

tracking the results of pre-donation testing; (3) the period within which a potential MSM donor would need to return to complete an actual blood donation; (4) concern that pre-donation testing of only MSM could be seen as discriminatory; and (5) the residual impact on safety due to window period donations that would not be reduced by pre-testing.

#### (b) Post-Donation Testing

In a post-donation testing strategy, MSM who are presently deferred, but who would be eligible to donate during the pilot under modified deferral criteria would have a unit of blood drawn. This unit would be segregated from other units and placed in a separate quarantine. The donor would be asked to return for "post-donation testing" within a specified period following the donation that would exceed the "window period" for transfusion-transmissible infections but be within the expiration dating period of the unit of blood (i.e., within 14 to 42 days post-donation for red blood cells or from 14 days to within one year for plasma for transfusion). For donors who continue to meet acceptance criteria and have negative "post-donation test" results, the unit would be released for transfusion. Such collections would be most applicable to repeat plasma donations given the longer shelf life of frozen plasma, providing greater flexibility for the time of "post-donation testing" of the donor. Also, plasma for transfusion could be collected at the time of "post-donation testing" initiating a new quarantine for a new collection.

Placing units drawn from MSM donors in quarantine until qualifying "post-donation testing" results are obtained would address the issue of recent (i.e. "incident") infections. Infectious units would be entered into a quarantine portion of the blood bank inventory prior to the availability of screening test results. However, if more infectious units are drawn and placed in inventory, these units would be subject to quarantine release errors.

There could be the same or similar unanswered questions for the post-donation testing strategy as are outlined above under the pre-donation testing strategy. In addition, blood establishments would need to maintain stratified and potentially larger quarantine inventories and would incur the costs of discarding all units in quarantine for which a donor failed to return for "post-donation testing."

#### (c) Combined Pre-Donation and Post-Donation Testing

Under this scenario, an MSM donor seeking to donate under modified deferral criteria would be screened with a questionnaire and asked to give a pre-donation testing sample. Assuming the blood sample is negative for infectious markers, and the donor meets all other eligibility criteria, the donor would be invited to return within a defined period to donate a unit of blood. This unit would be placed in quarantine and the donor again would be asked to return, this time for post-donation testing also within a specified time period.

This strategy would provide the strictest control over any increase in risk to the blood supply. Both incident and prevalent infection concerns would be addressed. However, this scenario would require a potential donor meeting the candidate MSM acceptability criteria to make three appearances at a blood collection facility within specified time periods in order to have a donation released for transfusion. Blood establishments would face challenging logistic issues in conducting such a study concurrently with normal, highly standardized blood collection operations.

(3) Input is requested on the data that should be gathered and the criteria used to evaluate the results of the pilot operational study. For example, should MSM donors and non-MSM donors be asked to participate in surveys on their understanding of the donor screening questions, their specific sexual behaviors and their motivations to donate blood? Should the study outcome be based on observed markers of transfusion-transmitted infections in MSM donors compared with other donors? Should MSM donors with positive screening tests be interviewed to better understand their risk factors, their understanding of the donor questionnaire and their motivations to donate if they did not appropriately self-defer or disclose their risk?

#### Requested RFI Responses:

Please comment on each of the above scenarios, or propose additional pilot operational study designs for consideration. In your response, please address each of the following:

- Revised criteria that should be considered to permit blood donation by MSM
- Blood safety considerations and safety mitigations that should be considered
- Impact on blood establishment operations
- Staff training and staff perceptions

- Tracking of pre-donation and/or post-donation test results
- Inventory management
- Donor perceptions regarding the possible changes in deferral policy within the operational study scenarios (including both MSM and non-MSM donors)
- Public reaction, if any, and impact on blood drives
- Potential venues where the study could be conducted
- Study costs
- Willingness of blood organizations to participate in a pilot study
- Data elements that should be gathered during the study, including those that may be associated with future emerging infections
- Criteria for evaluation of the study results and conclusions
- Expected timeframe for each proposed study.

Dated: March 8, 2012.

#### Richard Henry,

*Deputy Director, Blood Safety & Availability.*

[FR Doc. 2012-6091 Filed 3-12-12; 8:45 am]

**BILLING CODE 4150-41-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Advisory Council on Alzheimer's Research, Care, and Services; Request for Nominations

**AGENCY:** Office of the Assistant Secretary for Planning and Evaluation; Department of Health and Human Services.

**ACTION:** Request for Nominations.

**SUMMARY:** HHS is soliciting nominations for a new, non-Federal member of the Advisory Council on Alzheimer's Research, Care, and Services to fill the position of "representative of a state public health department." Nominations should include the nominee's contact information (current mailing address, email address, and telephone number) and current curriculum vitae or resume.

**DATES:** Submit nominations by email or USPS mail before COB on April 4, 2012.

**ADDRESSES:** Nominations should be sent to Helen Lamont at [helen.lamont@hhs.gov](mailto:helen.lamont@hhs.gov); Helen Lamont, Ph.D., Office of the Assistant Secretary for Planning and Evaluation, Room 424E Humphrey Building, Department of Health and Human Services, 200 Independence Avenue SW., Washington, DC 20201.

**FOR FURTHER INFORMATION CONTACT:** Helen Lamont (202) 690-7996, [helen.lamont@hhs.gov](mailto:helen.lamont@hhs.gov).

**SUPPLEMENTARY INFORMATION:** The Advisory Council on Alzheimer's Research, Care, and Services meets quarterly to discuss programs that impact people with Alzheimer's disease and related dementias and their caregivers. The Advisory Council makes recommendations about ways to reduce the financial impact of Alzheimer's disease and related dementias and to improve the health outcomes of people with these conditions. The Advisory Council provides feedback on the National Plan to Address Alzheimer's Disease. On an annual basis, the Advisory Council shall evaluate the implementation of the recommendations through an updated national plan.

The Advisory Council consists of designees from Federal agencies including the Centers for Disease Control and Prevention, Administration on Aging, Centers for Medicare and Medicaid Services, Indian Health Service, Office of the Director of the National Institutes of Health, National Science Foundation, Department of Veterans Affairs, Food and Drug Administration, Agency for Healthcare Research and Quality, and the Surgeon General. The Advisory Council also consists of 12 non-federal members selected by the Secretary who are Alzheimer's patient advocates (2), Alzheimer's caregivers (2), health care providers (2), representatives of State health departments (2), researchers with Alzheimer's-related expertise in basic, translational, clinical, or drug development science (2), and voluntary health association representatives (2). Members serve for overlapping 4 year terms, except that any member appointed to fill a vacancy for an unexpired term shall be appointed for the remainder of such term. A member may serve after the expiration of the member's term until a successor has taken office. Members serve as Special Government Employees. This announcement is seeking nominations for a "representative of a state public health department" who is not a Federal employee.

**Sherry Glied,**

*Assistant Secretary for Planning and Evaluation.*

[FR Doc. 2012-6083 Filed 3-12-12; 8:45 am]

**BILLING CODE P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention (CDC)**

**Request for Nominations of Candidates to Serve on the Advisory Committee on Immunization Practices (ACIP)**

The CDC is soliciting nominations for membership on the ACIP. The ACIP consists of 15 experts in fields associated with immunization, who are selected by the Secretary of the U. S. Department of Health and Human Services to provide advice and guidance to the Secretary, the Assistant Secretary for Health, and the CDC on the control of vaccine-preventable diseases. The role of the ACIP is to provide advice that will lead to a reduction in the incidence of vaccine preventable diseases in the United States, and an increase in the safe use of vaccines and related biological products. The committee also establishes, reviews, and as appropriate, revises the list of vaccines for administration to children eligible to receive vaccines through the Vaccines for Children (VFC) Program.

Nominations are being sought for individuals who have expertise and qualifications necessary to contribute to the accomplishments of the committee's objectives. Nominees will be selected based on expertise in the field of immunization practices; multi-disciplinary expertise in public health; expertise in the use of vaccines and immunologic agents in both clinical and preventive medicine; knowledge of vaccine development, evaluation, and vaccine delivery; or knowledge about consumer perspectives and/or social and community aspects of immunization programs. Federal employees will not be considered for membership. Members may be invited to serve for four-year terms. The next cycle of selection of candidates will begin in the fall of 2012, for selection of potential nominees to replace members whose terms will end on June 30, 2013.

Selection of members is based on candidates' qualifications to contribute to the accomplishment of ACIP objectives (<http://www.cdc.gov/vaccines/recs/acip>). The U.S. Department of Health and Human Services policy stipulates that committee membership be balanced in terms of points of view represented and the committee's function. Consideration is given to a broad representation of geographic areas within the U.S., as well as gender, race, ethnicity, and persons with disabilities. Nominees must be

U.S. citizens, and cannot be full-time employees of the U.S. Government.

Candidates should submit the following items:

- Current curriculum vitae, including complete contact information (telephone numbers, fax number, mailing address, email address)
- At least one letter of recommendation from person(s) not employed by the U.S. Department of Health and Human Services. Candidates may submit letter(s) from current HHS employees if they wish, but at least one letter must be submitted by a person not employed by HHS.

Nominations should be submitted (postmarked or received) by November 16, 2012 (for consideration for term beginning July 2013.) All files must be submitted electronically as email attachments to:

- Ms. Stephanie Thomas, c/o ACIP Secretariat, [SThomas5@cdc.gov](mailto:SThomas5@cdc.gov).
- Nominations may be submitted by the candidate or by the person/organization recommending the candidate.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: March 6, 2012.

**Elaine L. Baker,**

*Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.*

[FR Doc. 2012-6071 Filed 3-12-12; 8:45 am]

**BILLING CODE 4163-18-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

**Clinical Laboratory Improvement Advisory Committee, Centers for Disease Control and Prevention: Notice of Charter Renewal**

This gives notice under the Federal Advisory Committee Act (Pub. L. 92-463) of October 6, 1972, that the Clinical Laboratory Improvement Advisory Committee, Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS), has been renewed for a 2-year period through February 19, 2014.

For information, contact May Chu, Ph.D., Designated Federal Officer, Clinical Laboratory Improvement