in program planning and policy development within the department and in other federal agencies. Advises the Secretary, departmental components and other federal organizations on the characteristics, circumstances and needs of these populations and develops policies, plans and programs designed to promote their welfare.

The functions of the organizational units of ACL are described in detail in the succeeding chapters.

III. Under Section BA.20, Functions, delete Subsection 3. Office of Regional Operations (BAC) in its entirety.

IV. Delete Section B, Administration on Aging (BB), in its entirety and replace with the following:

B. Administration on Aging (BB)

BB.00 Mission

BB.10 Organization

BB.20 Functions

*BB.00 Mission.* The Administration on Aging (AoA) carries out programs operated under the OAA, Sections III, XXIX and 398 of the PHSA, and the EJA (Subtitle B of Title XX of the Social Security Act), including, but not limited to, those concerning the Elder Justice Coordinating Council and Adult Protective Services. The AoA helps elderly individuals maintain their dignity and independence in their homes and communities through comprehensive, coordinated, and cost

effective systems of long-term care, and livable communities across the United States.

**BB.10 Organization.** The AoA is headed by the Assistant Secretary for Aging, who is also the ACL Administrator. The Deputy Assistant Secretary for Aging supports the Assistant Secretary in overseeing the AoA. The Deputy Assistant Secretary for Aging also serves as the Director of the Office of Long-Term Care Ombudsman Programs consistent with Section 201 of the OAA. The AoA includes the following components:

Office of the Assistant Secretary for Aging (BBA)  
Office of Supportive and Caregiver Services (BBB)  
Office of Nutrition and Health Promotion Programs (BBC)  
Office of Elder Justice and Adult Protective Services (BBD)  
Office of American Indian, Alaskan Native, and Native Hawaiian Programs (BBE)

**BB.20 Functions.**

1. Office of the Assistant Secretary for Aging (BBA). The Office of the Assistant Secretary for Aging advises and supports the Administrator, the Secretary, and other elements of the department in serving as the visible and effective advocate for older people within the federal government. Provides leadership and expertise on program development, advocacy and initiatives affecting seniors and their caregivers. Plans and directs grant programs designed to provide planning, coordination and services to older Americans as authorized under the OAA and other legislation. Actively partners with other ACL subcomponents to develop coordinated programs and policies that jointly address the common needs of older adults and people with disabilities.

Performs functions under Title II of the OAA related to consultation with other federal agencies and the provision of information about aging services, programs and policies in order to enhance coordination and delivery. Supports the Administrator in implementing Section 203(1) of the OAA by advising and coordinating with the head of each department and agency and instrumentality of the federal government proposing or administering programs or services substantially related to the objectives of the OAA. Oversees the consultation process by which agency heads must consult with AoA before establishing programs or services related to the OAA. Plans and implements the process for the collaboration with AoA and all federal agencies executing programs and services related to the OAA.

Consults with and provides technical assistance to and education for State and Area Agencies on Aging, tribal grantees and local community service providers in the development of plans, goals, and system development activities. Ensures that statutory requirements, regulations, policies, and instructions are implemented for mandatory grant programs under Titles III, VI and VII of the OAA, and for the discretionary grant programs under Title II and Title IV of the OAA, as well as Sections XXIX and 398 of the PHSA and Title III of the EJA.

Provides oversight and leadership, technical assistance, and guidance to State

and Area Agencies on Aging and community service providers. Implements the national programs of the OAA in coordination with the Regional Support Centers and ensures that clear and consistent guidance is given on program and policy directives. Issues substantive operating procedures to guide central office and regional staff in the conduct of their programmatic responsibilities.

Monitors, assists and evaluates state agencies and tribal organizations administering programs supported under the OAA and other authorizing legislation as directed. Participates in the review of state plans and recommend approval or disapproval. Participates in the review of applications for tribal programs and recommend approval or disapproval. Reviews grantee financial and program reports and provide technical assistance on fiscal operations. Oversees disaster assistance and reimbursement activities pursuant to Section 310 of the OAA.

At all levels, from national to the local service delivery level, develops methods and collaborations to articulate the problems and concerns of the elderly to organizations beyond the traditional network of agencies and works with these organizations to be more sensitive and responsive to age-related needs and issues. In coordination with the Office of External Affairs (OEA), develops strategies for increasing public awareness of the needs of older Americans and their families, and programs designed to address them.

2. Office of Supportive and Caregiver Services (BBB). The Office of Supportive and Caregiver Services serves as the focal point for the operation, administration, and assessment of the programs authorized under Titles III-B and III-E of the OAA and Sections XXIX and 398 of the PHSA, as well as activities under Titles II and IV of the OAA that are designed to provide information and referral services to seniors and caregivers, and to support technical assistance, outreach, and information dissemination that are culturally and linguistically appropriate in order to meet the needs of diverse populations of older individuals. In addition, the Office performs the functions under Title II of the OAA related to consultation with other federal agencies and the provision of information about supportive and caregiver services in order to enhance service coordination and delivery.

Implements Titles III-B and III-E of the OAA through the development of regulations, policies and guidance governing the development and enhancement by State and Area Agencies on Aging of comprehensive and coordinated systems of home- and community-based supportive and caregiver services. This includes implementing and enhancing systems for home- and community-based supportive services, the operation of multi-purpose senior centers, and caregiver support and assistance services.

