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109TH CONGRESS, 1st Session | SENATE | REPORT 109–129

STEM CELL THERAPEUTIC AND RESEARCH ACT OF 2005

AUGUST 31, 2005.—Ordered to be printed

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Mr. ENZI, from the Committee on Health, Education, Labor, and Pensions, submitted the following

R E P O R T

[To accompany S. 1317]

The Committee on Health, Education, Labor, and Pensions, to which was referred the bill (S. 1317) to provide for the collection and maintenance of cord blood units for the treatment of patients and research, and to amend the Public Health Service Act to authorize the Bone Marrow and Cord Blood Cell Transplantation Program to increase the number of transplants for recipients suitably matched to donors of bone marrow and cord blood, having considered the same, reports favorably thereon with an amendment in the nature of a substitute and recommends that the bill (as amended) do pass.

CONTENTS

I. PURPOSE AND SUMMARY OF THE BILL

S. 1317, the Stem Cell Therapeutic and Research Act of 2005, does the following:

- Reauthorizes and expands the National Bone Marrow Donor Registry (NBMDR), renaming it the C.W. Bill Young Cell Transplantation Program (Program) to reflect its broadened scope of services, then providing those services through a mechanism of contracts which address bone marrow/peripheral blood stem cells and cord blood separately;
- Requires the Secretary of Health and Human Services (Secretary) to provide structure and funds for the collection and maintenance of units of cord blood, which are to be used for treatment of patients with transplant-amenable diseases and for research; and
- Amends the Public Health Service Act (PHSA), to increase the number of bone marrow and cord blood transplants performed, funding this function separately.

This legislation builds upon the firm foundation laid for stem cell therapy and research over the last two decades by the work of the National Marrow Donor Program (NMDP) and cord blood banks with bone marrow/peripheral blood stem cells and cord blood. This pioneering work of the NBMDR, mandated and funded by Congress, was ably carried out by NMDP under the direction of the Health Resources and Services Administration. In particular, Congress recognizes that the benefits, to date, of these life-saving treatments and the future realization of their therapeutic potential, could not occur without the past efforts by the NMDP, cord blood banks and others to facilitate and coordinate bone marrow/peripheral blood and cord blood therapies.

A principal effect of this legislation is to direct the Secretary to establish standards, including institutional accreditation criteria, for the collection, processing, storage and distribution of cord blood, as well as fund a substantial increase in the number of cord blood units banked (inventory goal = 150,000 new units), for use by unrelated recipients under the auspices of a national initiative, the Program. These changes should considerably expand and facilitate use of cord blood for therapy and research, meeting the needs of 80–90 percent of patients who require stem cell transplantation as an optimal therapy for more than 70 diseases.

A demonstration project is also authorized, which makes directed donation possible through qualified cord blood banks in those instances when need for cord blood transplantation can reasonably be anticipated for first-degree family members. In addition, the bill establishes parallel or joint administrative functions for all types of transplant material—bone marrow/peripheral blood stem cells and cord blood—that should increase their use: donor recruitment, particularly amongst underrepresented populations; single point access to transplant material for providers; patient advocacy and case management activities; and an Advisory Council of medical experts and other stakeholders to offer recommendations to the Secretary on all aspects related to the Program. Finally, the bill mandates establishment of a comprehensive clinical outcomes database—the Stem Cell Therapeutic Outcomes Database—for all stem cell therapeutics, enhancing the safety and efficacy of these treatments by providing access to all authorized healthcare providers and qualified researchers. This legislation intentionally places additional emphasis on cord blood therapies, predicating new initiatives on current programs; in doing so, however, it affirms the value of and

continues full support for work done, to date, with all types of stem cell therapy: bone marrow/peripheral blood and cord blood.

All stem cells have the potential to divide and multiply, so as to "self-renew" the population of stem cells, and also give rise to more specialized cells as seen in adult tissues through differentiation. All stem cells share these basic properties; however, what stratifies them is the range of cell types, tissues, and organs that they have the ability to create. Adult stem cells like the hematopoietic stem cells found in bone marrow/peripheral blood and cord blood can repopulate the wide array of blood cell lines—say in a patient in treatment for leukemia—but currently have limited potential to develop into non-blood cells. As such, their therapeutic potential may be significant for a circumscribed range of disorders, but is likely to be extremely limited for disorders outside this range.

