

after publication of this notice. All nominations must be submitted in sufficient time to be received by 5 p.m. Eastern Standard Time on the closing date March 14, 2014 and be addressed to email address ken.sandler@gsa.gov.

Dated: February 5, 2014.

Kevin Kampschroer,
Federal Director, Office of Federal High-Performance Green Buildings, Office of Government-wide Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Nominations to the Advisory Committee on Blood and Tissue Safety and Availability

AGENCY: Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services..

ACTION: Notice.

SUMMARY: The Office of the Assistant Secretary for Health (OASH) is seeking nominations of qualified members of the public to be considered for appointment as members of the Advisory Committee on Blood and Tissue Safety and Availability (ACBTSA). ACBTSA is a federal advisory committee within the Department of Health and Human Services (HHS). Management support for the activities of this committee is the responsibility of the OASH. The qualified individuals will be nominated to the Secretary of Health and Human Services for consideration of appointment as members of the ACBTSA. Members of the Committee, including the Chair, are appointed by the Secretary. Members are invited to serve on the Committee for up to four-year terms.

DATES: All nominations must be received no later than 4 p.m. EST on March 7, 2014, at the address listed below.

ADDRESSES: All nominations should be mailed or delivered to Mr. James Berger, Senior Advisor for Blood and Tissue Safety Policy; Office of the Assistant Secretary for Health; Department of Health and Human Services; 1101 Wootton Parkway, Suite 250; Rockville, MD 20852. Telephone: (240) 453-8803.

FOR FURTHER INFORMATION CONTACT: Mr. James Berger, Senior Advisor for Blood and Tissue Safety Policy. Contact information for Mr. Berger is provided above.

A copy of the Committee charter and roster of the current membership can be

obtained by contacting Mr. Berger or by accessing the ACBTSA Web site at <http://www.hhs.gov/ash/bloodsafety/advisorycommittee/>.

SUPPLEMENTARY INFORMATION: The ACBTSA shall provide advice to the Secretary through the Assistant Secretary for Health. The committee shall advise on a range of policy issues to include: (1) Identification of public health issues through surveillance of blood, and tissue safety issues with national biovigilance data tools; (2) identification of public health issues that affect availability of blood, blood products, and tissues; (3) broad public health, ethical and legal issues related to the safety of blood, blood products, and tissues; (4) the impact of various economic factors (e.g., product cost and supply) on safety and availability of blood, blood products, and tissues; (5) risk communications related to blood transfusion and tissue transplantation; and (6) identification of infectious disease transmission issues for blood, organs, blood stem cells and tissues.

The Committee consists of 23 voting members; 14 public members, including the Chair, and 9 individuals designated to serve as official representative members. The public members are selected from state and local organizations, patient advocacy groups, provider organizations, academic researchers, ethicists, physicians, surgeons, scientists, risk communication experts, consumer advocates, legal organizations, and from among communities of persons who are frequent recipients of blood or blood products or who have received tissues or organs. The nine individuals who are appointed as official representative members are selected to serve the interests of the blood, blood products, tissue, and organ professional organizations or business sectors. The representative members will be from the AABB (formerly the American Association of Blood Banks); American Association of Tissue Banks; Eye Bank Association of America; an organ procurement organization; and one of either the American National Red Cross or America's Blood Centers on a rotating basis. The Committee composition can include additional representation from either the plasma protein fraction community or a trade organization; a manufacturer of blood, plasma, or other tissue/organ test kits; a manufacturer of blood, plasma or other tissue/organ equipment; and a major hospital accreditation organization. Where more than one company produces a specified product or process, representatives from

those companies will rotate on the same schedule as public members.

All ACBTSA members are authorized to receive the prescribed per diem allowance and reimbursement for travel expenses that are incurred to attend meetings and conduct Committee-related business, in accordance with Standard Government Travel Regulations. Individuals who are appointed to serve as public members are authorized also to receive a stipend for attending Committee meetings and to carry out other Committee-related business. Individuals who are appointed to serve as representative members for a particular interest group or industry are not authorized to receive a stipend for the performance of these duties.

This announcement is to solicit nominations of qualified candidates to fill two (2) upcoming vacant public member positions. Public members on the ACBTSA are classified as special government employees (SGEs).

Nominations

In accordance with the charter, persons nominated for appointment as members of the ACBTSA should be among authorities knowledgeable in tissue banking, tissue transplantation, tissue/organ transplant safety, blood banking, transfusion medicine, plasma therapies, transfusion safety, bioethics, and/or related disciplines. Nominations should be typewritten. The following information should be included in the package of material submitted for each individual being nominated for consideration of appointment: (a) The name, return address, daytime telephone number and affiliation(s) of the individual being nominated, the basis for the individual's nomination, the category for which the individual is being nominated, and a statement bearing an original signature of the nominated individual that, if appointed, he or she is willing to serve as a member of the committee; (b) the name, return address, and daytime telephone number at which the nominator may be contacted. Organizational nominators must identify a principal contact person in addition to the contact; and (c) a copy of a current curriculum vitae or resume for the nominated individual.