In coordination with the Office of Nutrition and Health Promotion Programs, provides guidance regarding state plan processing and approval, the process and criteria for

approval of states' Intrastate Funding Formulas for the allocation and targeting of resources within states, and implementation of the Interstate Funding Formula for distribution of Title III-B and III-E funds among states. Through the analysis of state plans, evaluation findings and other relevant material, identifies potential program and management issues and develops recommendations on possible solutions.

Fosters, oversees, and ensures accountability for the implementation of programs by states and Area Agencies on Aging through guidance and direction to regional staff regarding program reviews and system development and enhancements. Designs and provides training and technical assistance for program compliance, effectiveness, and enhancement. Provides technical and subject matter expertise targeted at enhancing the capabilities of State and Area Agencies on Aging and local communities to improve service delivery to older people.

Directs and assesses the development of state-administered home- and community-based long-term care systems providing supportive services for the elderly and caregivers. Initiates and encourages expansion of the capacities of home- and community-based supportive and caregiver services.

Implements programs under Sections XXIX and 398 of the PHSA, as well as activities under Titles II and IV of the OAA, through the development of demonstrations designed to test the efficacy of new and innovative models in improving the delivery and effectiveness of community-based supportive services for seniors and caregivers. Plans and develops discretionary grant program announcements. Evaluates demonstration grant and contract proposals and recommends approval/disapproval. Monitors progress, gives technical guidance, and evaluates program performance.

Promotes the coordination of innovation and demonstration activities with other national, field and local programs related to aging. Develops standards and identifies successful service and systems development strategies and best practice models for use by the aging network. Provides technical assistance to aging network partners in utilizing the findings from program demonstrations to inform policy and program development and enhance service delivery and coordination at the federal, state and local level.

3. Office of Nutrition and Health Promotion Programs (BBC). The Office of Nutrition and Health Promotion Programs serves as the focal point for the operation, administration, and assessment of the programs authorized under Titles III-C and III-D of the OAA and Title III of the PHSA, as well as activities under Titles II and IV of the OAA designed to promote healthy behaviors and improved health status for older people. In addition, the office performs the functions under Title II of the OAA related to consultation with other federal agencies and the provision of information about nutrition and preventive health services in order to enhance service coordination and delivery.

Implements Titles III-C and III-D of the OAA through the development of regulations, policies and guidance governing the development and enhancement by State and Area Agencies on Aging of comprehensive and coordinated systems of home- and community-based nutrition and preventive health services. Carries out the functions of the designated Nutrition Officer, who coordinates nutritional services under the OAA, develops the regulations and guidelines, and provides technical assistance regarding nutrition to State and Area Agencies on Aging, nutrition service providers, and other organizations. Serves as the liaison to the Department of Agriculture and other federal agencies and organizations related to nutrition policy and program issues.

In coordination with ACL's Office of Supportive and Caregiver Services, provides guidance regarding state plan processing and approval, the process and criteria for approval of states' Intrastate Funding Formulas for the allocation and targeting of resources within states, and implementation of the Interstate Funding Formula for distribution of Title III-C and III-D funds among states. Through the analysis of state plans, evaluation findings and other relevant material, identifies potential program and management issues and develops recommendations on possible solutions.

Fosters, oversees, and ensures accountability for the implementation of programs by states and Area Agencies on Aging through guidance and direction to regional staff regarding program reviews and system development and enhancements. Designs and provides training and technical assistance for program compliance, effectiveness, and enhancement. Provides technical and subject matter expertise targeted at enhancing the capabilities of State and Area Agencies on Aging and local communities to improve service delivery to older people.

Directs and assesses the development of State-administered home- and community-based long-term care systems providing nutrition and preventive health services for the elderly and caregivers. Initiates and encourages expansion of the capacities of home- and community-based nutrition and preventive health services to deliver comprehensive services to the elderly.

Implements programs under Title III of the PHSA, as well as other activities under Titles II and IV of the OAA, through the development of demonstrations designed to test the efficacy of new and innovative models in improving the delivery and effectiveness of community-based nutrition, health promotion, and evidenced-based disease prevention. Prepares the planning documents for and develops discretionary grant program announcements. Evaluates demonstration grant and contract proposals; and recommends approval/disapproval. Monitors progress, gives technical guidance to, and evaluates the performance of grantees and contractors.

Promotes the coordination of innovation and demonstration activities with other national, field and local programs related to aging. Develops standards and identifies

successful service and systems development strategies and best practice models for use by the aging network. Provides technical assistance to aging network partners in utilizing the findings from program demonstrations to inform policy and program development and enhance service delivery and coordination at the federal, state and local level.

4. Office of Elder Justice and Adult Protective Services (BBD). The Office of Elder Justice and Adult Protective Services serves as the focal point for the operation, administration, and assessment of the elder abuse prevention, legal assistance development, and pension counseling programs under Titles II and VII of the OAA, and for Adult Protective Services and related activities carried out under the Elder Justice Act. The office also carries out the Long-Term Care Ombudsman functions established in Section 201(d)(1) of the OAA, serving as the advocate for older Americans in the development and implementation of federal policies and laws that may affect the health, safety, welfare, or rights of residents of long-term care facilities.

Reviews state plans to determine eligibility for funding under the OAA and recommends approval or disapproval. Implements Title VII in the field, through the provision of guidance and information, and the development and interpretation of Title VII program regulations and policy. Ensures the implementation of guidance and instructions concerning prevention of elder abuse, elder justice and legal assistance development programs. Provides guidance and leadership in the development of the pension counseling program and effective models for nationwide replication.