II. Background and Need for the Legislation

Human bone marrow and peripheral blood stem cell transplantation are well-established application of stem cell therapy. Human cord blood transplantation represents a variant of this therapy, in which blood, taken from the placenta and umbilical cord after birth of the baby and following separation of the cord, is used as the transplant material rather than bone marrow. All forms of stem cell transplantation can be life saving. Stem cell transplantation utilizing cord blood as the source material adds a third treatment option to the therapeutic armamentarium; providers can now balance the unique advantages and disadvantages of bone marrow/peripheral blood stem cells and cord blood to choose the optimal source material for transplantation in their adult and child patients. Note that, with each variant of therapy, the stem cells used for transplantation are derived from biological material which completely lacks all capacity for human life. In addition, all types of source material—bone marrow, peripheral blood stem cells and cord blood—are of value to the ongoing research that broadens the clinical applications of stem cell therapy.

The National Marrow Donor Program (NMDP), which has implemented the NBMDR, pioneered several of the features of this legislation, including the following: clinical registry of marrow donors, to facilitate timely identification of suitable transplant material (>5.5 M adults), including routine assessment of the search function; recruitment of marrow donors, especially in underserved populations; development and maintenance of medical emergency contingency response capacity to a radiation disaster; and patient advocacy and case management services. Over 20,000 bone marrow/peripheral blood stem cell and cord bood transplants have taken place to date. The NMDP has demonstrably advanced the application of bone marrow transplantation. This legislation would modify and expand established programs, providing the Federal support that is necessary in order to more fully realize the potential of cord blood as a source material for stem cell transplantation.

Particular issues to be addressed by the legislation include the following:

- The inventory of cord blood now available falls far short of the estimated need (150,000 new units);
- Lack of consistent standards for donor identification, collection and storage of cord blood have made some of the cur-

rent inventory unsuitable for treatment or, possibly, for research;

- A common, comprehensive, readily accessible information system, designed to facilitate timely identification of compatible transplant material, would be of singular benefit to patients and providers alike;
- A database which records pertinent clinical outcome measures would be of particular value to this developing therapy; and
- Patients require informational/educational, advocacy and cases management services, which may be duplicated or unmet.

Technologies pertinent to bone marrow/peripheral blood stem cell and cord blood collection often differ remarkably; however, given the complimentary nature of these stem cell therapies, it makes sense to combine federal support for them into a single Program, rather than reauthorizing the NBMDR and passing new legislation pertaining to cord blood alone. Both economies of scale and decreased duplication of services (e.g. patient education and advocacy, case management, and clinical outcomes database) should help reduce the costs of broadening support to include cord blood-related considerations. Given the complexities and rapid developments in these areas of stem cell therapy, the Advisory Council will provide the Secretary with a consolidated yet comprehensive source of expert, unbiased analysis and recommendations.

A small proportion ($\leq 5\%$) of the Program's funding is devoted to a demonstration project that allows for directed donation of cord blood for the benefit of first-degree relatives with conditions amenable to cord blood transplantation therapy. Cord blood units banked for this purpose must adhere to public standards and, if not used, will revert to the public inventory. Application for the demonstration project is at the discretion of the individual cord blood banks and is not a prerequisite for receiving the award of a contract for broader cord blood services.

HIPAA regulations are sufficient to guarantee proper use of both the single portal of access to transplant material and to the outcomes database.

Federal funding is necessary to create an inventory of cord blood units sufficient to meet estimated current patient needs. Funds authorized and appropriated for this purpose should be available only until the inventory goal specified is met by U.S. public cord blood banks. These funds are not intended to pay for individual clinical treatment that involves the use of cord blood; in particular, they are not intended to substitute for treatment-related reimbursement available through other federal programs (e.g. Medicaid/SCHIP, or through private insurance). The legislation also authorizes additional appropriations in support of the C.W. Bill Young Cell Transplantation Program; these latter funds are completely separate and distinct from the former and are not time-limited.

III. Legislative History and Committee Action

The Cord Blood Stem Cell Act of 2003 (H.R. 2852) was introduced on July 24, 2003 by Representative Chris Smith and 35 cosponsors, with the Senate version of the bill, S. 1717, introduced by Senators Orrin Hatch, Christopher Dodd, Arlen Specter and

Sam Brownback on October 3, 2003. S. 1717/H.R. 2852 directed the Secretary of Health and Human Services, through the Administrator of the Health Resources and Services Administration, to enter into contracts with qualified cord blood stem cell banks to assist in the establishment, provision and maintenance of a national Cord Blood Stem Cell Bank Network of at least 150,000 units of human cord blood stem cells. The legislation also established qualification requirements for participating banks and created a registry to allow patients and physicians to identify and obtain appropriate cord blood transplant material from the Network.

