

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Council on Blood Stem Cell Transplantation; Request for Nominations for Voting Members

AGENCY: Health Resources and Services Administration (HRSA), HHS.

ACTION: Notice.

SUMMARY: The Health Resources and Services Administration (HRSA) is requesting nominations of qualified candidates to fill expected vacancies on the Advisory Council on Blood Stem Cell Transplantation (ACBSCT).

The ACBSCT was established pursuant to Public Law 109–129 as amended by Public Law 111–264; 42 U.S.C. 274k; Section 379 of the Public Health Service Act. In accordance with Public Law 92–463, the ACBSCT was chartered on December 19, 2006.

DATES: The agency will receive nominations on a continuous basis.

ADDRESSES: Nominations should be submitted to the Executive Secretary, ACBSCT, Healthcare Systems Bureau, HRSA, 5600 Fishers Lane, Room 08N182, Rockville, MD 20857. Federal Express, Airborne, or UPS, mail delivery should be addressed to Executive Secretary, ACBSCT, Healthcare Systems Bureau, HRSA, at the above address. Nominations submitted electronically should be emailed to PStroup@hrsa.gov and PTongele@hrsa.gov.

FOR FURTHER INFORMATION CONTACT: Patricia A. Stroup, M.B.A., M.P.A., Executive Secretary, ACBSCT, at (301) 443–1127 or email PStroup@hrsa.gov.

SUPPLEMENTARY INFORMATION: The Council was established to implement a statutory requirement of the Stem Cell Therapeutic and Research Act of 2005 (Pub. L. 109–129). The Council is governed by the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), which sets forth standards for the formation and use of advisory committees.

The ACBSCT advises the Secretary and the Administrator, HRSA on matters related to the activities of the C.W. Bill Young Cell Transplantation Program (Program) and the National Cord Blood Inventory Program.

The ACBSCT shall, as requested by the Secretary, discuss and make recommendations regarding the Program. It shall provide a consolidated, comprehensive source of expert, unbiased analysis and recommendations to the Secretary on the latest advances in the science of blood stem cell

transplantation. The ACBSCT shall advise, assist, consult and make recommendations, at the request of the Secretary, on broad Program policy in areas such as the necessary size and composition of the adult donor pool available through the Program and the composition of the National Cord Blood Inventory; requirements regarding informed consent for cord blood donation; accreditation requirements for cord blood banks; the scientific factors that define a cord blood unit as high quality; public and professional education to encourage the ethical recruitment of genetically diverse donors and ethical donation practices; criteria for selecting the appropriate blood stem source for transplantation; Program priorities; research priorities; and the scope and design of the Stem Cell Therapeutic Outcomes Database. It also shall, at the request of the Secretary, review and advise on issues relating more broadly to the field of blood stem cell transplantation, such as regulatory policy pertaining to the compatibility of international regulations, and actions that may be taken by the state and federal governments and public and private insurers to increase donation and access to transplantation. The ACBSCT also shall make recommendations regarding research on emerging therapies using cells from bone marrow and cord blood.

The ACBSCT consists of up to 25 members, including the Chair. Members of the ACBSCT shall be chosen to ensure objectivity and balance, and reduce the potential for conflicts of interest. The Secretary shall establish bylaws and procedures to prohibit any member of the ACBSCT who has an employment, governance, or financial affiliation with a donor center, recruitment organization, transplant center, or cord blood bank from participating in any decision that materially affects the center, recruitment organization, transplant center, or cord blood bank; and to limit the number of members of the ACBSCT with any such affiliation.

The members and chair shall be selected by the Secretary from outstanding authorities and representatives of marrow donor centers and marrow transplant centers; representatives of cord blood banks and participating birthing hospitals; recipients of a bone marrow transplant; recipients of a cord blood transplant; persons who require such transplants; family members of such a recipient or family members of a patient who has requested the assistance of the Program in searching for an unrelated donor of bone marrow or cord blood; persons

with expertise in bone marrow and cord blood transplantation; persons with expertise in typing, matching, and transplant outcome data analysis; persons with expertise in the social sciences; basic scientists with expertise in the biology of adult stem cells; ethicists; hematology and transfusion medicine researchers with expertise in adult blood stem cells; persons with expertise in cord blood processing; and members of the general public.

In addition, representatives from HRSA's Division of Transplantation, the Department of Defense Marrow Recruitment and Research Program operated by the Department of the Navy, the Food and Drug Administration, the National Institutes of Health, the Centers for Medicare & Medicaid Services, and the Centers for Disease Control and Prevention serve as non-voting ex officio members.

Specifically, HRSA is requesting nominations for voting members of the ACBSCT in these categories: Marrow donor centers and transplant center representatives; cord blood banks and participating hospitals' representatives; recipients of cord blood transplant; family members of bone marrow transplant and cord blood transplant recipients or family members of a patient who has requested assistance by the Program in searching for an unrelated donor; persons with expertise in bone marrow or cord blood transplantation; persons with expertise in typing, matching, and transplant outcome data analysis; persons with expertise in social sciences; basic scientists with expertise in the biology of adult stem cells; researchers in hematology and transfusion medicine with expertise in adult blood stem cells; persons with expertise in cord blood processing; and members of the general public. Nominees will be invited to serve a 2-year term, beginning the date of appointment, with the possibility of additional 2-year terms, not to exceed 6 years consecutively.

HHS will consider nominations of all qualified individuals to ensure that the ACBSCT includes the areas of subject matter expertise noted above. Individuals may nominate themselves or other individuals, and professional associations and organizations may nominate one or more qualified persons for membership on the ACBSCT. Nominations shall state that the nominee is willing to serve as a member of the ACBSCT. Potential candidates will be asked to provide detailed information concerning financial interests, consultancies, research grants, and/or contracts that might be affected by recommendations of the ACBSCT to

permit evaluation of possible sources of conflicts of interest. In addition, nominees will be asked to provide detailed information concerning any employment, governance, or financial affiliation with any donor centers, recruitment organizations, transplant centers, and/or cord blood banks.

A nomination package should be sent in as hard copy, email communication, or on compact disc. A nomination package should include the following information for each nominee: (1) A letter of nomination stating the name, affiliation, and contact information for the nominee, the basis for the nomination (*i.e.*, what specific attributes recommend him/her for service in this capacity), and the nominee's field(s) of expertise; (2) a biographical sketch of the nominee and a copy of his/her curriculum vitae; and (3) the name, return address, email address, and daytime telephone number at which the nominator can be contacted.

HHS strives to ensure that the membership of HHS federal advisory committees is balanced in terms of points of view represented, consistent with the committee's authorizing statute and charter. Appointment to the ACBSCT shall be made without discrimination on the basis of age, race, ethnicity, gender, sexual orientation, disability, and cultural, religious, or socioeconomic status. The Department encourages nominations of qualified candidates from all groups and locations.

Jackie Painter,

Director, Division of the Executive Secretariat.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Committee on Organ Transplantation Request for Nominations for Voting Members

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice of request for nominations.

SUMMARY: The Health Resources and Services Administration (HRSA) is requesting nominations to fill vacancies on the Advisory Committee on Organ Transplantation (ACOT). The ACOT was established by the Amended Final Rule of the Organ Procurement and Transplantation Network (OPTN) (42 CFR part 121) and, in accordance with

Public Law 92-463, was chartered on September 1, 2000.

DATES: The agency must receive nominations on a continuous basis.

ADDRESSES: All nominations should be submitted to the Executive Secretary, ACOT, Healthcare Systems Bureau, HRSA, 5600 Fishers Lane, Room 08N182, Rockville, Maryland 20857. Federal Express, Airborne, UPS, etc., mail delivery should be addressed to Executive Secretary, Advisory Committee on Organ Transplantation, Healthcare Systems Bureau, HRSA, at the above address, or via email to: PStroup@hrsa.gov and PTongele@hrsa.gov.

FOR FURTHER INFORMATION CONTACT: Patricia A. Stroup, M.B.A., M.P.A., Executive Secretary, ACOT, at (301) 443-1127 or email PStroup@hrsa.gov.

SUPPLEMENTARY INFORMATION: As provided by 42 CFR 121.12, the Secretary established the ACOT. The ACOT is governed by the Federal Advisory Committee Act (5 U.S.C. Appendix 2), which sets forth standards for the formation and use of advisory committees.

The ACOT advises the Secretary on all aspects of organ procurement, allocation, and transplantation, and on other such matters that the Secretary determines. One of its principal functions is to advise the Secretary on federal efforts to maximize the number of deceased donor organs made available for transplantation and to support the safety of living organ donation.

The ACOT consists of up to 25 members, who are Special Government Employees, and 6 ex-officio, non-voting members. Members and the Chair shall be appointed by the Secretary from individuals knowledgeable in such fields as deceased and living organ donation, health care public policy, transplantation medicine and surgery, critical care medicine and other medical specialties involved in the identification and referral of donors, non-physician transplant professions, nursing, epidemiology, immunology, law and bioethics, behavioral sciences, economics and statistics, as well as representatives of transplant candidates, transplant recipients, living organ donors, and family members of deceased and living organ donors. Members shall not serve while they are also serving on the OPTN Board of Directors. To the extent practicable, Committee members should represent minority, gender and geographic diversity of transplant candidates, transplant recipients, organ donors and family members served by the OPTN.

The ex-officio, non-voting members shall include the Directors of the National Institutes of Health, the Centers for Disease Control and Prevention, and the Agency for Healthcare Research and Quality; the Administrator of the Centers for Medicare & Medicaid Services; the Commissioner of the Food and Drug Administration; and the Chair, Advisory Committee on Blood and Tissue and Safety Availability—or their designees.

Specifically, HRSA is requesting nominations for voting members of the ACOT representing: Health care public policy; transplantation medicine and surgery, including pediatric and heart/lung transplantation; critical care medicine; nursing; epidemiology and applied statistics; immunology; law and bioethics; behavioral sciences; economics and econometrics; organ procurement organizations; transplant candidates/recipients; transplant/donor family members; and living donors. Nominees will be invited to serve up to a 4-year term.

The Department of Health and Human Services (HHS) will consider nominations of all qualified individuals with a view to ensuring that the ACOT includes the areas of subject matter expertise noted above. Individuals may nominate themselves or other individuals, and professional associations and organizations may nominate one or more qualified persons for membership on the ACOT. Nominations shall state that the nominee is willing to serve as a member of the ACOT and appears to have no conflict of interest that would preclude the ACOT membership. Potential candidates will be asked to provide detailed information concerning financial interests, consultancies, research grants, and/or contracts that might be affected by recommendations of the ACOT to permit evaluation of possible sources of conflicts of interest.

A nomination package should include the following information for each nominee:

(1) A letter of nomination stating the name, affiliation, and contact information for the nominee, the basis for the nomination (*i.e.*, what specific attributes, perspectives, and/or skills does the individual possess that would benefit the workings of ACOT), and the nominee's field(s) of expertise; (2) a biographical sketch of the nominee and a copy of his/her curriculum vitae; and (3) the name, address, daytime telephone number, and email address at which the nominator can be contacted.

HHS strives to ensure that the membership of HHS federal advisory committees is balanced in terms of