Fosters, coordinates, and ensures accountability for the implementation of Title VII by states through guidance and direction to regional staff regarding program reviews, and program and system development and enhancements. Designs and provides training and technical assistance for program compliance, effectiveness, and enhancement. Develops program plans and instructions for State and Area Agencies on Aging to improve the Title VII protection and representational programs funded under the OAA.

Implements demonstration activities under Titles II and IV of the OAA and the EJA designed to test the efficacy of new and innovative models in improving the delivery and effectiveness of elder rights activities. Prepares the planning documents for and develops discretionary grant program announcements. Evaluates demonstration grant and contract proposals and recommends approval/disapproval. Monitors progress, gives technical guidance, and evaluates program performance.

Promotes the coordination of innovation and demonstration activities with other national, field and local programs related to aging. Develops standards and identifies successful service and systems development strategies and best practice models for use by the aging network. Provides technical assistance to aging network partners in utilizing the findings from program demonstrations to inform policy and program

development and enhance service delivery and coordination at the federal, state and local level.

Provides federal leadership for the development and implementation of comprehensive Adult Protective Services systems in order to provide a coordinated and seamless response for helping adult victims of abuse and to prevent abuse before it happens. Develops national Adult Protective Services data systems and standards, and provides technical assistance to states on using and interfacing with the system. Develops model Adult Protective Services program standards that help states improve the quality and consistency of programs. Advances a coordinated federal research strategy to fill the gaps in knowledge and develop evidence-based interventions to prevent, identify and report, and respond to elder abuse, neglect and exploitation. Provides support for the Elder Justice Coordinating Council.

Reviews federal legislation, regulations, and policies regarding long-term care ombudsman programs and makes recommendations to the Assistant Secretary for Aging. Coordinates the activities of ACL with other federal, state and local entities relating to long-term care ombudsman programs; prepares an annual report to Congress on the effectiveness of services provided by state long-term care ombudsman programs; and establishes standards for the training of state long-term care ombudsman staff. Coordinates the administration of the Long-Term Care Ombudsman Program and the National Ombudsman Resource Center to ensure alignment with agency initiatives related to elder justice and adult protective services. Makes recommendations to the Administrator regarding the operation of the National Ombudsman Resource Center, and the review and approval of the provisions in state plans submitted under section 307(a) of the OAA that relate to state long-term care ombudsman programs.

5. Office for American Indian, Alaskan Native, and Native Hawaiian Programs (BBE). The Office for American Indian, Alaskan Native, and Native Hawaiian Programs serves as advocate within the Department of Health and Human Services and with other departments and agencies of the federal government regarding all federal policies affecting older individuals who are Native Americans. Works with state, local and tribal governments providing leadership and coordination of activities, services and policies affecting American Indians, Alaskan Natives and Native Hawaiian elders. Promotes linkages among national Indian organizations, national aging organizations, and national provider organizations with the goal of enhancing the interests of and services to Native American elders. Recommends policies and priorities with respect to the development and operation of programs and activities relating to individuals who are older Native Americans. Coordinates activities among other federal departments and agencies to ensure a continuum of improved services through memoranda of agreements or through other appropriate means of coordination.

Evaluates outreach under Title III and Title VI of the OAA and recommends necessary

action to improve service delivery, outreach, and coordination between Title III and Title VI services. Encourages and assists with the provision of information to older Native Americans to ensure a continuum of services. Develops research plans, conducts and arranges for research in the field of Native American aging; collects, analyzes, and disseminates information related to problems experienced by older Native Americans, including information on health status of older individuals who are Native Americans, elder abuse, in-home care, and problems unique to Native Americans. Develops, implements, and oversees the uniform data collection procedures for tribal and Native Hawaiian Organizations and implements and oversees the consultation requirements of Title II as they apply to Native American issues.

Serves as the AoA focal point for the administration of the programs authorized under Title VI and the Native American Organization provisions of Title VII–B of the OAA, including administering grants, cooperative agreements and contracts. Provides program guidance, policy direction, training, technical assistance, and monitoring of Title VI grantees. Oversees the development and operation of Resource Centers on Native American Elders under Title IV of the OAA, which gather information, perform research, provide for dissemination of results, and provide technical assistance and training to those who provide services to Native American elders. Arranges for and manages ongoing training and technical assistance for Title VI grantees. Coordinates additional training and technical assistance related to diversity and national minority aging organizations and coalitions with other projects managed by other components of the agency.

V. Delete Section C, Administration on Disabilities (BC), in its entirety and replace with the following:

C. Administration on Disabilities (BC)

BC.00 Mission

BC.10 Organization

BC.20 Functions

**BC.00 Mission.** The Administration on Disabilities (AoD) advises the Secretary, through the Administrator and Principal Deputy Administrator for Community Living, on matters relating to services and supports for individuals with disabilities and their families, and serves as a focal point in the department to support and encourage the provision of quality services and supports, and implementation of program and policy that benefit people with disabilities and their families. AoD supports states and communities in increasing the independence, productivity and community inclusion of individuals with disabilities; empowers individuals with disabilities to maximize opportunities for competitive integrated employment, economic self-sufficiency, independence and integration into society; promotes consumer control and self-advocacy; and ensures that the rights of individuals with disabilities are protected. Carries out programs operated under the DD Act, Title VII of the Rehabilitation Act, Section 262 and 292 of the HAVA, Section

5 of the Assistive Technology Act of 1998, Title III of the PHSA, and the Traumatic Brain Injury Program Reauthorization Act of 2018.

