

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Office of Refugee Resettlement; Statement of Organization, Functions, and Delegations of Authority

AGENCY: Administration for Children and Families, HHS.

ACTION: Notice.

SUMMARY: Statement of Organizations, Functions, and Delegations of Authority. The Administration for Children and Families has reorganized the Office of Refugee Resettlement. This reorganization includes the organization and its substructure components as listed in this document. This reorganization establishes the Division of Refugee Health. It renames the Division of Community Resettlement to the Division of Refugee Services. It renames the Division of Unaccompanied Children's Services to the Division of Children's Services. It deletes the Division of Budget, Policy, and Data Analysis and moves the function to the Office of the Director. The notice also serves to establish an Associate Deputy Director position.

FOR FURTHER INFORMATION CONTACT: Eskinder Negash, Director, Office of Refugee Resettlement, Administration for Children and Families, 901 D Street SW., Washington, DC 20447, (202) 401-9246.

This notice amends Part K of the Statement of Mission, Organization, Functions, and Delegations of Authority of the Department of Health and Human Services (HHS), Administration for Children and Families (ACF) as follows: Chapter KR, the Office of Refugee Resettlement (ORR) (73 FR 5199), as last amended January 29, 2008.

Under Chapter KR, Office of Refugee Resettlement, delete KR in its entirety and replace with the following:

KR.00 Mission. The Office of Refugee Resettlement (ORR) advises the Secretary, through the Assistant Secretary for Children and Families, on matters relating to refugee resettlement, immigration, victims of severe forms of trafficking in persons, victims of torture, unaccompanied alien children and the repatriation of U.S. citizens. The Office plans, develops and directs implementation of a comprehensive program for domestic refugee and entrant resettlement assistance to include cash assistance, medical assistance and associated social services in support of early self-sufficiency. It develops, recommends, and issues

program policies, procedures and interpretations to provide program direction. The Office monitors and evaluates the performances of States and other public and private agencies in administering these programs and supports actions to improve them. It provides leadership and direction in the development and coordination of national public and private programs that provide assistance to refugees, asylees, Cuban and Haitian entrants, and certain Amerasians and victims of severe forms of trafficking in persons. The Office is also responsible for the care and custody of unaccompanied alien children, the issuance of eligibility letters for victims of severe forms of trafficking in persons, the provision of specific consent in Special Immigrant Juvenile status cases, and the policies, procedures and interpretations needed in these program areas.

KR.10 Organization. The Office of Refugee Resettlement (ORR) is headed by a Director who reports directly to the Assistant Secretary for Children and Families.

The Office is organized as follows: Office of the Director (KRA); Division of Refugee Assistance (KRE); Division of Refugee Services (KRF); Division of Children's Services (KRH); Division of Anti-Trafficking in Persons (KRI); Division of Refugee Health (KRJ).

KR.20 Functions. A. The Office of the Director is directly responsible to the Assistant Secretary for Children and Families for carrying out ORR's mission and providing guidance and general supervision to the components of ORR. The Office provides direction in the development of general supervision to the components of ORR. The Office provides direction in the development of program policy and budget and in the formulation of salaries and expense budgets. Staff also provide administrative and personnel support services.

The Office coordinates with the lead refugee and entrant program offices of other Federal departments; provides leadership in representing refugee and entrant programs, policies and administration to a variety of governmental entities and other public and private interests; and acts as the coordinator of the total refugee and entrant resettlement effort for ACF and the Department. The Office oversees the care and custody of unaccompanied alien children, grants specific consent for those who wish to invoke the jurisdiction of a state court for a dependency order to seek Special Immigrant Juvenile (SIJ) status and

makes determinations of eligibility for the Unaccompanied Refugee Minors (URM) Program.

The Office prepares annual budget estimates and related materials; and develops regulations, legislative proposals, and routine interpretations of policy as they relate to each of the program areas. The Office performs allocation and tracking of funds for all programs. The Office collects data and performs analysis on the changing needs of the refugee and entrant population; provides leadership to identify data needs and sources, and formulates data and reporting requirements.

Within the Office, the Deputy Director assumes the Director's responsibilities in the absence of the Director and provides oversight to the Division of Refugee Health, Division of Refugee Services and the Division of Refugee Assistance.

The Associate Deputy Director provides oversight to the Division of Children's Services and the Division of Anti-Trafficking in Persons.

B. Division of Refugee Assistance represents ORR in coordinating services and capacity for refugees in a manner that helps refugees to become employed and economically self-sufficient as soon after their arrival in the United States. The Division monitors and provides technical assistances to the State-administered domestic assistance programs and Wilson/Fish projects. The Division works closely with each state in designing a resettlement program specific to the needs of incoming populations. The Division develops guidance and procedures for their implementation; manages special initiatives to increase refugee self-sufficiency such as through state funded discretionary grants or pilot programs. The Division also assists public and private agencies on data reporting and the resolution of reporting problems. The Division develops and supports the flow of information on refugee profiles and community resources in support of effective placement at the State and local level. The Division works closely with the Department of State to ensure effective and seamless orientation from overseas to local resettlement community. The Division manages the effective allocation of formula social services and targeted assistance in support of newly arriving populations. The Division tracks all state costs related to refugee assistance.