In the 109th Congress, Senator Hatch re-introduced this cord blood bill as S. 681 on March 17, 2005, with Senators Christopher Dodd, Arlen Specter, Sam Brownback and Tom Harkin. Subsequently, in response to the Institute of Medicine's report, "Cord Blood: Establishing a National Hematopoietic Stem Cell Bank Program", as well as the House bill (H.R. 2520), introduced by Representative Chris Smith and co-sponsored by 78 other legislators, Senator Hatch, along with Senators Richard Burr, Christopher Dodd, John Ensign, and Jack Reed, began work on a revised bill that, like H.R. 2520, linked the creation of a national cord blood bank network with the reauthorization of the National Marrow Donor Program and on June 27, 2005, they introduced S. 1317, the Bone Marrow and Cord Blood Therapy and Research Act of 2005. S. 1317 provides for the collection and maintenance of cord blood units, for the treatment of patients and research, and to amend the PHSA to authorize creation of the Program, to increase the number of transplants for recipients suitably matched to donors of bone marrow and cord blood; this subsequent legislation incorporated key elements of the authoritative Institute of Medicine (IOM) report, "Cord Blood: Establishing a National Hematopoietic Stem Cell Bank Program (2005)". On June 29, 2005, the committee, meeting in executive session, modified the bill by approving a manager's amendment (Senator Enzi, for himself and Senators Hatch, Dodd, Burr, Reed, DeWine, Mikulski, Frist, Clinton, Enzi, Roberts, and Murray), then favorably ordered the bill reported.

IV. Explanation of Bill and Committee Views

This legislation builds upon the firm foundation established by the NMDP, which has advanced the public health by facilitating the application of one form of stem cell therapy—bone marrow transplantation—to the care of patients with a variety of malignant, metabolic and other diseases. It also draws upon the strength and experience of the long-established blood banking profession in defining standards for collection and storage of blood products and accreditation of facilities. Each will do much to promote the use of this analogous therapy—cord blood transplantation. Yet the legislation acknowledges that more needs to be done in the area of cord blood transplantation.

The committee, in its deliberations on S. 1317, placed particular emphasis on several aspects of the legislation and wants to state clearly the following points of consensus.

Cord blood units collected through the program, but which subsequently prove unsuitable for use as transplant material, are still of great value for research purposes. For example, units that are collected and cryopreserved, but which later test positive on initial

screening for infectious agents, as well as units with insufficient cell counts, can nevertheless be used for quality assurance testing and for ex vivo expansion, adoptive immunotherapy or graft engineering trials. The committee supports the use of some cord blood units collected under the auspices of the Program for research.

It is not the intent of the committee that all clinical expenses pertaining to cord blood transplantation should be borne by the Program. It is expected that all pertinent public and private insurance reimbursement for clinical expenses related to cord blood transplantation will be fully utilized; in particular, no funds are available through the legislation for this purpose. This pertains to both public and private cord blood banks and includes both directed and random donation of cord blood. Cord blood units are owned by the cord blood banks to which they were donated. Eventual financial self-sufficiency regarding the inventory provisions of the legislation is desired and anticipated.

The committee believes strongly in the value of Congressional oversight of the programs it authorizes and considers thoughtful, candid, timely reports to Congress to be an important part of this process. Thus, it anticipates that the reports mandated by this legislation will contain at least the following features:

- Related Cord Blood Donors Demonstration Project—
  Number of cord blood banks participating.
  Number of cord blood units banked.
  Number of units used for transplantation and for research transplant or research results.
  Amount of money spent by the bank in support of this project.
- Advisory Council—
  Recommendations made to the Secretary on all matters related to the Program.
  Actions taken by the Program on those recommendations.

The committee recognizes that cord blood transplantation is a promising, but emerging, therapy and that they have a unique opportunity to advance the science and practice through establishment of the Stem Cells Therapeutic Outcomes Database. Currently, the Bone Marrow Scientific Registry (BMSR) compiles outcomes data on transplant patients. Given the creation of the cord blood program, the BMSR is expanded and renamed the Stem Cells Therapeutic Outcomes Database. While the Advisory Council must play a leading role in its expansion, the database should contain at least the following elements: clinical diagnosis; donor selection criteria/matching considerations; preparatory regimen; transplant procedure; dosages; results; post-transplant procedures; adverse events; and long-term follow-up.