**BC.10 Organization.** AoD is headed by a Commissioner on Disabilities who also serves as the Director of the Independent Living Administration. This dual role reports directly to the Administrator and is appointed by the Secretary consistent with DD Act and Section 701A of the Rehabilitation Act. This role serves as a member of the Administrator's senior leadership team. AoD includes the following components:

Office of the Commissioner on Disabilities (BCA)

Office of Intellectual and Developmental Disability Programs (BCB)

President's Committee for People with Intellectual Disabilities (BCB1A)

Office of Independent Living Programs (BCC)

Office of Disability Services Innovation (BCD)

**BC.20 Functions.**

1. Office of the Commissioner on Disabilities (BCA). The Office of the Commissioner on Disabilities provides executive leadership and management strategies for all components of AoD. Advises the ACL Administrator on issues related to services and supports, civil rights and other matters affecting individuals with disabilities and their families. Plans, coordinates and controls AoD policy, planning and management activities which include the development of legislative proposals, regulations and policy issuances for AoD.

Provides executive direction to AoD's components and establishes goals and objectives for AoD programs. Assists states, through the design and implementation of state plans for independent living, developmental disabilities, and protection and advocacy programs, in making optimal use of federal, state, and local resources that maximize the independence, productivity, economic self-sufficiency and community inclusion and integration of individuals with disabilities and their families.

In concert with other components of ACL as well as other public, private, and volunteer sector partners, develops and implements research, demonstration and evaluation strategies for discretionary funding of activities designed to improve and enrich the lives of individuals with disabilities. Serves as a resource in the development of policies and programs to reduce or eliminate barriers experienced by individuals with disabilities through the identification of promising practices and dissemination of information. Supports and encourages programs or services and manages initiatives, involving the private and voluntary sectors that benefit individuals with disabilities and their families.

Initiates, executes and supports the development of interagency, intergovernmental and public-private sector agreements, committees, task forces, commissions or joint-funding efforts as appropriate. Actively partners with other ACL subcomponents to develop coordinated programs and policies that jointly address the common needs of older adults and people

with disabilities. In coordination with OEA, develops strategies for increasing public awareness of the needs of individuals with disabilities, their families, and programs designed to address them.

2. Office of Intellectual and Developmental Disability Programs (BCB). The Office of Intellectual and Developmental Disability Programs is responsible for the coordination, oversight, management and evaluation of programs authorized by the DD Act. The office is responsible for the coordination, oversight, management and evaluation of the State Councils on Developmental Disabilities, and the University Centers for Excellence in Developmental Disabilities grant programs as authorized by the DD Act. Develops procedures and performance standards that ensure compliance with the DD Act and that improve the outcomes of the programs in increasing the independence, productivity and community inclusion of persons with developmental disabilities. Conducts routine and special analyses of state plans of State Councils on Developmental Disabilities, and five-year plans of the University Centers for Excellence in Developmental Disabilities, to ensure consistent application of program goals and objectives. Provides program development services, develops and initiates guidelines, policy issuances and actions with team participation by other components of AoD, ACL, HHS and other government agencies to fulfill the mission and goals of the DD Act, as amended.

Oversees activities that support state efforts to improve accessibility for individuals with the full range of disabilities to polling places and voting facilities. The office also provides general staff support for the President's Committee for People with Intellectual Disabilities (BCB1A) as established by Executive Order. Coordinates all meetings, provides advice and assistance in the areas of intellectual disabilities as requested by the President or the Secretary, and prepares and issues an annual report concerning intellectual disabilities and additional reports or recommendations as appropriate.

3. Office of Independent Living Programs (BCC). The Office of Independent Living Programs, which serves as the Independent Living Administration as specified in Section 701A of the Rehabilitation Act, aims to maximize the leadership, empowerment, independence, and productivity of individuals with disabilities while promoting the independent living philosophy of consumer control, self-help and self-advocacy, development of peer relationships and peer role models, and equal access for individuals with significant disabilities to all aspects of society. The office administers grants to support independent living programs that offer financial assistance to provide expanded and improved independent living services. Develops and supports statewide networks of centers for independent living and improves working relationships among state independent living rehabilitation programs, centers for independent living, statewide Independent Living Councils, Rehabilitation Act programs outside of Title VII, and other relevant federal and non-federal programs. Funds grants for consumer-controlled, community-

based, cross-disability, nonresidential, private nonprofit agencies that are designed and operated within a local community by individuals with disabilities and provide an array of independent living services, such as community planning and decision making; school-based peer counseling, transition services, role modeling, and skills training. Manages other grants, contracts or cooperative agreements to provide training and technical assistance with respect to planning, developing, conducting, administering, and evaluating centers for independent living. Ensures compliance with the Rehabilitation Act, which establishes a set of standards and assurances that centers for independent living must meet and requires development and publication of indicators of minimum compliance with the standards.

In addition, participates in the development and dissemination of policy guidance, regulations, and program guidance related to Independent Living Programs. In collaboration with the Center for Policy and Evaluation (CPE), develops program performance measures, which are used to evaluate and monitor grantees. Provides program development services, develops and initiates guidelines, policy issuances and actions with team participation by other components of ACL, HHS and other government agencies to fulfill the purpose and goals of Title VII of the Rehabilitation Act, as amended.

