

Dated: June 16, 2004.

Joan E. Ohl,

Commissioner, Administration on Children, Youth and Families.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Statement of Organization, Functions, and Delegations of Authority

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 KC, the Administration on Developmental Disabilities (ADD) (65 FR 18337-38), as last amended April 7, 2000. This notice incorporates the provisions governing election assistance for individuals with disabilities in the Help America Vote Act (HAVA) of 2002, Pub. L. 107-252, 116 Stat 1666 (2002). The authority to administer HAVA was delegated to the Assistant Secretary, ACF by the Secretary on February 9, 2004, and subsequently redelegated to the Commissioner, Administration on Developmental Disabilities by the Assistant Secretary, ACF on April 2, 2004. In addition, the notice establishes the Office of Programs and the Office of Operations, eliminates the Deputy Commissioner position, and moves the Administration and Planning Staff and their functions to the newly established Office of Operations.

This Chapter is amended as follows:

1. Chapter KC, Administration on Developmental Disabilities

A. Delete KC.00 Mission in its entirety and replace with the following:

KC.00 Mission. The Administration on Developmental Disabilities 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, the State Developmental Disabilities Councils and the 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 is responsible for administering three grant programs under the voter accessibility provisions of HAVA. Two are formula grants, one to states and local governments and one to protection and advocacy systems, and the other is a discretionary grant for training and technical assistance.

B. Delete KC.10 Organization in its entirety and replace with the following:

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

- Office of the Commissioner (KCA).
- Office of Programs (KCB).
- Office of Operations (KCC).

C. Delete KC.20 Functions, paragraph A in its entirety and replace with the following:

KC.20 Functions. A. The Office of the Commissioner (OC) 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. The Office provides executive direction and management strategy to ADD's components and establishes goals and objectives for ADD programs.

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 and programs designed to address them.

D. Delete KC 20 Functions, paragraph B in its entirety and replace with the following:

B. Office of Programs is responsible for the coordination, management, and evaluation of the State Developmental Disabilities Councils Program and the Protection and Advocacy Grants Program, including the development of procedures and performance standards that ensure compliance with the Developmental Disabilities Assistance and Bill of Rights (DD) Act and improve the outcomes of Developmental Disabilities Councils and Protection and Advocacy Systems in increasing the independence, productivity and community inclusion of persons with developmental disabilities.

The Office administers two formula grants under HAVA that improves accessibility to individuals with 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 under HAVA that supports training, demonstration, and evaluation of the use of new voting systems and technologies by individuals with disabilities.

The Office conducts routine and special analyses of state plans under the Basic State Grants Program, including an examination of priority area activities, to assure consistent application of ADD program goals and objectives. The Office conducts reviews of programs to ensure compliance with the DD Act to improve program outcomes; and identify and disseminate information regarding excellence in advancing the independence, productivity and community inclusion of people with developmental disabilities.

The Office 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 Office provides program and administrative guidance to regional offices on matters related to the implementation of the DD Act; and

ensures timely and effective communication with the regional offices regarding program compliance, policy clarification, and the approval of required state plans and reports.

E. Delete KC 20 Functions, paragraph C in its entirety and replace with the following:

C. Office of Operations 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 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 coordinates interagency collaboration, program outreach, and convener functions.

The Office manages the discretionary grants and contracts mandated by the DD Act, and provide program development services. The Office originates cross-cutting research, demonstration and evaluation initiatives with other components of ADD, ACF, HHS, and other government agencies; and manages discretionary grants and contracts and assists in monitoring and evaluating discretionary grants at the national level.

The Office plans for and implements experimental program services based on advice from state and local organizations on program needs. The Office formulates and prepares annual demonstration and evaluation plans, coordinates and administers the University Affiliated Programs (UAP's) activities, and develops quality assurance criteria for the UAP Program.

The Office 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. The Office ensures the dissemination of project results and information produced by ADD grantees.

The Office coordinates national 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.

Dated: June 16, 2004.

Wade F. Horn,

Assistant Secretary for Children and Families.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N-0456]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Prevention of Medical Gas Mixups at Health Care Facilities; Survey

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 July 26, 2004.

ADDRESSES: The Office of Management and Budget (OMB) is still experiencing

significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. 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: Fumie Yokota, Desk Officer for FDA, FAX: 202-395-6974.

FOR FURTHER INFORMATION CONTACT: Karen Nelson, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1482.

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.

Prevention of Medical Gas Mixups at Health Care Facilities

Background

FDA has received four reports of medical gas mixups occurring during the past 5 years. These reports were received from hospitals and nursing homes and involved 7 deaths and 15 injuries to patients who were thought to be receiving medical grade oxygen, but who were actually receiving a different gas (e.g., nitrogen, argon) that had been mistakenly connected to the facility's oxygen supply system. In 2001, FDA published guidance making recommendations to help hospitals, nursing homes, and other health care facilities avoid the tragedies that result from medical gas mixups and alerting these facilities to the hazards. This survey is intended to assess the degree of facilities' compliance with safety measures to prevent mixups, to determine if further steps are warranted to ensure the safety of patients.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN¹

| 21 CFR Part | No. of Respondents | Annual Frequency per Response | Total Annual Responses | Hours per Response | Total Hours |
|-------------|--------------------|-------------------------------|------------------------|--------------------|-------------|
| 210 and 211 | 285 | 1 | 285 | .25 | 71.25 |
| Total | 285 | 1 | 285 | .25 | 71.25 |

¹ There are no capital costs or operating and maintenance costs associated with this collection.

In the **Federal Register** of October 10, 2003 (68 FR 58691), FDA published a 60-day notice requesting public comment on the information collection provisions. The agency received two

comments. One comment had specific questions regarding the requirements to register firms exporting foods from Korea.

The responder of the second comment feels the agency is gathering facts with the intent of developing and implementing future guidance that would be enforced on manufacturers,