download an electronic version of the Guideline, go to *http://www.regulations.gov, Docket CDC–2011–0011.* You may submit written comments electronically at this Web site. Please follow directions at *http://www.regulations.gov* to submit comments.

You may also submit written comments to the following *address:* Office of Blood, Organ and Other Tissue Safety, Division of Healthcare Promotion, National Center for Emerging and Zoonotic Infectious Diseases, Centers for Disease Control and Prevention, (CDC), *Attn: Public Health Service Guideline for Reducing Transmission of Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV) and Hepatitis C Virus (HCV) through Solid Organ Transplantation,* Docket No. CDC–2011–0011, 1600 Clifton Rd, NE., Mailstop A–07, Atlanta, Georgia, 30333. All written materials identified will be available for public inspection Monday through Friday, except for legal holidays, from 9 a.m. until 5 p.m., Eastern Standard Time, at 1600 Clifton Road, NE., Atlanta, Georgia 30333. Please call ahead to (404) 639–4000 and ask for a representative from the Office of Blood, Organ and Other Tissue Safety to schedule your visit. All relevant comments received will be posted publicly at this Web site without change, including any personal or proprietary information.

**FOR FURTHER INFORMATION CONTACT:** Debbie Seem, Division of Healthcare Quality Promotion, National Center for Emerging and Zoonotic Diseases, Centers for Disease Control and Prevention, 1600 Clifton Road NE., Mailstop A–07, Atlanta, Georgia, 30329–4018; *Telephone:* (404) 639–4000.

**SUPPLEMENTARY INFORMATION:** Since 2008, HHS/CDC has collaborated with state and federal agencies, national partners, academicians, public and private health professionals, the transplant field, public health organizations, and other partners to revise and expand the 1994 *Guidelines for Preventing Transmission of Human Immunodeficiency Virus (HIV) through Transplantation of Human Tissue and Organs.* The 2011 draft Guideline updates the previous recommendations about HIV and also includes recommendations to reduce disease transmission of HBV and HCV, and addresses issues such as donor risk assessment, donor screening, HBV- and HCV-infected donors and transplantation, recipient informed consent, recipient screening, donor and recipient specimen collection and storage, and tracking and reporting of HIV, HBV, and HCV.

As with the 1994 *Guideline,* the recommendations address adult and pediatric donors who are living or deceased, as well as transplant candidates and recipients. In addition to summarizing current scientific knowledge about solid organ transplant safety, the draft 2011 *Guideline* also identifies important gaps in the literature where further research is needed.

HHS/CDC worked with the University of Pennsylvania's Health System Center for Evidence-based Practice (CEP) and sought input in each phase of the *Guideline's* development from subject matter experts in HIV and hepatitis through formation of a *Guideline* Expert Panel to develop the new *Guideline.* HHS/CDC also formed a *Guideline* Review Committee to provide feedback on the draft *Guideline* recommendations. Members of the Review Committee included representation from public health, regulatory, transplant infectious disease and other stakeholders. This new Draft Guideline will not be a federal rule or regulation.

**Juliana K. Cyril,**

*Deputy Director, Office of Science Quality, Office of the Associate Director for Science, Centers for Disease Control and Prevention.*

[FR Doc. 2011–30205 Filed 11–22–11; 8:45 am]

**BILLING CODE 4163–18–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Children and Families

### Statement of Organization, Functions, and Delegations of Authority; Administration on Developmental Disabilities

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

**ACTION:** Notice.

**SUMMARY:** Statement of Organization, Functions, and Delegations of Authority. The Administration for Children and Families (ACF) has reorganized the Office of the Assistant Secretary (OAS) and the Administration on Developmental Disabilities (ADD). This reorganization realigns the President's Committee for People with Intellectual Disabilities Staff within the OAS and moves the function to ADD as a result of the Charter Amendment for PCPID governed by Public Law 92–463 signed by the Secretary, HHS, on May 9, 2011.

**FOR FURTHER INFORMATION CONTACT:** Sharon Lewis, Commissioner, Administration on Developmental Disabilities, 200 Independence Avenue SW., Washington, DC 20201, (202) 690–6590.

This notice amends Part K of the Statement of Organization, Functions and Delegations of Authority of the Department of Health and Human Services (HHS), Administration for Children and Families (ACF) as follows: Chapter KA, Office of the Assistant Secretary (OAS) last amended, 75 FR 60471–60473, September 30, 2010, and Chapter KC, Administration on Developmental Disabilities (ADD) last amended 75 FR 63186–63187, October 14, 2010.