4. Office of Disability Services Innovation (BCD). The Office of Disability Services Innovation works across disability populations, programs and resources to advance education and technical assistance while addressing the most prevailing issues and opportunities for Americans with disabilities. The office administers the Protection and Advocacy programs as authorized by the DD Act, Section 292 of the HAVA, Section 5 of the Assistive Technology Act, and the Traumatic Brain Injury Program Reauthorization Act of 2018, that together work to protect individuals with disabilities in every state and territory by empowering them to fight for personal and civil rights, providing legal support to traditionally unserved or underserved populations to help them navigate the legal system to achieve resolution and encourage systems change, and advocating on their behalf to help ensure they are able to exercise their rights to make choices, contribute to society, and live independently. This includes administering a training and technical assistance grant program under the HAVA that provides technical assistance to Protection and Advocacy systems in their mission to promote the full participation in the electoral process for individuals with the full range of disabilities, including registering to vote, casting vote, and accessing polling places.

The office is also responsible for the coordination, oversight, management and evaluation of the Projects of National Significance program authorized by the DD Act. Ensures the dissemination of grantee results, including project results and information produced by grantees, in coordination with the Office of Intellectual and Developmental Disability Programs, the

Office of Independent Living Programs, and the Office of the Commissioner on Disabilities. Manages cross-cutting research, demonstration and evaluation initiatives consistent with the purposes of the DD Act and Rehabilitation Act, with other components of ACL, HHS and other government agencies to promote and integrate the grant programs into cross-agency and cross-disability efforts. Coordinates information sharing and other activities related to national program trends and studies, reviews and analyzes other federal programs providing services applicable to persons with disabilities for the purpose of integrating and coordinating program efforts.

The office also administers grants to states to expand and improve capability for individuals with traumatic brain injury and their families have better access to comprehensive and coordinated services, to encourage systems change, and to address barriers to needed services as authorized by the Traumatic Brain Injury Program Reauthorization Act of 2018. The office also carries out activities under Title III of the PHSA that promote the health and well-being of people living with paralysis and limb loss. Supports their families and caregivers by providing comprehensive information and referral services that assist individuals to remain at home and in the community.

VI. Delete Section D, Center for Integrated Programs (BD), in its entirety and replace with the following:

D. Center for Innovation and Partnership (BD):

BD.00 Mission

BD.10 Organization

BD.20 Functions

*BD.00 Mission.* The Center for Innovation and Partnership (CIP) serves as the locus within ACL for the administration of programs and initiatives that serve both older adults and persons with disabilities, including consumer access and protection programs. Manages programs and initiatives that promote the use of self-directed and person-centered service models and advance the development of health and long-term care services and support systems that are responsive to the needs and preferences of older adults, persons with disabilities, caregivers, and families. Carries out programs authorized under Titles II and IV of the OAA, Section 119 of the MIPPA, Section 4360 of the OBRA of 1990, and Section 4 of the Assistive Technology Act that focus on helping states make their health care and long-term service and support systems more person-centered, improve access to health care and assistive technology services, and promote the values of self-determination, full participation in community, integration and independence. Also implements initiatives at the national, state and local level to strengthen the capacity of ACL's network of state and community-based organizations to play a meaningful role in the transformation of our nation's health and long-term service and support systems.

*BD.10 Organization.* CIP is headed by a Deputy Administrator, who reports directly

to the ACL Administrator. The Center includes the following components:

Office of the Deputy Administrator for Innovation and Partnership (BDA)  
Office of Healthcare Information and Counseling (BDB)  
Office of Network Advancement (BDC)  
Office of Interagency Innovation (BDD)

*BD.20 Functions.*

1. Office of the Deputy Administrator for Innovation and Partnership (BDA). The Office of the Deputy Administrator for Innovation and Partnership supports the ACL Administrator and the Principal Deputy Administrator in advancing programmatic and systemic changes to make state health and long-term services and supports systems more person-centered and responsive to the needs and preferences of older Americans, people with disabilities, their families, and caregivers. Works with other ACL components, federal partners and key external stakeholder groups to engage the multiple state agencies involved in long-term services and supports in developing high performing, consumer-oriented, and responsive systems of care for all populations.

Provides leadership and strategic direction to guide the administration of ACL programs that assist consumers in understanding their health care and long-term services and supports options, improve access to services including assistive technologies, and prevent fraud and abuse. Consults with, provides technical assistance to, and supports the education of states and local community service providers in the development of plans, goals, and system development activities. Supports the coordination of programs within HHS and with federal, state, community and private-sector partners.

Works closely with AoA, AoD, NIDILRR and other ACL components to facilitate the coordination across ACL of multiple consumer protection and family support programs and various systems change and network capacity initiatives to fully optimize the potential synergies of these investments across ACL. Uses data and learnings from the programs administered to inform the work of other ACL components and ACL's policy priorities and provides guidance to the Regional Support Centers to ensure clear and consistent direction to the states on relevant program implementation issues.

2. Office of Healthcare Information and Counseling (BDB). The Office of Healthcare Information and Counseling oversees the operation and administration of the State Health Insurance Assistance Program, authorized under the section 4360 of the OBRA of 1990, and the Senior Medicare Patrol Program, authorized under Title IV of the OAA, that help Medicare and Medicaid beneficiaries as well as coming-of-agers navigate the complexities of health and long-term care systems and educate them on how to prevent fraud, waste, and abuse. The office also manages related activities funded under section 119 of the MIPPA that focus on outreach to help beneficiaries understand and apply for their Medicare benefits including the Low Income Subsidy program (LIS), Medicare Savings Program (MSP), and Medicare Prescription Drug Coverage (Part D).

