material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm*. Scroll down to the appropriate advisory committee link.

Procedure: On November 16, 2009, from 8 a.m. to 5:30 p.m. and on November 17, 2009, from 8 a.m. to 3:15 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before November 9, 2009. Oral presentations from the public will be scheduled between approximately 11 a.m. and 11:30 a.m. and between 4 p.m. and 4:30 p.m. on November 16, 2009, and between approximately 10:30 a.m. and 11 a.m., and 2:15 and 2:45 p.m. on November 17, 2009. Those desiring to make formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before October 30, 2009. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by November 2, 2009.

Closed Committee Deliberations : On November 17, 2009, from approximately 3 p.m. until 5 p.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential commercial information (5 U.S.C. 552b(c)(4)). The committee will hear presentations and discuss sponsor, trade secret and confidential information.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact William Freas or Pearline K. Muckelvene at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: September 23, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9–23434 Filed 9–28–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

''CORRECTED Version of 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://www.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.

Tanja Popovic,

Chief Science Officer, Centers for Disease Control and Prevention.

[FR Doc. E9–23427 Filed 9–28–09; 8:45 am]

BILLING CODE P

DEPARTMENT OF HOMELAND SECURITY

Office of the Secretary

[Docket No. DHS–2009–0038]

Privacy Act of 1974; Department of Homeland Security/ALL–004 General Information Technology Access Account Records System of Records

AGENCY: Privacy Office; DHS.

ACTION: Notice of Privacy Act system of records update.

SUMMARY: In accordance with the Privacy Act of 1974 the Department of Homeland Security proposes to update and reissue a Department of Homeland Security system of records notice titled, Department of Homeland Security/ALL–004 General Information Technology Access Account Records System of Records. As a result of the biennial review of this system, the Department proposes to include the addition of social security numbers in the categories of records covered by the system for the purpose of identifying an individual for system access. Additionally, a new routine use has been added for the purpose of sharing with the media where appropriate. This updated system will be included in the Department of Homeland Security's inventory of record systems.

DATES: Written comments must be submitted on or before October 29, 2009.

ADDRESSES: You may submit comments, identified by Docket Number DHS–2009–0038 by one of the following methods:

- *Federal e-Rulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* 703–483–2999.
- *Mail:* Mary Ellen Callahan, Chief Privacy Officer, Privacy Office, Department of Homeland Security, Washington, DC 20528.
- *Instructions:* All submissions received must include the agency name and docket number for this rulemaking. All comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided.
- *Docket:* For access to the docket to read background documents or comments received go to *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: For general questions and for privacy issues please contact: Mary Ellen Callahan (703–235–0780), Chief Privacy Officer, Privacy Office, U.S. Department of Homeland Security, Washington, DC 20528.

SUPPLEMENTARY INFORMATION:

I. Background

As part of its efforts to maintain its Privacy Act record systems, the Department of Homeland Security (DHS) is updating and reissuing a Department-wide system of records under the Privacy Act (5 U.S.C. 552a) for DHS/ALL–004 General Information Technology Access Account Records System of Records (73 FR 28139, May 15, 2008). This will ensure that all components of DHS follow the same privacy rules for collecting and handling information technology access account records. The collection and maintenance of this information will assist DHS in managing the Department's information technology access account records.

This system of records is part of DHS' ongoing record integration and management efforts. This system consists of information collected in order to provide authorized individuals with access to DHS information technology resources. This information includes user name, business affiliation, account information and passwords.

In accordance with the Privacy Act of 1974, DHS is giving notice that it proposes to update and reissue a DHS system of records notice titled, DHS/ALL–004 General Information Technology Access Account Records System of Records. As a result of the biennial review of this system, the