**I. Under Chapter, KA, Amend the Office of the Assistant Secretary as Follows**

A. Delete KA.10 Organization in its entirety and replace with the following: KA.10 Organization. The Office of the Assistant Secretary for Children and Families is headed by the Assistant Secretary for Children and Families who reports directly to the Secretary and consists of:

Office of the Assistant Secretary for Children and Families (KA)
Executive Secretariat Office (KAF)
Office of Human Services Emergency Preparedness and Response (KAG)
Office of the Deputy Assistant Secretary and Inter-Departmental Liaison for Early Childhood Development (KAH)

B. Delete KA.20 Functions B in Its entirety.

**II. Under Chapter, KC, Administration on Developmental Disabilities, Delete in Its Entirety and Replace With the Following**

KC.00 Mission. The Administration on Developmental Disabilities (ADD) advises the Secretary, through the Assistant Secretary for Children and Families, on matters relating to individuals with developmental disabilities and their families. ADD serves as the focal point in the Department to support and encourage the provision of quality services to individuals with developmental disabilities and their families. ADD assists states, through the design and implementation of a comprehensive and continuing state plan, in increasing the independence, productivity and community inclusion of individuals with developmental disabilities. These state plans make optimal use of existing Federal and state resources for the provision of services and supports to these individuals and their families to achieve these outcomes. ADD works

with the states to ensure that the rights of all individuals with developmental disabilities are protected.

ADD administers two formula grant programs, State Developmental Disabilities Councils and Protection and Advocacy Systems, and two discretionary grant programs, University Affiliated Programs and Projects of National Significance, including Family Support. These programs support the provision of services to individuals with developmental disabilities and their families. In concert with other components of ACF as well as other public, private, and voluntary sector partners, ADD develops and implements research, demonstration and evaluation strategies for discretionary funding of activities designed to improve and enrich the lives of individuals with developmental disabilities. In addition, ADD serves as a resource in the development of policies and programs to reduce or eliminate barriers experienced by individuals with developmental disabilities through the identification of promising practices and dissemination of information. ADD supports and encourages programs or services, which prevent developmental disabilities and manages initiatives involving the private and voluntary sectors that benefit individuals with developmental and other disabilities and their families.

ADD provides staff and administrative support to the President's Committee for People with Intellectual Disabilities (Committee). In order to promote full participation of people with intellectual disabilities in their communities, the Committee provides advice to the President and to the Secretary of Health and Human Services (Secretary) through the Commissioner of ADD concerning a broad range of topics relating to people with intellectual disabilities.

KC.10 Organization. The Administration on Developmental Disabilities (ADD) is headed by a Commissioner who reports directly to the Assistant Secretary for Children and Families. ADD consists of:

Office of the Commissioner (KCA)
President's Committee for People with Intellectual Disabilities (KCA1)
Office of Program Support (KCB)
Office of Innovation (KCC)

KC.20 Functions. A. The Office of the Commissioner provides executive leadership and management strategies for all components of the Administration on Developmental Disabilities (ADD), and serves as the principal advisor to the Assistant Secretary for Children and Families, the Secretary, and other elements of the Department for individuals with developmental disabilities and their families. The Office plans, coordinates and controls ADD policy, planning and management activities which include the development of legislative proposals, regulations and policy issuances for ADD. The Office provides executive direction, leadership, and management strategy to ADD's components and establishes goals and objectives for ADD programs. The Office manages the formulation and execution of the program and operating budgets; provides administrative, personnel and information systems support services; serves as the ADD Executive Secretariat controlling the flow of correspondence; and coordinates with appropriate ACF components in implementing administrative requirements and procedures. The Office also initiates, executes and supports the development of interagency, intergovernmental and public-private sector agreements, committees, task forces, commissions or joint-funding efforts as appropriate.

The President's Committee for People with Intellectual Disabilities (PCPID) staff provides general staff support for a Presidential-level advisory body. It coordinates all meetings and Congressional hearing arrangements; provides such advice and assistance in the areas of intellectual disabilities as the President, the Secretary or the Commissioner may request and prepares and issues reports to the President concerning intellectual disabilities. It works with other Federal, State, local governments, and private-sector organizations to achieve Presidential goals related to intellectual disabilities, and develops and disseminates information to increase public awareness of intellectual disabilities. The staff supporting PCPID reports to the Commissioner of ADD. In coordination with the ACF Office of Public Affairs, the Office of the Commissioner develops a strategy for increasing public awareness of the needs of individuals with developmental disabilities, their families, and programs designed to address them. The Deputy Commissioner assists the Commissioner in carrying out the responsibilities of the Office.

B. The Office of Program Support is responsible for the coordination, oversight, management and evaluation of the State Councils on Developmental Disabilities, the Protection and Advocacy Systems, and the University Centers for Excellence in Developmental Disabilities grant programs as authorized by the Developmental Disabilities Assistance and Bill of Rights Act (DD Act). The Office is responsible for the development of 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 as well as program outreach activities. The Office conducts routine and special analyses of state plans of State Councils on Developmental Disabilities, statement of goals and objectives of State Protection and Advocacy Systems, and five-year plans of the University Centers for Excellence in Developmental Disabilities, to assure consistent application of ADD program goals and objectives.

In addition, the Office of Program Support provides program development services, develops and initiates guidelines, policy issuances and actions with team participation by other components of ADD, ACF, HHS and other government agencies to fulfill the mission and goals of the DD Act, as amended. The Office ensures the dissemination of grantee results, including project results and information produced by ADD grantees, by coordinating with the Office of Innovation and the Office of the Commissioner for information sharing.