The committee thinks it is of pre-eminent importance that the Secretary promptly develops a scientifically sound definition of a "high-quality cord blood unit" and anticipates that the Advisory Council will play a prominent role in this process. Such a definition is likely to include quantitative measures of cell counts and viability, HLA typing resolution, match algorithms, and agreement on outcomes measurements; it is also likely to address quality testing, selection criteria, collection and transportation standards, confidentiality and integration of files, searches and general procedures. We

feel that additional features of this legislation will facilitate the establishment of optimal standards:

- FDA participation on the Advisory Council;
- Establishment by the FDA of licensure requirements for cord blood units;
- Continued authority of current FDA, other Federal Government and state regulations; and
- Institutional accreditation.

The committee understands that the actual practice of clinical medicine is and should be a highly individualized and personalized interaction between provider and patient. Nothing in this legislation should be construed, then, to limit the provider's right and responsibility to explore any and all sources of transplant material for their patient. This legislation is intended to help physicians to determine which source of stem cell material is best for their patient. Incumbent on the program, then, is the duty to present all pertinent information clearly and without bias or conflict of interest.

To ensure equitable and efficient operation of the program, however, it is likely that the Secretary, in consultation with the Advisory Council and subject to public comment, will develop guidelines for participation, which should include at least the following:

- Unit reservation policies for cord blood units;
- Informed consent policies for cord blood donation;
- Accreditation requirements for public and private cord blood banks; and
- Standardized data requirements for the outcomes database and the single portal of access.

The committee recognizes that health information technology has revolutionized the management of medical data. Thus, as per the IOM report recommendation, the committee intends that the statute be neutral regarding whether centralized ("real") or decentralized ("virtual") models of management are employed. It anticipates that the competitive process of contracting will encourage innovative solutions to the needs of the Program, especially those unique to the transplantation of cord blood. In determining that standard dataset, the Secretary should consider HLA typing, size of the cord blood unit, sex, and blood type of the donor.

The requirements of the bone marrow and cord blood programs may differ; therefore, the Secretary is required to conduct a competition for the initial establishment of this cord blood function of the Program separate from that for the bone marrow/peripheral blood stem cell function. The contracting competition should be transparent and without preconceptions; in particular, it should not exclude, de novo, any applicant or any particular model from the process.

We emphasize, however, that any successful solution must provide for a single portal of entry for provider and patient alike, one that is accurate, comprehensive, understandable, easy to use and secure; in particular, the provider must have sufficient information readily available to choose intelligently and objectively amongst the various stem cell transplant materials available. A standardized, electronic format for presentation of the data to provider and patient will considerably facilitate this use.

The committee expects that, with passage of this legislation, consideration of cord blood banking will be given, as a matter of routine, in all of the organ donation education and awareness campaigns currently sponsored by the Secretary. Furthermore, the committee anticipates that, as with other donor organ procurement programs, the Secretary will consider carefully how best to promote donation of cord blood.

The committee strongly supports the IOM report recommendation that women be provided with a balanced perspective and clear information in order to participate, actively and knowledgably, in the choice of whether or how to donate cord blood. Informed consent is likely to include, at least, consideration of the following options: public donation or private storage; and disposal. Pertinent cost information must be conveyed to the potential donor. The discussion must be informed, objective, non-coercive and culturally sensitive; timing may be a crucial factor. Experience with other types of organ transplant may be instructive and should be considered in designing the approach to be used for cord blood donation.

Medical contingency response to a terrorist emergency is particularly pertinent to cord blood as the source of stem cell transplant material most likely to be immediately available. It is the committee's expectation that the Secretary will, through the contracting process, address developing the capacity for urgent, large scale searches and attendant logistic considerations, including transportation and security. In addition, cord blood banks must be prepared to increase collection in order to maintain their public inventory in the case of an emergency.

It is the committee's expectation that those Program functions which remain under the direct oversight of the Secretary, i.e. Patient Advocacy and Case Management, single point of access, and the Stem Cell Therapeutic Outcomes Database, will operate in a objective and unbiased manner, free from conflicts of interest, such that they can support use of the stem cell source material that is most appropriate for the individual patient.

