- How is adverse event information from these sources being received, reviewed, and processed?
- What challenges are presented in handling adverse event information from these sources?
- What uncertainties are there regarding what should be reported from these sources to meet FDA adverse event reporting obligations?

IV. Notice of Hearing Under 21 CFR Part 15

The Commissioner is announcing that the public hearing will be held in accordance with part 15 (21 CFR part 15). The hearing will be conducted by a presiding officer, accompanied by FDA senior management from the Office of the Commissioner and the Center for Drug Evaluation and Research.

Under § 15.30, the hearing is informal, and the rules of evidence do not apply. No participant may interrupt the presentation of another participant. Only the presiding officer and panel members may question any person during or at the conclusion of each presentation. Public hearings under part 15 are subject to FDA's policy and procedures for electronic media coverage of FDA's public administrative proceedings (part 10 (21 CFR part 10), subpart C). Under § 10.205, representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants. The hearing will be transcribed as stipulated in § 15.30(b). To the extent that the conditions for the hearing, as described in this document, conflict with any provisions set out in part 15, this document acts as a waiver of those provisions as specified in § 15.30(h).

V. Comments

Regardless of attendance at the public hearing, interested persons may submit written or electronic comments to the Division of Dockets Management (see **ADDRESSES**). Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments should be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

VI. Transcripts

Please be advised that as soon as a transcript is available, it will be accessible at *http://www.regulations.gov*. It may be viewed at the Division of Dockets Management (see **ADDRESSES**). A transcript will also be available in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. Written requests are to be sent to Division of Freedom of Information (HFI–35), Office of Management Programs, Food and Drug Administration, 5600 Fishers Lane, rm. 6–30, Rockville, MD 20857.

Dated: September 16, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9–22618 Filed 9–18–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Request for Information Regarding Development and Operation of a Transplantation Sentinel Network

AGENCY: Office of Blood, Organ and Other Tissue Safety, Division of Healthcare Quality Promotion, Center for Preparedness, Detection, and Control of Infectious Diseases, Centers for Disease Control and Prevention, Department of Health and Human Services.

ACTION: Request for information notice.

SUMMARY: The Centers for Disease Control and Prevention (CDC) is seeking information on development and operation of a national transplantation sentinel network (TSN) for the United States, including resources needed for management of such a system. The purpose of the network is to detect and prevent disease transmission from organ and tissue allografts recovered for transplantation.

In June 2005, the CDC announced a Request for Application (RFA) through a cooperative agreement for development of a TSN for organizations that recover, process, distribute, and implant organs and tissues. The overall goal of the system was to improve patient safety for organ and tissue recipients. The RFA objectives were to: (1) Identify and track organs and tissues to facilitate intervention following recognition of infections among recipients or donors; (2) improve communication among those in the transplant community, healthcare facilities and public health agencies concerning potential risks for transmission of infections; and (3) improve pathologic and microbiologic capabilities on cadaveric donor specimen samples through shared resources. Development and field testing of the prototype was completed in 2008.

For this RFI, respondents are asked to describe experiences, plans or opinions regarding aspects of completing and operating a TSN system; system governance, security, and marketing; user training; and operational and infrastructure management. Responses need not address every aspect of this RFI; responses may be limited to address specific components or portions of a section. The specific sections requested for comments are: (1) Transition of Transplantation Transmission Sentinel Network (TTSN) Prototype to Full Production; (2) Standardization and Compatibility Issues; (3) Reporting Criteria; (4) Interoperability and Interfacing with Existing Data Sources; (5) System Operation and Infrastructure Management; (6) Analysis Plan including Feedback to Users; (7) Patient Health Information Privacy and Security; and (8) System Governance.

DATES: Comments must be submitted on or before December 11, 2009.

ADDRESSES: The entire TSN RFI can be accessed at *http://wwwdev.cdc.gov/ncidod/dhqp/pdf/ttsn/RFI_TSN_FedRegDoc_9909.pdf*. Electronic responses are preferred and should be sent to *TransplantRFI@cdc.gov.* Responses sent in hard copy format must be securely bound and sent to Debbie Seem, Office of Blood, Organ and other Tissue Safety, Division of Healthcare Quality Promotion, Centers for Disease Control and Prevention, Building 16, MS–A07, 1600 Clifton Road, NE., Atlanta, GA, 30329–4018, Telephone number: 404–639–3234, E-mail Address: *gqi4@cdc.gov.*

SUPPLEMENTARY INFORMATION: Each year in the United States, more than 28,000 solid organs and 2 million tissues are transplanted, including heart, lung, liver, kidneys, pancreas, intestine, bone, skin, heart valves, tendons, fascia and corneas. Donor-derived infections have been identified as a source of morbidity and mortality among both solid organ and tissue transplant recipients.

Infectious transmission identified in the past few years among solid organs have reflected a broad array of viruses, bacteria, and parasites, resulting in a high proportion of mortality amongst infected recipients; examples include HIV, hepatitis C virus (HCV), lymphocytic choriomeningitis virus, *Mycobacterium tuberculosis, Pseudomonas aeruginosa, Strongyloides spp,* and *Trypanosoma cruzi,* the etiologic agent of Chagas Disease.