The Office of Program Support manages cross-cutting initiatives with other components of ADD, ACF, HHS and other government agencies to promote and integrate the grant programs into cross-agency and cross-disability efforts.

C. The Office of Innovation is responsible for the coordination, oversight, management and evaluation of the Projects of National Significance, Family Support, and the Direct Support Workers grant programs as authorized by the Developmental Disabilities Assistance and Bill of Rights Act (DD Act). The Office is responsible for the development of procedures that ensure compliance with the DD Act and that improve the outcomes of the programs, grants and contracts in increasing the independence, productivity and community inclusion of persons with developmental disabilities. The Office also ensures the dissemination of project results and information produced by ADD grantees.

The Office of Innovation also administers two formula grants under the Help America Vote Act (State and Local Grants for Election Assistance for Individuals with Disabilities and Grants to Protection and Advocacy Systems) that improve accessibility for individuals with the full range of disabilities, including the blind and

visually impaired, to polling places, including the path of travel, entrances, exits and voting facilities. The Office also administers a training and technical assistance grant program under the Help America Vote Act 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 of Innovation originates and manages cross-cutting research, demonstration and evaluation initiatives with other components of ADD, ACF, HHS and other government agencies. The Office also coordinates information sharing and other activities related to national Developmental Disability program trends with other ACF programs and HHS agencies; and studies, reviews and analyzes other Federal programs providing services applicable to persons with developmental disabilities for the purpose of integrating and coordinating program efforts.

**III. Continuation of Policy**

Except as inconsistent with this reorganization, all statements of policy and interpretations with respect to organizational components affected by this notice within the Administration for Children and Families, heretofore issued and in effect on this date of this reorganization are continued in full force and effect.

**IV. Delegation of Authority**

All delegations and redelegations of authority made to officials and employees of affected organizational components will continue in them or their successors pending further redelegations, provided they are consistent with this reorganization.

**V. Funds, Personnel, and Equipment**

Transfer of organizations and 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: November 10, 2011.

**George H. Sheldon,**

*Acting Assistant Secretary for Children and Families.*

[FR Doc. 2011–30176 Filed 11–22–11; 8:45 am]

**BILLING CODE 4184–06–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2011–N–0439]**

### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Food and Drug Administration Recall Regulations

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Fax written comments on the collection of information by December 23, 2011.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, *Attn:* FDA Desk Officer, *Fax:* (202) 395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0249. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, (301) 796–5156, *Daniel.Gittleson@fda.hhs.gov.*

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

**FDA Recall Regulations—(OMB Control Number 0910–0249)—Extension**

Section 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371) and part 7 (21 CFR part 7), subpart C set forth the recall regulations (guidelines) and provide guidance to manufacturers on recall responsibilities. The guidelines apply to all FDA regulated products (*i.e.,* food, including animal feed; drugs, including animal drugs; medical devices, including in vitro diagnostic products; cosmetics; biological products intended for human use; and tobacco). These responsibilities include development of a recall strategy that requires time by the firm to determine the actions or procedures required to manage the recall (§ 7.42); providing FDA with complete details of the recall including reason(s) for the removal or correction, risk evaluation, quantity produced, distribution information, firm's recall strategy, a copy of any recall communication(s), and a contact official (§ 7.46); notifying direct accounts of the recall, providing guidance regarding further distribution, giving instructions as to what to do with the product, providing recipients with a ready means of reporting to the recalling firm (§ 7.49); and submitting periodic status reports so that FDA may assess the progress of the recall. Status report information may be determined by, among other things, evaluation return reply cards, effectiveness checks, and product returns (§ 7.53); and providing the opportunity for a firm to request in writing that FDA terminate the recall (§ 7.55(b)).

A search of the FDA database was performed to determine the number of recalls, and terminations that took place during fiscal years (FYs) 2008 to 2010. The resulting number of total recalls (9,303) and terminations (2,858) from this database search were then averaged over the 3 years, and the resulting per year average of recalls (3,101) and terminations (953) are used in estimating the current annual reporting burden for this report. FDA estimates the total annual industry burden to collect and provide the previous information to be 443,820 burden hours.

The following is a summary of the estimated annual burden hours for recalling firms (manufacturers, processors, and distributors) to comply with the voluntary reporting requirements of FDA's recall regulations recognizing that there may be a vast difference in the information collection and reporting time involved in different recalls of FDA's regulated products.

The annual reporting burdens are explained as follows:

**I. Total Annual Reporting**

*A. Recall Strategy*

Request firms develop a recall strategy including provision for public warnings and effectiveness checks. Under this portion of the collection of information, the Agency estimates it will receive 3,101 responses annually based on the average number of recalls over the last 3 FYs.

*B. Firm Initiated Recall and Recall Communications*

Request firms voluntarily remove or correct foods and drugs (human or animal), cosmetics, medical devices,