The legislation does not presume any fixed, pre-determined distribution of funds appropriated amongst the various functions of the program, save for the limit established for the demonstrations programs; rather, that is left to the Secretary's determination, providing the Secretary with the flexibility necessary to meet the preeminent goal of better patient care through stem cell transplantation therapy. However, in providing this flexibility, the committee does not intend to imply that the funds should be divided equally between the operators of the bone marrow and cord blood functions. When determining how to allocate funds under this program, the Secretary should ensure that his actions do nothing that would put the bone marrow functions of the Program at risk. The allocation of funds between section 3 and the Stem Cell Therapeutic Outcomes Database should be proportional to the relative functions of each. By combining the funding for emergency contingency planning with other program operations, the committee does not intend to diminish the importance of providing sufficient funds for the Program's activities related to national security and encourages the Secretary to ensure that the emergency contingency planning activities are adequately funded.

The committee anticipated that the funding authorized for establishing and strengthening the cord blood unit inventory will be devoted primarily to defraying the start-up expenses, including developing the expanded inventory in an optimal fashion. While we feel that such activities clearly have the potential to be self-supporting in time, we also recognize that sufficient funding over an adequate period of time will be necessary for these activities to realize their full potential. It is the committee's expectation that the Secretary will closely scrutinize all costs related to this legislation, so that tax dollars are spent judiciously to achieve the maximum effect.

The legislation neither requires nor precludes the Secretary from developing new regulations, either temporary or permanent, governing the program; however, the committee expects that, if passed, the legislation will be implemented promptly.

The committee recognizes that some existing blood banks may have particular expertise in managing private or directed donation of cord blood, i.e. donations made expressly for the benefit of a first degree family member with a disease amenable to treatment with cord blood transplantation. In order to take advantage of this expertise, the committee interprets the legislation to permit applications from such blood banks for participation in the demonstration project only. These blood banks would not be required to provide analogous donor services, nor would they be required to submit an application for a more comprehensive contract. Blood banks submitting an application for the demonstration project only will, however, still need to meet all quality, accreditation and research requirements specified in the legislation. Funding for contracts awarded to these blood banks for a demonstration project would be apportioned from the same ≤ 5 percent of the authorization of appropriations that funds demonstration projects awarded to blood banks under a more comprehensive contract. All qualified cord blood units donated through any form of the demonstration project which are not utilized by the intended recipient will revert to the public inventory established by the C.W. Bill Young Cell Transplantation Program.

The Secretary has consistently required that the operator of the National Bone Marrow Donor Registry (NMBDR) conduct research to analyze data pertaining to blood stem cell transplantation. As part of previous contracts, the Secretary requires the contractor to establish and maintain a program of analysis and research regarding the operation of the Registry and persons' decisions regarding enrolling in the Registry, using data in the National Registry of Unrelated Marrow Transplants (renamed, in S. 1317, the Stem Cell Therapeutics Outcomes Database). Research priorities are established collaboratively with Registry committees possessing expertise in research and histocompatibility. The Secretary also requires the contractor to ensure that research conducted or sponsored by the Registry results in peer-reviewed published articles whenever possible.

The committee recognizes the important research the NMDP has accomplished while operating the Registry. We support its goal to systematically remove all barriers to transplant and to increase the likelihood of finding a match for all who could potentially benefit from transplantation. There, S. 1317 includes language authorizing the Secretary to continue having the contractor engage in the type

of research projects it has historically required. The committee seeks to ensure that the contractor maintains the relationships the NMDP has established with other research organizations, donor centers, leading investigators, and the government. The committee seeks to formalize the existing research aspects of the program.

V. COST ESTIMATE

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, DC, July 14, 2005.

Hon. MIKE ENZI,
Chairman, Committee on Health, Education, Labor, and Pensions, U.S. Senate, Washington, DC.

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed cost estimate for S. 1317, the Stem Cell Therapeutic and Research Act of 2005.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contact is Tom Bradley.

Sincerely,

DOUGLAS HOLTZ-EAKIN,
Director.

Enclosure.

S. 1317—Stem Cell Therapeutic and Research Act of 2005

Summary: S. 1317 would amend the Public Health Service Act to provide for the collection and storage of umbilical cord blood and to authorize establishment of a program to increase the number of transplants of bone marrow and cord blood.