Coordinates, implements, monitors, and promotes efforts to provide consumer information and education designed to increase access to, and detect, prevent and report error, fraud and abuse in, the Medicare and Medicaid programs. Provides in-depth expertise, information, leadership and technical assistance to assist the State Health Insurance Assistance Program and Senior Medicare Patrol networks, and serves as a reliable clearinghouse of information for older persons, people with disabilities, and their families and caregivers.

Develops funding opportunities and monitors grants to ensure all necessary activities are completed. Manages the full spectrum of contract requirements including identifying contractual needs, developing statements of work and necessary planning documents, and ensuring that contractors are completing assigned tasks. Ensures that grantees and their volunteers have the necessary information and training to carry out program functions. Develops and refines the performance management systems and provides specialized guidance and technical assistance to help grantees improve their performance. Coordinates with the Centers for Medicare & Medicaid Services (CMS) and other national partnerships to advance program objectives.

Administers, in partnership with the CMS, the Duals Demonstration Ombudsman Technical Assistance Program which supports grantees serving beneficiaries of state demonstrations to integrate care for Medicare-Medicaid enrollees associated with the CMS Financial Alignment Initiative. Ensures that grantees and their volunteers have the necessary information and training to carry out program functions. Coordinates with CMS and the state grantees in developing and refining performance management systems and provides specialized guidance and technical assistance to help grantees improve their performance. Analyzes program reports, including consumer feedback and complaints, and makes recommendations to CMS for improving the Ombudsman Program and the Financial Alignment Initiative.

3. Office of Network Advancement (BDC). The Office of Network Advancement oversees a variety of initiatives to ensure that the interests and needs of older adults and people with disabilities, as well as the state and local organizations that serve these populations, are adequately reflected in the transformations occurring in our nation's health and long-term services and support systems as those systems shift toward the use of managed care, Health Information Technology (IT), and other models and approaches to better integrate the delivery of health and long-term services and supports as well as to make those systems more person-centered. These initiatives involve partnerships with other federal agencies and external stakeholders at the national, state, and local level and the management and execution of technical assistance activities, including the identification and dissemination of best practices and program models.

Serves as the focal point for the administration the Aging and Disability

Resource Center program authorized under Title II of the OAA, providing leadership and a central strategic focus for ACL's efforts to work with states and communities to develop single entry point/no wrong door systems of access to long-term services and supports for seniors, persons with disabilities, and their families and caregivers, in coordination with CMS and other Federal agencies. Leads ACL's Business Acumen work to help community-based organizations that serve older adults and persons with disabilities to build their business capacity and align their service capabilities in order to work effectively with integrated healthcare entities (e.g., accountable care organizations, health plans, managed care organizations, hospitals, health systems, etc.) to provide community-based long-term services and supports and/or evidence-based preventive health programs and services. Works with other ACL components to coordinate the various business acumen and related activities across ACL, and oversees the provision of the business acumen technical assistance that is delivered through a variety of methods and techniques to state level and community-based aging and disability agencies and organizations. Develops partnerships with external stakeholders at the national, state and local level in both the public and private sectors, including private foundations, to enhance and complement ACL's work in this area.

Works with the HHS Office of the National Coordinator for Health Information Technology, CMS, and other internal and external stakeholders on Health IT initiatives that have a potential impact on older adults and persons with disabilities and the state and local agencies and organizations that serve these populations to ensure that the needs and interests of these populations and organizations are reflected in the Health IT initiatives that are shaping the future of our nation's health and long-term services and support systems. Works with CPE and other ACL components to track policy and program trends and emerging issues related to integrated care to inform ACL's ongoing program and policy development work as the transformations in health and long-term services and supports continue to evolve.

4. Office of Interagency Innovation (BDD). The Office of Interagency Innovation plans and directs the implementation of programs designed to enhance consumer access to long-term services and supports, including integrated systems of services and person-centered programs and systems at the state and local level that support community living. Supports state and community efforts to improve the provision of assistive technology for individuals with disabilities of all ages through comprehensive, statewide programs that are consumer responsive. Serves as the focal point for the administration of the Assistive Technology state programs authorized under Section 4 of the Assistive Technology Act, the Veteran-Directed Home and Community-Based Services program, and other activities as deemed appropriate.

Promotes initiatives to expand access to services and the development of more responsive service systems, including

person-centered planning and self-directed service models. Implements partnerships with external stakeholder organizations to enhance access to integrated systems of services that support both older Americans and persons of all ages with disabilities. Coordinates with the Department of Veterans Affairs on the development and implementation of their long term services and support programs, including the Veteran-Directed Home and Community-Based Services program and caregiver support programs. Provides technical assistance and support services to programs funded under the Assistive Technology Act to make assistive technology devices and services more available and accessible to individuals with disabilities and their families. Works with NIDILRR and other ACL components to facilitate and accelerate the translation of relevant research findings into practice nationwide. Supports the development and maintenance of a database of technical assistance resources, best practices and model programs for use by federal, state and local agencies and organizations involved in advancing system changes that make long-term services and support systems more person-centered and more responsive to the needs and preferences of older adults and persons with disabilities. Partners with other federal departments on innovative activities, policies and technical assistance, including the Department of Transportation, Department of Housing and Urban Development, Department of Agriculture, among others.

Develops funding opportunities and monitors grants to ensure all necessary activities are completed. Manages the full spectrum of contract requirements including identifying contractual needs, developing statements of work and necessary planning documents, and ensuring that contractors are completing assigned tasks. Ensures that grantees have the necessary information and training to carry out program functions. Develops and refines performance management systems and provides specialized guidance and technical assistance to help grantees improve their performance.

