and Drugs regarding recommended classification or reclassification of these devices into one of three regulatory categories; (3) advise on any possible risks to health associated with the use of devices; (4) advise on formulation of product development protocols; (5) review premarket approval applications for medical devices; (6) review guidelines and guidance documents; (7) recommend exemption to certain devices from the application of portions of the Act; (8) advise on the necessity to ban a device; (9) respond to requests from the agency to review and make recommendations on specific issues or problems concerning the safety and effectiveness of devices; and (10) make recommendations on the quality in the design of clinical studies regarding the safety and effectiveness of marketed and investigational devices.

II. Selection Procedure

Any organization in the medical device manufacturing industry wishing to participate in the selection of a nonvoting member to represent industry on a particular panel should send a letter stating that interest to the FDA contact (see **FOR FURTHER INFORMATION CONTACT**) within 30 days of publication of this notice. Persons who nominate themselves as industry representatives for the panels will not participate in the selection process. It is, therefore, recommended that nominations be made by someone within an organization, trade association, or firm who is willing to participate in the selection process. Within the subsequent 30 days, FDA will send a letter to each organization and a list of all nominees along with their resumes. The letter will state that the interested organizations are responsible for conferring with one another to select a candidate, within 60 days after receiving the letter, to serve as the nonvoting member representing on a particular device panel. If no individual is selected within the 60 days, the Commissioner may select the nonvoting member to represent industry interests.

III. Application Procedure

Individuals may nominate themselves or an organization representing the medical device industry may nominate one or more individuals to serve as nonvoting industry representatives. A current curriculum vitae (which includes the nominee's business address, telephone number, and e-mail address) and the name of the panel of interest should be sent to the FDA contact person. FDA will forward all nominations to the organizations that have expressed interest in participating in the selection process for that panel.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: June 24, 2004.

William K. Hubbard,

Associate Commissioner for Policy and Planning.

[FR Doc. 04–15012 Filed 7–1–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

CDC/HRSA Advisory Committee on HIV and STD Prevention and Treatment; Ryan White Comprehensive AIDS Resources Emergency (CARE) Act; Reauthorization Workgroup

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice of opportunity to provide written comments.

SUMMARY: On May 15, 2003, the Centers for Disease Control and Prevention (CDC)/Health Resources and Services Administration (HRSA) Advisory Committee on HIV and STD Prevention and Treatment (CHACHSPT) established the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act Reauthorization Workgroup. The workgroup is seeking public input about future HIV/AIDS care program directions pertaining to resource allocation issues related to the third reauthorization of the Ryan White CARE Act. The CHACHSPT will subsequently submit a set of formal recommendations relating to resource allocation issues for reauthorization of the Ryan White CARE Act to the HRSA Administrator and the Secretary of the Department of Health and Human Services.

DATES: To be assured of consideration, written comments should be postmarked no later than July 30, 2004.

ADDRESSES: Written comments should be sent to the CHACHSPT, c/o HRSA, HIV/AIDS Bureau, Office of Policy and Program Development, Attention: Shelley Gordon, Parklawn Building, Room 7–18, 5600 Fishers Lane, Rockville, Maryland 20857.

FOR FURTHER INFORMATION CONTACT: Ms. Shelley Gordon, HRSA, HIV/AIDS Bureau, Office of Policy and Program Development, (301) 443–9684, fax (301) 443–3323, or e-mail: *SGordon@hrsa.gov.*

SUPPLEMENTARY INFORMATION: The purpose of the request for comments is to obtain public input regarding resource allocation issues related to the Ryan White CARE Act, as amended. Resource allocation issues relate to the CARE Act provisions or statutory requirements which affect the distribution of funds across and within the various components of the CARE Act.

In 2003, the CHACHSPT carefully examined all aspects of the CARE Act and considered testimony from three public meetings held around the country designed to gather suggestions about future program directions in HIV and AIDS care and treatment programs. The CHACHSPT developed recommendations which were adopted by the Committee in November 2003 and formally submitted to the HRSA Administrator and the Secretary of the Department of Health and Human Services in 2004. Since that time, the report on Public Financing and Delivery of HIV Care was released by the Institute of Medicine, and new and ongoing issues about HIV/AIDS resources have been raised by communities and CARE constituents. Therefore, further examination by the CHACHSPT of resource allocation issues is desired.

Written comments should be limited to no more than 10 single-spaced pages (or 20 double-spaced) and should contain the name, address, telephone and fax numbers, and any organizational affiliation of the person(s) providing written comments. Respondents may be contacted by the CHACHSPT Ryan White CARE Act Reauthorization Workgroup to answer questions regarding their submitted comments. We are particularly interested in comments which address the following issues:

1. The use of HIV case reporting and service utilization data to determine eligibility under Title I and funding under Titles I and II of the CARE Act;

2. Changes to the existing Titles I and II hold harmless provisions;

3. Changes in the percentages of the Title I grant awarded by formula and competitively;

4. Changes in the percentages of the Title II AIDS Drug Assistance Program (ADAP) distributed by formula and supplemental awards;

5. Comparability and portability of the ADAP; and

6. Institute of Medicine report on: ''Public Financing and Delivery of HIV Care: Securing the Legacy of Ryan White.''

(Authority: Pub. L. 92–463 (5 U.S.C., App. 2); 42 U.S.C. 217a, Sec. 222 of the Public Health Service Act)

Dated: June 25, 2004.