CBO estimates that implementing S. 1317 would cost $3 million in 2006 and $212 million over the 2006–2010 period, subject to the appropriation of the authorized amounts. Enacting S. 1317 could affect direct spending. This estimate assumes that S. 1317 will be enacted near the end of fiscal year 2005, in which case, CBO estimates the bill would not have a significant effect on direct spending. (If the bill is enacted by early August, CBO estimates that S. 1317 would shift outlays of $2 million from 2005 to 2006, thereby reducing direct spending by $2 million in 2005 and increasing direct spending by $2 million in 2006.) S. 1317 would have no effect on revenues.

S. 1317 contains no intergovernmental or private-sector mandates as defined in the Unfunded Mandates Reform Act (UMRA) and would impose no costs on state, local, or tribal governments.

Estimated cost to the Federal Government: The estimated budgetary impact of S. 1317 is shown in the following table. The costs of this legislation fall within budget function 550 (health).

	By fiscal year, in millions of dollars—					
	2005	2006	2007	2008	2009	2010
SPENDING SUBJECT TO APPROPRIATION						
Spending Under Current Law:						
Budget Authority[1]	10	0	0	0	0	0
Estimated Outlays	3	10	6	0	0	0
Proposed Changes:						
Authorization Level	0	49	53	53	53	53
Estimated Outlays	0	15	43	50	52	52

	By fiscal year, in millions of dollars—					
	2005	2006	2007	2008	2009	2010
Spending Under S. 1317:						
Authorization Level [1]	10	49	53	53	53	53
Estimated Outlays	3	25	49	50	53	53

[1] The 2005 level is the amount appropriated in that year for the National Cord Blood Stem Cell Bank program.

Basis of estimate: For this estimate, CBO assumes that S. 1317 will be enacted in the fall of 2005, that the authorized amounts will be appropriated for each year, and that outlays will follow historical spending patterns for similar activities administered by the Health Resources and Services Administration (HRSA).

Spending subject to appropriation

S. 1317 would require the Secretary of Health and Human Services to enter into contracts with cord-blood banks to establish and maintain an inventory of cord blood for transplantation. The bill also would require the Secretary to establish the C.W. Bill Young Cell Transplantation Program, with the purpose of increasing the number of transplants of bone marrow and cord blood.

The bill would authorize the appropriation of $49 million in 2006 and $53 million a year in 2007 through 2010. (For the program to establish an inventory of cord blood, the bill also would make available through 2007 the amounts appropriated in 2004 and 2005 for similar purposes—the effect of that provision is discussed below, under "Direct Spending.") CBO estimates that implementing S. 1317 would cost $15 million in 2006 and $212 million over the 2006–2010 period, assuming appropriation of the authorized amounts.

Cord Blood Inventory. The bill would authorize the Secretary to contract with qualified cord-blood banks to collect and maintain an inventory of 150,000 units of cord blood, and to make those units available for transplantation to recipients who are not related to the donor. In addition, the Secretary would conduct a demonstration program in which those cord-blood banks would collect and maintain cord-blood units donated by a family member for directed transplantation to a relative diagnosed with a condition that will benefit from transplantation.

C.W. Bill Young Cell Transplantation Program. The bill would require the Secretary to establish an advisory council to make recommendations concerning the design and operation of a program to encourage the donation of bone marrow and cord blood and to facilitate the matching and distribution of those substances for transplantation. The bill also would require the Secretary to contract with one or more entities to carry out those activities.

Direct spending

In both 2004 and 2005, the Congress appropriated $10 million to ramain available until expended to establish a National Cord Blood Stem Cell Bank program within HRSA. The agency contracted with the Institute of medicine (IOM) to conduct a study and recommend a structure for that program. That study was completed in April 2005, and HRSA currently is engaged in the process of implementing the IOM's recommendations. Under current law, CBO estimates that HRSA will spend $3 million in 2005, $10 million in

2006, and $6 million in 2007 on the National Cord Blood Stem Cell Bank program.

The bill would make available for the program to collect and maintain an inventory of cord blood the funds appropriated in 2004 and 2005 for the National Cord Blood Stem Cell Bank program. Those funds would be available through 2007.

Assuming enactment near the end of the fiscal year, CBO estimates that S. 1317 would not have a significant effect on the rate as which the previously appropriated funds will be spent. Therefore, CBO estimates that enacting S. 1317 would not have a significant effect on spending.