C. Division of Refugee Services directs and manages effective refugee resettlement through the programmatic implementation of grants, contracts and special initiatives, such as the Match Grant Program. The Division oversees

and monitors most ORR discretionary grants; recommends grantee allocation; coordinates with the grants management office to review the financial expenditures under discretionary grant programs; provides data in support of apportionment requests; and provides technical assistance on discretionary grants operations. The Division coordinates and provides liaison with the Department and other Federal agencies on discretionary grant operational issues and other activities as specified by the Director or required by Congressional mandate. The Division responds to unanticipated refugee and entrant arrivals or significant increases in arrivals to communities where adequate or appropriate services do not exist through supplemental initiatives. The Division works to promote economic independence among refugees through social services, educational services, and intensive case management and community development initiatives.

D. Division of Children's Services supports services to unaccompanied children, who are referred to ORR for care as refugees, asylees, Cuban and Haitian entrants, children granted Special Immigrant Juvenile Visas and those pending immigration status or identified as victims of trafficking. The Division implements intake and placement decisions for all unaccompanied refugee and alien children. The Division supports specialized care through grants, contracts and state administered unaccompanied minors programs. The Division conducts monitoring and inspections of facilities and placement locations in which unaccompanied children reside. The Division also maintains statistical information and data on each child and any actions concerning the child while the child is under the Director's care.

The Division ensures consideration of the child's best interest in care and custody decisions. The Division coordinates all decisions related to sponsor reunification, background checks, home assessments, follow-up services, medical assessment and treatment, sponsorship breakdowns, repatriation and movement of children into the Unaccompanied Refugee Minors (URM) Program.

The Division develops policy to ensure all children's programs are administered in a manner that ensures the best interest of the child and that services are administered in a manner that supports child welfare standards of care and services to include; training, accreditation, legal services, assessment and trauma related initiatives. The

Division administers the pro bono legal services and child advocate program and compiles a state-by-state list of professionals or entities qualified to provide the children with a guardian and attorney representational services.

E. Division of Anti-Trafficking in Persons is responsible for implementing certain provisions of the Trafficking Victims Protection Act. The Division coordinates the certification of, and services to, victims of severe forms of trafficking, promotes public awareness on human trafficking, and increases identification of potential victims of severe forms of trafficking. The Division manages these activities through grants and contracts. It also coordinates with other Federal Government agencies on certification activities and policy issues related to the trafficking laws. The Division certifies victims of severe forms of trafficking following consultation with appropriate Federal and State Government agencies and social service agencies. The Division coordinates with the appropriate entities for the determination and placement of identified and certified unaccompanied minor victims of trafficking. It maintains statistical information and data on each victim, including certification documentation and services provided. The Division compiles an annual report, in coordination with other Federal agencies, on the number of certifications issued to and services accessed by identified victims.

F. Division of Refugee Health provides direction for assuring that refugees are provided medical assistance and mental health services through the State-administered program and alternative programs such as the Wilson/Fish projects. The Division ensures the quality of medical screening and initial medical treatment of refugees through its administration of grant programs, technical assistance and interagency agreements in support of comprehensive medical and mental health services. The Division supports coordination of services to refugees under the Affordable Care Act. The Division also supports mental health services to victims of torture.

The Division works closely with State Refugee Health Coordinators in the planning and provision of medical and mental health services to meet the individual needs of incoming populations. The Division tracks all state costs related to refugee medical assistance and screening.

Dated: November 1, 2011.

George H. Sheldon,

Acting Assistant Secretary for Children and Families.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-D-0787]

Draft Guidance for Industry and Food and Drug Administration Staff; Investigational Device Exemptions for Early Feasibility Medical Device Clinical Studies, Including Certain First in Human Studies; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled "Investigational Device Exemptions (IDE) for Early Feasibility Medical Device Clinical Studies, Including Certain First in Human (FIH) Studies." Through the approaches announced in this draft guidance, FDA intends to facilitate early feasibility studies of medical devices, using appropriate risk mitigation strategies, under the IDE requirements. Early feasibility studies allow for limited early clinical evaluations of devices to provide proof of principle and initial clinical safety data before the device design is finalized. This draft guidance addresses the information that should be provided to FDA in support of an early feasibility study IDE application and explains the requirements applicable to modifications to the device design or clinical protocol during the early feasibility study. This draft guidance is not final nor is it in effect at this time.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by February 8, 2012.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled "Investigational Device Exemptions (IDE) for Early Feasibility Medical Device Clinical Studies, Including Certain First in Human (FIH) Studies" to the Division of Small Manufacturers, International, and