CHARTER

ADVISORY COUNCIL ON BLOOD STEM CELL TRANSPLANTATION (ACBSCT)

Authority

Public Law 109-129 as amended by Public Law 111-264; 42 U.S.C. 274k; Section 379 of the Public Health Service Act. 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.

Objectives and Scope of Activities

42 U.S.C. 274k authorizes the operation of the C.W. Bill Young Cell Transplantation Program and the National Cord Blood Inventory (NCBI). 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. The recommendations of the Advisory Council on Blood Stem Cell Transplantation assist HHS in overseeing these programs.

The statute requires the Advisory Council's involvement in submitting reports to Congress.

Description of Duties

The Council advises the Secretary, Department of Health and Human Services and Administrator, Health Resources and Services Administration (HRSA) 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 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 cell 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.

Agency or Official to Whom the Committee Reports
The Council provides advice to the Secretary of Health and Human Services, acting through the Administrator of HRSA.

Support
Management and support services shall be provided by HRSA's Healthcare Systems Bureau.

Estimated Annual Operating Costs and Staff Years
The estimated annual cost for operating the Council, including compensation and travel expenses for members but excluding staff support, is $120,200. Estimated annual person-years of staff support required is .70, at an estimated annual cost of $118,719.

Designated Federal Officer (DFO)
A full-time employee, appointed in accordance with Agency procedures, will serve as the Designated Federal Officer (DFO) (or designee). In the event that the DFO cannot fulfill the assigned responsibilities for the Committee, then the HRSA Administrator (or designee) will temporarily appoint one or more permanent full-time or part-time employees to carry out the assigned duties. The DFO will approve or call all of the ACBSCT and subcommittees' meetings, prepare and approve all meeting agendas, attend all ACBSCT and subcommittee meetings, adjourn any meeting when the DFO determines adjournment to be in the public interest, and chair meetings when directed to do so by the official to whom the Advisory Council reports.

Estimated Number and Frequency of Meetings
Meetings may be held up to three (3) times during the fiscal year. Meetings shall be open to the public except as determined otherwise by the Secretary or designee in accordance with the Government in the Sunshine Act 5 U.S.C. 552b(c) and the Federal Advisory Committee Act. Notice of all meetings shall be given to the public. Meetings shall be conducted, and records of the proceedings kept, as required by applicable laws and departmental regulations.

Duration
Continuing.

Termination
Unless renewed by appropriate action prior to its expiration, the charter for the Committee will expire 2 years from the date it's filed.

Membership and Designation
The Council shall consist 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 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 appointed 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 include as non-voting, ex officio 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 Navy, the Food and Drug Administration, the National Institutes of Health, and the Centers for Disease Control and Prevention.

Members shall be invited to serve for a term of 2 years, and each such member may serve as many as three 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. Members may continue to serve after the expiration of the term of such member until a successor is appointed. 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.

Subcommittees

Subcommittees may be established with the approval of the Secretary or designee. Subcommittees members may be members of the parent Advisory Council. The subcommittees shall make recommendations to be deliberated by the parent Advisory Council. The Department's Committee Management Officer will be notified upon the establishment of each subcommittee and will be provided information on the subcommittee's name, membership, function, and estimated frequency of meetings.

Recordkeeping

Records of the ACBSCT, formally established subcommittees, or other subgroups of ACBSCT, shall be handled in accordance with General Records Schedule 6.2, Item 010 or other approved Agency records disposition schedule. These records shall be available for public inspection and copying, subject to the Freedom of Information Act, 5 U.S.C. 552.

Filing Date

February 19, 2017

APPROVED:

FEB 17 2017
Date

Thomas E. Price, M.D.,
Secretary