However, if the bill is enacted by early August, CBO expects that HRSA would postpone the expenditure of about $2 million from fiscal year 2005 to 2006, thereby reducing outlays by $2 million in 2005 and increasing outlays by $2 million in 2006. Any such changes in the use of funds previously appropriated would constitute a change in direct spending. (That potential timing shift would have no net effect on outlays over the 2005–2006 period, and there would be no effect on budget authority.)

Intergovernmental and private-sector impact: S. 1317 contains no intergovernmental or private-sector mandates as defined in UMRA and would impose no costs on State, local, or tribal governments.

Estimate prepared by: Federal Costs: Tom Bradley. Impact on State, Local, and Tribal Governments: Leo Lex. Impact on the Private Sector: Jennifer Doleac.

Estimate approved by: Peter H. Fontaine, Deputy Assistant Director for Budget Analysis.

VI. Application of Law to the Legislative Branch

S. 1317 provides for the collection and maintenance of cord blood units for the treatment of patients and research. S. 1317 also amends the PHSA to authorize the program, which will subsume and reauthorize the current NBDMR and add a new cord blood program.

VII. Regulatory Impact Statement

This legislation requires the Secretary to develop standards that regulate the collection and storage of cord blood for undirected public use and for directed donation on behalf of a first-degree relative. It also requires the Secretary to identify a mechanism through which facilities can be accredited to perform these functions. The committee has determined that the bill will not have a significant regulatory impact.

VIII. Section-by-Section Analysis

Sec. 1. Short title

The Stem Cell Therapeutic and Research Act of 2005.

Sec. 2. Cord blood inventory

Instructs the Secretary of Health and Human Services (HHS) to enter into one time contracts with qualified cord blood banks in order to create and maintain a national inventory of 150,000 new high quality cord blood units suitable for transplantation into unre-

lated recipients. In order to be considered qualified, a cord blood bank must meet certain quality standards, including accreditation by an entity recognized by the Secretary.

Establishes a three year demonstration program, under which qualified banks can use a portion of funding for the collection and storage of cord blood units for a family where a first-degree relative has been diagnosed with a condition that will benefit from transplantation. That donated unit is then reserved for use by that family until it is used or no longer needed, at which point it is released into the public inventory. Funding for this demonstration project is capped at five percent of appropriations, and units collected do not count toward the goal of 150,000.

Specifies that previously appropriated funds shall remain available until the end of fiscal year 2007, and authorizes new appropriations of $15 million in each of fiscal years 2007–2010.

Sec. 3. C.W. Bill Young Cell Transplantation Program

379—NATIONAL PROGRAM

Establishes a transplantation program whose mission is to increase the amount of transplant material, both bone marrow and cord blood, available for use by unrelated patients. Toward that end, the Secretary of HHS may award a separate contract to perform each of the program's main functions—i.e., a national cord blood bank network and a national bone marrow registry program.

Establishes an Advisory Council to advise the Secretary on how best to carry out program activities.

Requires the Secretary to recognize one or more accreditation entities to accredit cord blood banks and ensure that they are meeting quality standards.

Bone marrow functions: Details the responsibilities of the bone marrow entity within the Program. Language is very similar to existing statute that established the National Bone Marrow Donor Registry. Functions of the bone marrow program include operating a system to match patients to donors, recruiting donors (with an emphasis on ethnic and racial minorities), maintaining medical emergency contingency response capabilities, carrying out informational and educational activities, providing patient advocacy and case management, analyzing data on the functioning of the search process, and facilitating non-clinical research to improve transplantation.

Cord blood functions: Details the responsibilities of the cord blood entity within the Program. Functions are similar to those listed for bone marrow, with some minor changes as appropriate.

Single point of access; standard data: Requires the Secretary to ensure that health care professionals and patients are able to search electronically for and facilitate access to, in the manner and to the extent defined by the Secretary and consistent with the bone marrow and cord blood functions for operating a system for identifying, matching, and facilitating the distribution of bone marrow or cord blood that is suitably matched to candidate patients, cells from bone marrow and cord blood units through a single point of access. Mandates that the Secretary shall require all recipients of contracts under this section to make available a standard dataset for the single point of access in a standardized electronic format

that enables transplant physicians to compare among and between bone marrow donors and cord blood units to ensure the best possible match for patients.

Bone marrow recruitment; priorities; information and education: Requires the program to carry out activities for the recruitment and education of bone marrow donors and the general public, with an emphasis on increasing donation within underrepresented populations.