VII. Delete Section G, National Institute on Disability, Independent Living, and Rehabilitation Research (BG), in its entirety and replace with the following:

G. National Institute on Disability, Independent Living, and Rehabilitation Research (BG):

BG.00 Mission  
BG.10 Organization  
BG.20 Functions

*BG.00 Mission.* The National Institute on Disability, Independent Living and Rehabilitation Research (NIDILRR) administers research programs authorized under Sections 202 and 204 of the Rehabilitation Act of 1973, NIDILRR supports the generation of new knowledge and promotes the effective use of this knowledge to: improve the abilities of individuals with disabilities to participate in community activities of their choice; and, enhance society's capacity to provide opportunities

and accommodations for these individuals. NIDILRR fulfills its mission through research, development, and dissemination and related activities designed to contribute to community living and participation, employment, and health and function of individuals of all ages with all types and degrees of disability, including low-incidence disability.

**BG.10 Organization.** NIDILRR is headed by a Deputy Administrator, who serves as the Director as defined in Section 202 of the Rehabilitation Act, and as a member of the Administrator's senior leadership team. NIDILRR includes the following components:

Office of the Director of Disability, Independent Living, and Rehabilitation Research (BGA)  
 Disability, Independent Living, and Rehabilitation Research Advisory Council (BGA1)  
 Office of Research Administration (BGB)  
 Office of Research Sciences (BGC)

**BG.20 Functions.**

1. Office of the Deputy Administrator of Disability, Independent Living, and Rehabilitation Research (BGA). The Office of the Deputy Administrator for Disability, Independent Living and Rehabilitation Research provides executive leadership and management strategies for all components of NIDILRR. The office, which includes a Deputy Director, manages all internal and external activities of the NIDILRR, including the research, dissemination, and public information programs, research evaluation, and provides direction and guidance to NIDILRR's scientific peer review. Prepares and issues an annual report and coordinates with OEA and other agency components to ensure that the results of research are disseminated to, and utilized by service providers, people with disabilities and their families, and the general public.

Responsible for the coordination and management of research and research capacity building programs. Promotes the widespread dissemination of research results and other new knowledge both nationally and internationally to individuals with disabilities, families, service providers, researchers, and others through appropriate and accessible media, training, and technical assistance. Sponsors research that can be used to promote the use of appropriate assistive technology and the development of coordinated systems of technology services. Provides general staff support for the Disability, Independent Living, and Rehabilitation Research Advisory Council. Coordinates all meetings, provides advice and assistance, and prepares and issues reports or recommendations as appropriate. Chairs and supports the Interagency Committee on Disability Research (ICDR), authorized by Section 203 of the Rehabilitation Act, and promotes the coordination of disability independent living, and research throughout the federal Government. The ICDR is responsible for identifying, assessing, and seeking to coordinate and promote cooperation among all federal program activities, projects, and plans with respect to the conduct of research related to rehabilitation of individuals with disabilities; facilitating the compilation of

information about the status of disability, independent living and rehabilitation research sponsored by federal agencies. Coordinates its activities with other federal agencies and participates in joint-funding of rehabilitation research and related activities, in collaboration with the ICDR. Prepares and submits to Congress a long-range plan for rehabilitation research and provides necessary data and information required by the National Council on Disability. The ICDR is also responsible for preparing a comprehensive government-wide strategic plan for disability, independent living and rehabilitation research and ensuring accountability for achievement of measurable goals, objectives and timetables.

2. Office of Research Administration (BGB). The Office of Research Administration supports the administration of NIDILRR's grants and contracts portfolio. The office also coordinates NIDILRR's program evaluation activities and collaborates with the Office of Research Sciences in program planning and priority setting. Coordinates with the Office of Research Sciences staff in the preparation of all contract packages, development of requirements and performance work statements. Conducts routine contract management activities to include completion of administrative and fiscal tasks required throughout the contract lifecycle. Maintains and monitors annual grant forecasts and schedules, and provides grants administration support for NIDILRR including packaging grant announcements and application kits.

Makes recommendations to the Deputy Administrator of NIDILRR regarding allocation of NIDILRR program funds for current and future budget years. Coordinates and collaborates with Office of Research Sciences program staff in the preparation of the annual spending plan and facilitate the implementation of the plan to ensure compliance with established departmental guidance. Provides administrative support in the monitoring of grants and cooperative agreements, and facilitates the administrative execution of interagency agreements.

Administers NIDILRR evaluation activities to improve the effectiveness of NIDILRR's research activities. This includes collaborating with NIDILRR's senior management to define and facilitate the conduct of analyses of program and budget data as well as focused, special program evaluation activities. In its evaluation function, it coordinates with CPE to prepare planning and evaluation documents required by ACL, HHS, OMB and Congress.

3. Office of Research Sciences (BGC). The Office of Research Sciences is responsible for national and international programs of research, training, and knowledge translation. Develops and manages a comprehensive program of grants, cooperative agreements, and contracts that address all of NIDILRR's research, capacity building, and knowledge translation activities. Sponsors research on, and development of programs and interventions involving technological systems, techniques and devices to overcome environmental barriers, and enable persons with disabilities to maximize community living and

participation, employment, and their health and functional abilities. Responsible for providing research-based knowledge to industry to facilitate development, marketing, and distribution of aids and devices that can be used by people with disabilities. Determines criteria and standards and sets priorities for all NIDILRR research, training, and evaluation activities in the areas of community living and participation, employment, and health and function.