Malignancies also have been transmitted by solid organs. The Health Resources and Services Administration (HRSA) oversees the transplantation of solid organs through the Organ Procurement and Transplantation Network (OPTN) administered by the United Network for Organ Sharing (UNOS). OPTN policy requires reporting of all potential donor-derived infections to UNOS and notification of institutions that recovered organs and tissues from that donor.

For tissues, disease transmission reports are less frequent but include transmission of HCV, Group A streptococcus, *Clostridium spp,* and *Chryseobacterium meningosepticum.* Unlike solid organs, risk of disease transmission depends on multiple factors related to the graft, including the feasibility and effectiveness of processing, which may vary according to tissue type and specific processing or manipulation procedures. The Food and Drug Administration (FDA), Center for Biologics Evaluation and Research, regulates articles containing or consisting of human cells or tissues intended for implantation, transplantation, infusion, or transfer into a human recipient as human cells, tissues, or cellular or tissue-based products (HCT/Ps). HCT/P establishments are required to report to FDA all serious infections following graft transplantation. However, healthcare providers are not required to report adverse events, and healthcare facilities that do not perform any steps in tissue manufacture (recovery, processing, storage, labeling, packaging, distribution, or donor screening or testing) are not subject to any FDA regulation for HCT/Ps.

Because organs and tissues can come from the same donor, a TSN should provide the mechanism for standardizing allograft identifiers, tracking of organ and tissue receipt, rapid notification of and response to potential disease transmissions, benchmarking of sentinel events and integration into a national biovigilance network. Specifically utilizing these system characteristics, all relevant recovery, processing, distributing and implanting institutions could rapidly communicate when a possible disease transmission is identified. This may prevent any further use of allografts with transmissible diseases in additional recipients after a problem is recognized and allow for earlier initiation of treatment or prophylaxis of recipients, potentially resulting in reduction of transmission events or resulting morbidity and mortality.

A national TSN needs to avoid duplication of the OPTN or of FDA reporting mechanisms; however, interfacing with these existing systems is critical. A national TSN could be coordinated by CDC in collaboration with other agencies of the Department of Health and Human Services (HHS) and external partners. In addition, HHS has recognized health information technology (IT) data and exchange standards to promote the exchange of health information across the healthcare landscape. The National Health IT activities initiated by the HHS Office of the National Coordinator for Health IT (ONC) has examined incorporating reporting criteria into Electronic Health Records (EHRs) which could assist in the possible identification and reporting of public health cases and adverse events. Reporting criteria which are incorporated and utilized by EHRs may include: general and specific reporting considerations, as well as the identification of data and events that may trigger a report, additional questions that may need to be asked of reporters, and the identification of specific data that may need to be reported. Integrating these requirements into a national TSN system is vital to the long term viability of the program.

Dated: September 14, 2009.

Tanja Popovic,

Chief Science Officer, Centers for Disease Control and Prevention.

[FR Doc. E9–22658 Filed 9–18–09; 8:45 am]

BILLING CODE P

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 74 FR 37718–37723 dated July 29, 2009).

This notice reflects organizational changes in the Health Resources and Services Administration. This notice renames the Office of Performance Review (RE) to the Office of Regional Operations (ORO) (RE), and changes the mission and functions of the office.

Chapter RE—Office of Regional Operations (RE)

Section RE–00, Mission

Delete in its entirety and replace with the following:

The mission of ORO is to improve health care systems and America's health care safety net, increase access to quality care, reduce disparities, and advance public health by providing leadership in support of the HHS and HRSA missions, goals and strategic priorities in each region.

Section RE–10, Organization

Delete in its entirety and replace with the following:

The Office of Regional Operations (RE) is headed by the Associate Administrator who reports directly to the Administrator, Health Resources and Services Administration. The Office of Regional Operations includes the following components:

1. Office of the Associate Administrator (RE);
2. Boston Regional Division (RF12) serves Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island and Vermont;
3. New York Regional Division (RF13) serves New Jersey, New York, Puerto Rico and the United States Virgin Islands;
4. Philadelphia Regional Division (RF11) serves Delaware, Maryland, Pennsylvania, Virginia, West Virginia and the District of Columbia;
5. Atlanta Regional Division (RF21) serves Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina and Tennessee;
6. Chicago Regional Division (RF31) serves Illinois, Indiana, Michigan, Minnesota, Ohio and Wisconsin;
7. Dallas Regional Division (RF41) serves Arkansas, Louisiana, New Mexico, Oklahoma and Texas;
8. Kansas City Regional Division (RF32) serves Iowa, Kansas, Missouri and Nebraska;
9. Denver Regional Division (RF42) serves Colorado, Montana, North Dakota, South Dakota, Utah and Wyoming;
10. San Francisco Regional Division (RF51) serves Arizona, California, Hawaii, Nevada, American Samoa, Commonwealth of the Northern Mariana Islands, Federated States of Micronesia, Guam, Republic of the Marshall Islands and the Republic of Palau; and
11. Seattle Regional Division (RF52) serves Alaska, Idaho, Oregon and Washington.

Section RE–20, Functions

Delete in its entirety and replace with the following: