



THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

CHARTER

ADVISORY COUNCIL ON BLOOD STEM CELL TRANSPLANTATION

Purpose

The Department of Health and Human Services (HHS) has a vital role in safeguarding and promoting public health by overseeing the implementation and operation of the C.W. Bill Young Cell Transplantation Program (successor to the National Bone Marrow Donor Registry) and the National Cord Blood Inventory. Public Law 109-129, the Stem Cell Therapeutic and Research Act of 2005, recently authorized both programs. The principal purpose of these programs is to make blood stem cells from adult donors and cord blood units available for patients who need a transplant to treat life-threatening conditions such as leukemia, and who lack a suitably matched relative who can be the donor. Over 70% of patients who need blood stem cell transplants lack a related donor. The recommendations of the Advisory Council on Blood Stem Cell Transplantation will assist HHS in establishing and overseeing these new programs.

Authority

Public Law 109-129; 42 U.S.C. 274k; Section 379 of the Public Health Service Act as amended. The Council is governed by the provisions of Public Law 92-463, as amended (5 U.S.C. Appendix 2), which sets forth standards for the formation and use of advisory committees.

Function

The Council advises the Secretary and Administrator, Health Resources and Services Administration, on matters related to the activities of the C.W. Bill Young Cell Transplantation Program and the National Cord Blood Inventory Program.

The Council shall, as requested by the Secretary, discuss and make recommendations regarding the C.W. Bill Young Cell Transplantation Program (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 Council 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 including 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 Advisory Council also shall make recommendations regarding research on emerging therapies using cells from bone marrow and cord blood.

Structure

The Council shall consist of up to 25 members, including the Chair. Members of the Advisory Council 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 Advisory Council 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 Advisory Council 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.

The Council also shall include as nonvoting members representatives from the Division of Transplantation of the Health Resources and Services Administration, the Department of Defense Marrow Recruitment and Research Program operated by the Department of the Navy, the Food and Drug Administration and the National Institutes of Health. The Secretary may also appoint other non-voting ex officio members, or designees of such officials, as the Secretary deems necessary for the Council to effectively carry out its functions.

As necessary, subcommittees composed of members of the parent Council, may be established with the approval of the Secretary of HHS or his designee to perform specific functions within the Council's jurisdiction. The Department Committee Management Officer shall be notified upon establishment of each subcommittee, and shall be provided information on its name, membership, function, and estimated frequency of meetings.

Members shall be invited to serve for a term of 2 years, and each such member may serve as many as 3 consecutive 2-year terms, except that such limitations shall not apply to the Chair of the Council (or the Chair-elect) or to the member of the Council who most recently served as the Chair; and one additional consecutive 2-year term may be served by any member of the Council who has no employment, governance, or financial affiliation with any donor center, recruitment organization, transplant center, or cord blood bank. A member of the Advisory Council may continue to serve after the expiration of the term of such member until a successor is appointed. In order to ensure the continuity of the Council, the Council shall be appointed so that each year the terms of approximately one-third of the members of the Council expires. Any member of the Council who has an employment, governance, or financial affiliation with a donor center, recruitment organization, transplant center, or cord blood bank will be prohibited from participating in any decision that materially affects the donor center, recruitment organization, transplant center, or cord blood bank. The number of members with such affiliations on the Council shall be limited.

A vacancy on the Council shall be filled in the manner in which the original appointment was made and shall be subjected to any conditions that applied with respect to the original appointment. An individual chosen to fill a vacancy shall be appointed for the remainder of the term of the member replaced. The vacancy shall not affect the power of the remaining members to execute the duties of the Council.

Management and support services shall be provided by the Director, Division of Transplantation, Healthcare Systems Bureau, Health Resources and Services Administration.

Meetings

Meetings shall be held up to 3 times per year at the call of the Designated Federal Official or designee who shall approve the agenda and shall be present at all meetings.

A majority of the Council shall constitute a quorum.

Meetings shall be open to the public except as determined by the Secretary or other officials to whom the authority has been delegated in accordance with the Government in the Sunshine Act (5 U.S.C. 552b(c)). Notice of all meetings shall be provided to the public.

Meetings shall be conducted, and records of the proceedings kept, as required by applicable laws and departmental regulations.

Compensation

Members shall be paid at a rate of \$200 for each day they are engaged in the performance of their duties as members of the Council. Members shall receive per diem and travel

expenses as authorized by 5 U.S.C. 5703, as amended, for person employed intermittently in the Government service. Members who are officers or employees of the United States Government shall not receive compensation for service on the Council.

Annual Cost Estimate

The estimated annual cost for operating the Council, including compensation and travel expenses for members but excluding support staff is \$217,186. The estimated annual person-years of staff support are 1.4, at an estimated annual cost of \$203,582.

Reports

In the event a portion of a meeting is closed to the public, as determined by the Secretary of HHS, in accordance with the Government in the Sunshine Act (5 U.S.C. 552b(c)) and the Federal Advisory Committee Act, a report shall be prepared that shall contain, at a minimum, a list of members and their business addresses, the Council's function, dates and places of meetings, and a summary of the Council activities and recommendations made during the fiscal year. A copy of the report shall be provided to the Department Committee Management Officer.

The Secretary, acting through the Advisory Council, shall submit to Congress (A) an annual report on the activities carried out under Section 379 of the Public Health Service Act (42 U.S.C. 274k); and (B) not later than 6 months after the date of the enactment of the Stem Cell Therapeutic and Research Act of 2005, a report of recommendations on the scientific factors necessary to define a cord blood unit as a high-quality unit.

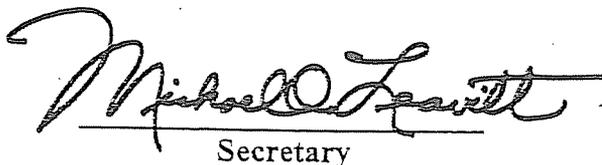
Termination Date

Unless renewed by appropriate action prior to its expiration, the Advisory Council on Blood Stem Cell Transplantation will terminate two years from the date this Charter is filed.

APPROVED:

DEC 19 2006

Date



Secretary

DATE FILED: 2/7/07