Plans, develops, implements, and manages a comprehensive national and international program of research, training, and knowledge translation in specific program areas. Identifies trends and needs and recommends research and development priorities to the leadership of NIDILRR. Manages a comprehensive scientific peer review of all grant applications and conducts pre-award site visits, as required by statute. Recommends new and continuation awards, as well as award terminations. Performs program oversight and monitoring of the progress of grants and contracts. Collaborates with ACL senior leaders, the CPE, and the Center for Management and Budget in developing and publishing regulatory documents, including annual announcements of priorities and grant application packages.

Enhances the public understanding of the barriers to and facilitators of optimal outcomes for individuals with disabilities through the dissemination of research findings and other data, to include statistical data on disability status and outcomes, as evidenced by the annual publication of the Annual Compendium of Disability Statistics, distributed widely each year. Coordinates with OEA as well as ACL subcomponents to plan, develop, and administer knowledge translation, research utilization, public information, public education, and publications which address NIDILRR research activities and findings; and manages a comprehensive program to disseminate NIDILRR research findings through accessible media to a range of target audiences. Provides research-based information from grantees to the ICDR, the National Council on Disability, and other agencies and private organizations serving individuals with disabilities. Sponsors studies to determine innovative techniques and systems for the dissemination and utilization of rehabilitation research findings.

VIII. Insert Section H, Center for Regional Operations (BH), as follows:

H. Center for Regional Operations (BH):

BH.00 Mission  
 BH.10 Organization  
 BH.20 Functions

**BH.00 Mission.** The Center for Regional Operations (CRO) serves as the liaison, advocate and representative for the agency regionally across the United States for all of ACL's programs areas. This includes working with and connecting stakeholders to other HHS divisions and federal agencies to help advance the development of programs and activities serving older adults, persons with disabilities and their caregivers, and developing new partnerships with and

coordinating with public and private organizations in the planning and development of comprehensive and coordinated services and supports.

**BG.10 Organization.** CRO is directed by a Deputy Administrator and includes a coordinating central office and Regional Support Centers around the country. The Center for Regional Operations includes the following components: Office of the Deputy Administrator for Regional Operations (BHA) Regional Support Centers (BHB1–BHB10)

**BG.20 Functions.**

1. Office of the Deputy Administrator of Regional Operations (BHA). The Office of the Deputy Administrator of Regional Operations directs and coordinates the work of all ACL regional operations and activities and supervises the ten Regional Administrators who each serve as a liaison to their assigned region.

The Regional Support Centers (BHB1–BHB10) serve as the focal point for the coordination of ACL programs within their designated HHS region, and support state and local efforts to improve community living for older adults and persons with disabilities. Represent the agency within the region, providing information for, and helping to advance the development of, national programs serving older adults and persons with disabilities. Serve as advocates for ACL stakeholders to other federal agencies in their geographic jurisdictions; advise, consult and cooperate with each federal agency proposing or administering programs or services that affect ACL stakeholders; coordinate and assist public (including federal, state, tribal and local agencies) and private organizations in the planning and development of comprehensive and coordinated services; and conduct education of officials and the broader community to ensure understanding of the need for community-based services and supports for older adults and people with disabilities.

Advise the Deputy Administrator on problems and progress of programs; evaluate the effectiveness of programs and services in the regions and recommend changes that would improve program operations and enhance effectiveness; and provide guidance to agencies and grantees in applications of policy to specific operational issues requiring resolution. Facilitate interagency cooperation at the federal, regional, state and tribal levels to enhance resources and assistance available to older adults and persons with disabilities. Disseminate and provide technical assistance regarding program guidelines and developments to state agencies, tribal organizations, and local community service providers.

**IX. Delegations of Authority:** All delegations and re-delegations of authority made to officials and employees of affected organizational components will continue in them or their successors pending further redelegation, provided they are consistent with this reorganization.

**X. Funds, Personnel and Equipment:** Transfer of functions affected by this reorganization shall be accompanied in

each instance by direct and support funds, positions, personnel, records, equipment, supplies and other resources.

This reorganization will be effective upon date of signature.

Dated: May 2, 2019.

**Alex M. Azar II,**  
*Secretary.*

[FR Doc. 2019–09444 Filed 5–8–19; 8:45 am]

**BILLING CODE 4154–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2018–D–4525]

#### Clinical Lactation Studies: Considerations for Study Design; Draft Guidance for Industry; Availability

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

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled “Clinical Lactation Studies: Considerations for Study Design.” This guidance reflects FDA’s current recommendations to sponsors regarding lactation studies during drug development. This guidance provides recommendations to facilitate the conduct of lactation studies. Such studies can inform breastfeeding with drug use recommendations included in the *Lactation* subsection of labeling. The recommendations in this guidance also reflect discussions from the 2007 Pediatric Advisory Committee meeting and the 2016 Lactation Workshop, which considered how data from clinical lactation studies can inform the safety of a drug when used during lactation. This guidance replaces the draft guidance for industry entitled “Clinical Lactation Studies—Study Design, Data Analysis, and Recommendations for Labeling” issued February 2005.

**DATES:** Submit either electronic or written comments on the draft guidance by July 8, 2019 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

**ADDRESSES:** You may submit comments on any guidance at any time as follows:

#### Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the

instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

#### Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand Delivery/Courier (for written/paper submissions):** Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

**Instructions:** All submissions received must include the Docket No. FDA–2018–D–4525 for “Clinical Lactation Studies: Considerations for Study Design.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the