

postmarketing adverse events can choose either option to electronically submit ICSRs and ICSR attachments to VAERS.

The ICSR eSubmitter software is a government-issued software provided in support of the Government Paperwork Elimination Act of 1998 (44 U.S.C. 3504). As users of the eSubmitter software, applicants and others required to report postmarketing adverse events are not required to perform their own file validation process. The purpose of the ICSR eSubmitter template is to facilitate the electronic submission of postmarketing vaccine safety reports using internationally adopted data standards to enhance regulatory review, exchange and dissemination of vaccine safety information. Applicants and others who choose to use the eSubmitter program for required postmarketing reporting of adverse events for human vaccine products must first download the eSubmitter software and then manually enter information into the ICSR template form to create each electronic ICSR or ICSR attachment for submission to FDA through the ESG for uploading to the VAERS database. Further information on submitting ICSRs and ICSR attachments using eSubmitter is included in the August 2015 Guidance (available at: <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Vaccines/default.htm>), and on the CBER eSubmitter Web page referenced above.

Dated: April 25, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Health Resources and Services Administration**

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

This notice amends Part R of the Statement of Organization, Functions and Delegations of Authority of the Department of Health and Human Services (HHS), Health Resources and Services Administration (HRSA) (60 FR 56605, as amended November 6, 1995; as last amended at 80 FR 19981-19982 dated April 6, 2016).

This notice reflects organizational changes in the Health Resources and

Services Administration (HRSA), Office of the Administrator (RA). Specifically, this notice: (1) Renames the Office of Equal Opportunity, Civil Rights and Diversity Management (RA2) to the Office of Civil Rights, Diversity and Inclusion (RA2); and (2) updates the functional statement for Office of Civil Rights, Diversity and Inclusion (RA2).

#### **Chapter RA2—Office of Civil Rights, Diversity and Inclusion**

##### *Section RA2—00, Mission*

The mission of the Office of Civil Rights, Diversity and Inclusion is to protect and serve the rights of all HRSA employees, applicants and beneficiaries of federal funds by enforcing federal laws, policies and practices prohibiting discrimination, resolves workplace disputes and conflict at the earliest possible stage, and helps to leverage diversity throughout HRSA.

##### *Section RAE-10, Organization*

Delete the organization for the Office of the Administrator (RA) in its entirety and replace with the following:

Rename the Office of Equal Opportunity, Civil Rights and Diversity Management to the Office of Civil Rights, Diversity and Inclusion within the Office of the Administrator. The Office of the Administrator is headed by the Administrator, who reports directly to the Secretary, Department of Health and Human Services.

- (1) Immediate Office of the Administrator (RA);
- (2) Office of Legislation (RAE);
- (3) Office of Communications (RA6);
- (4) Office of Health Equity (RAB);
- (5) Office of Civil Rights, Diversity and Inclusion (RA2);
- (6) Office of Planning, Analysis and Evaluation (RA5);
- (7) Office of Women's Health (RAW); and
- (8) Office of Global Health (RAI).

##### *Section RA2-20, Functions*

This notice reflects organizational changes in the Health Resources and Services Administration (HRSA), Office of the Administrator (RA). Specifically, this notice: (1) Updates the functional statement.

Delete the function for the Office of Equal Opportunity, Civil Rights and Diversity Management and replace in its entirety.

#### **Office of Civil Rights, Diversity and Inclusion (RA2)**

Serves as the focal point for HRSA's formulation, implementation,

coordination and management of the equal opportunity, civil rights, and diversity and inclusion activities. Specifically: (1) Provides advice, counsel, and recommendations to HRSA personnel, including regional offices, on equal opportunity, civil rights, and diversity and inclusion issues; (2) analyzes Agency data to determine underrepresentation and/or underutilization of diverse groups in the workforce; (3) identifies barriers and devises strategies to eliminate those barriers; (4) manages the equal employment opportunity complaint process for HRSA civilian employees; (5) manages the equal employment opportunity complaint process for Public Health Service (PHS) Commissioned Corps personnel under the provisions of PHS Personnel Instruction 6 and issues recommendations to the Surgeon General; (6) approves and executes equal opportunity complaint settlement agreements; (7) develops and directs implementation of the requirements of Section 504 of the Rehabilitation Act of 1973, Title VI of the Civil Rights Act of 1964, the Age Discrimination Act of 1975, the Americans With Disabilities Act, The Genetic Information Nondiscrimination Act of 2008, and Section 1557 of the Affordable Care Act, as they apply to HRSA and recipients of HRSA funds; (8) provides comprehensive EEO, Civil Rights and Diversity and Inclusion training to HRSA's supervisors, managers and employees to prevent discrimination and harassment in the workplace; (9) applies all applicable laws, guidelines, rules and regulations; and (10) provides leadership and guidance in HRSA's efforts to develop and maintain a diverse and inclusive workforce.

##### *Delegations of Authority*

All delegations of authority and re-delegations of authority made to HRSA officials that were in effect immediately prior to this reorganization, and that are consistent with this reorganization, shall continue in effect pending further re-delegation.

This reorganization is effective upon date of signature.

Dated: April 21, 2016.

**James Macrae,**

*Acting Administrator.*

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