Elizabeth M. Duke,

Administrator.

[FR Doc. 04–15088 Filed 7–1–04; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

Statement of Organization, Functions, and Delegations of Authority

This notice amends Part A (Office of the Secretary) of the Statement of Organization, Functions, and Delegations of Authority for the Department of Health and Human Services (HHS) to reflect a realignment of functions within the Office of Inspector General's (OIG) Immediate Office of the Inspector General (IOIG), Office of Management and Policy (OMP), Office of Evaluation and Inspections (OEI), Office of Counsel to the Inspector General (OCIG), Office of Audit Services (OAS), and Office of Investigations (OI). The statement of organization, functions, and delegations of authority conforms to and carries out the statutory requirements for operating OIG. Chapter AF was last published in its entirety on October 28, 1997.

The realignment of functions within IOIG, OMP, OEI, OCIG, OAS, and OI has been done to allow greater staff flexibility and to better reflect the current work environment and priorities within OIG. In addition, this notice sets forth a number of technical changes in Chapter AF that serve to update references to office titles and clarify OIG's organizational structure and responsibilities with respect to information technology.

As amended, Chapter AF now reads as follows:

Section AF.00, Office of Inspector General—Mission

The Office of Inspector General (OIG) was established by law as an independent and objective oversight unit of the Department to carry out the mission of promoting economy, efficiency and effectiveness through the elimination of waste, abuse and fraud. In furtherance of this mission, the organization:

A. Conducts and supervises audits, investigations, inspections and evaluations relating to HHS programs and operations.

B. Identifies systemic weaknesses giving rise to opportunities for fraud and abuse in HHS programs and operations and makes recommendations to prevent their recurrence.

C. Leads and coordinates activities to prevent and detect fraud and abuse in HHS programs and operations.

D. Detects wrongdoers and abusers of HHS programs and beneficiaries so appropriate remedies may be brought to bear.

E. Keeps the Secretary and the Congress fully and currently informed about problems and deficiencies in the administration of HHS programs and operations and about the need for and progress of corrective action, including imposing sanctions against providers of health care under Medicare and Medicaid who commit certain prohibited acts.

In support of its mission, OIG carries out and maintains an internal quality assurance system and a peer review system with other Offices of Inspectors General, including periodic quality assessment studies and quality control reviews, to provide reasonable assurance that applicable laws, regulations, policies, procedures, standards, and other requirements are followed, are effective, and are functioning as intended in OIG operations.

Section AF.10, Office of Inspector General—Organization

There is at the head of OIG a statutory Inspector General, appointed by the President and confirmed by the Senate. This office consists of six organizational units:

A. Immediate Office of the Inspector General (AFA).

B. Office of Management and Policy (AFC).

C. Office of Evaluation and Inspections (AFE).

D. Office of Counsel to the Inspector General (AFG).

E. Office of Audit Services (AFH).

F. Office of Investigations (AFJ).

Section AF.20, Office of Inspector General—Functions

The component sections that follow describe the specific functions of the organization.

Section AFA.00, Immediate Office of the Inspector General—Mission

The Immediate Office of the Inspector General (IOIG) is directly responsible for meeting the statutory mission of OIG as a whole and for promoting effective OIG internal quality assurance systems, including quality assessment studies and quality control reviews of OIG processes and products. The office also plans, conducts and participates in a variety of interagency cooperative projects and undertakings relating to fraud and abuse with the Department of Justice (DOJ), the Centers for Medicare & Medicaid Services (CMS) and other governmental agencies, and is responsible for the reporting and legislative and regulatory review functions required by the Inspector General Act.

Section AFA.10, Immediate Office of the Inspector General—Organization

IOIG is comprised of the Inspector General, the Principal Deputy Inspector General and an immediate office staff, including the Office of External Affairs.

Section AFA.20, Immediate Office of the Inspector General—Functions

As the senior official of the organization, the Inspector General supervises the Chief Counsel to the Inspector General and the Deputy Inspectors General who head the major OIG components. The Inspector General is appointed by the President, with the advice and consent of the Senate, and reports to and is under the general supervision of the Secretary or, to the extent such authority is delegated, the Deputy Secretary, but does not report to and is not subject to supervision by any other officer in the Department. In keeping with the independence conferred by the Inspectors General Act, the Inspector General assumes and exercises, through line management, all functional authorities related to the administration and management of OIG and all mission-related authorities stated or implied in the law or delegated directly from the Secretary.

The Inspector General provides executive leadership to the organization and exercises general supervision over the personnel and functions of its major components. The Inspector General determines the budget needs of OIG, sets OIG policies and priorities, oversees OIG operations and provides reports to the Secretary and the Congress. By statute, the Inspector General exercises general personnel authority, *e.g.*, selection, promotion, and assignment of employees, including members of the senior executive service. The Inspector General delegates related authorities as appropriate.

The Principal Deputy Inspector General assists the Inspector General in the management of OIG, and during the absence of the Inspector General, acts as the Inspector General.

The Office of External Affairs is comprised of three components—Public Affairs, Legislative and Regulatory Affairs, and the Executive Secretariat. The office conducts and coordinates reviews of existing and proposed legislation and regulations related to HHS programs and operations to