Individuals can nominate themselves for consideration of appointment to the Committee. All nominations must include the required information. Incomplete nominations will not be processed for consideration. The letter from the nominator and certification of the nominated individual must bear original signatures; reproduced copies of these signatures are not acceptable.

The Department is legally required to ensure that the membership of HHS federal advisory committees is fairly balanced in terms of points of view represented and the functions to be performed by the advisory committee. Every effort is made to ensure that the views of women, all ethnic and racial groups, and people with disabilities are represented on HHS federal advisory committees. Therefore, the Department encourages nominations of qualified candidates from these groups. The Department also encourages geographic diversity in the composition of the committee. Appointment to this committee shall be made without discrimination on the basis of age, race, ethnicity, gender, sexual orientation, disability, and cultural, religious, or socioeconomic status.

The Standards of Ethical Conduct for Employees of the Executive Branch are applicable to individuals who are appointed as public members of federal advisory committees. Individuals appointed to serve as public members of federal advisory committees are classified as SGEs. SGEs are government employees for purposes of the conflict of interest laws. Therefore, individuals appointed to serve as public members of the ACBTSA are subject to an ethics review. The ethics review is conducted to determine if the individual has any interests and/or activities in the private sector that may conflict with performance of their official duties as a member of the Committee. Individuals appointed to serve as public members of the Committee will be required to disclose information regarding financial holdings, consultancies, and research grants and/or contracts.

Dated: February 6, 2014.

James J. Berger,

Senior Advisor for Blood and Tissue Safety Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-14-13AHB]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the

Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404-639-7570 or send comments to Leroy Richardson, 1600 Clifton Road, MS-D74, Atlanta, GA 30333 or send an email to omb@cdc.gov.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Written comments should be received within 60 days of this notice.

Proposed Project

Risk Factors for Community-Associated *Clostridium difficile* Infection through the Emerging Infections Program (EIP)—New ICR—National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The epidemiology of *C. difficile* has changed dramatically during recent years, with increases in incidence and severity of disease being reported across several countries. In addition, populations previously thought to be at low risk, such as young, healthy individuals residing in the community, are now being identified with severe *C. difficile* infection (CDI). Community-associated CDI is estimated to represent 32% of all CDI based on population-based CDI surveillance data, with an incidence of 30–40 per 100,000 population in the United States. Previous reports have shown that approximately 40% of patients acquiring community-associated CDI (CA-CDI) were not exposed to antibiotics, which is a well-recognized risk factor for CDI; suggesting that additional factors may contribute to infections. Other factors such as proton pump inhibitors have been raised as a risk factor for CDI in the community and on February 8, 2012 the U.S. Food and Drug Administration issued a communication advising physicians to consider the diagnosis of CDI among

patients taking proton pump inhibitors. However, the data on the association of CDI with proton pump inhibitors are still controversial and studies to quantify this association are needed. In addition to the understanding of the factors that predispose patients to CDI, further evaluation of potential *C. difficile* exposure sources in the community is necessary to guide prevention efforts.

The sources of *C. difficile* and the risks for developing CDI in previously thought to be low-risk community populations are not well defined. Although initial evaluation of CA-CDI cases identified several potential risk factors (e.g., outpatient healthcare exposures, infants in the home, and proton pump inhibitor use), the magnitude of association of these risks with disease development using a control population has not been evaluated to date. This proposed case-control study will enable investigators to evaluate these associations and focus future investigations and prevention strategies on those factors identified as significantly associated with disease development.

CDC requests OMB approval to collect information from the public using a standardized questionnaire over a three-year period. The study will have a pediatric and an adult component given that *C. difficile* exposure sources in the community may vary by age. For example, *C. difficile* has been isolated from daycare centers' environment which may be a potential source for *C. difficile* acquisition in pediatric population, but less likely to be a source for adults.

For this project, we estimate that 129 persons $\geq$ 18 years of age with *C. difficile* infection (case-patients) will be contacted for the CDI study interview annually. Of those, 71 will agree and be eligible to participate in the study and will proceed to the full telephone interview. A total of 142 persons $\geq$ 18 years of age without *C. difficile* infection (control-patients) will be contacted for the interview annually. Of those, 71 will agree and be eligible to participate in the study and will complete the full interview. Among the pediatric group, we estimate that 141 and 194 parents of children between 1 and 5 years of age with and without *C. difficile* infection will be contacted for the interview, respectively. Among the case- and control-patients, we estimate that 78 in each group will agree and be eligible to participate in the study and will proceed to the full interview. We anticipate the screening questions to take about 5 minutes and the telephone interview 30 minutes per respondent in