Bone marrow criteria, standards, and procedures: Reauthorizes existing statute, with slight modifications, regarding the quality standards for entities involved bone marrow transplantation. [Note: Parallel language does not exist for cord blood, as quality assurance will be the primary responsibility of the accreditation entities and the FDA.]

Cord blood recruitment; priorities; information and education: Parallels above bone marrow language.

Patient advocacy and case management for bone marrow and cord blood: Establishes a single office to assist physicians, patients, donors, and families for whom the program has been requested to conduct a search for bone marrow and/or cord blood.

379A—STEM CELL THERAPEUTIC OUTCOMES DATABASE

Requires the Secretary to contract for the establishment of an outcomes database (presumably built on the existing Bone Marrow Scientific Registry), which will collect and maintain information on outcomes for all patients who have received treatments with stem cell therapeutics products.

379B—AUTHORIZATION OF APPROPRIATIONS

Authorizes appropriations of $34 million in fiscal year 2006 and $38 million in each of fiscal year 2007–2010.

IX. CHANGES IN EXISTING LAW

In compliance with rule XXVI paragraph 12 of the Standing Rules of the Senate, the following provides a print of the statute or the part or section thereof to be amended or replaced (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, existing law in which no change is proposed is shown in roman):

PUBLIC HEALTH SERVICE ACT

* * * * * * *

PART I—[NATIONAL BONE MARROW DONOR REGISTRY] *C.W. BILL YOUNG CELL TRANSPLANTATION PROGRAM*

[SEC. 379. NATIONAL REGISTRY.

[(a) ESTABLISHMENT.—The Secretary shall by contract establish and maintain a National Bone Marrow Donor Registry (referred to in this part as the "Registry") that has the purpose of increasing the number of transplants for recipients suitably matched to biologically unrelated donors of bone marrow, and that meets the requirements of this section. The Registry shall be under the general

supervision of the Secretary, and under the direction of a board of directors meeting the following requirements:

[(1) Each member of the board shall 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 board (or the Chair-elect) or to the member of the board who most recently served as the Chair.

[(2) A member of the board may continue to serve after the expiration of the term of such member until a successor is appointed.

[(3) In order to ensure the continuity of the board, the board shall be appointed so that each year the terms of approximately one-third of the members of the board expire.

[(4) The membership of the board shall include representatives of marrow donor centers and marrow transplant centers; recipients of a bone marrow transplant; persons who require or have required such a transplant; family members of such a recipient or family members of a patient who has requested the assistance of the Registry in searching for an unrelated donor of bone marrow; persons with expertise in the social sciences; and members of the general public; and in addition nonvoting representatives from the Naval Medical Research and Development Command and from the Division of Organ Transplantation of the Health Resources and Services Administration.

[(b) FUNCTIONS.—The Registry shall—

[(1) establish a system for finding marrow donors suitably matched to unrelated recipients for bone marrow transplantation:

[(2) carry out a program for the recruitment of bone marrow donors in accordance with subsection (c), including with respect to increasing the representation of racial and ethnic minority groups (including persons of mixed ancestry) in the enrollment of the Registry;

[(3) carry out informational and educational activities in accordance with subsection (c);

[(4) annually update information to account for changes in the status of individuals as potential donors of bone marrow;

[(5) provide for a system of patient advocacy through the office established under subsection (d);

[(6) provide case management services for any potential donor of bone marrow to whom the Registry has provided a notice that the potential donor may be suitably matched to a particular patient (which services shall be provided through a mechanism other than the system of patient advocacy under subsection (d)), and conduct surveys of donors and potential donors to determine the extent of satisfaction with such services and to identify ways in which the services can be improved;

[(7) with respect to searches for unrelated donors of bone marrow that are conducted through the system under paragraph (1), collect and analyze and publish data on the number and percentage of patients at each of the various stages of the search process, including data regarding the furthest stage reached; the number and percentage of patients who are unable to complete the search process, and the reasons underlying such circumstances; and comparisons of transplant cen-

ters regarding search and other costs that prior to transplantation are charged to patients by transplant centers; and

[(8) support studies and demonstration projects for the purpose of increasing the number of individuals, especially minorities, who are willing to be marrow donors.

[(c) RECRUITMENT; PRIORITIES; INFORMATION AND EDUCATION.—

[(1) RECRUITMENT; PRIORITIES.—The Registry shall carry out a program for the recruitment of bone marrow donors. Such program shall identify populations that are underrepresented among potential donors enrolled with the Registry. In the case of populations that are identified under the proceeding sentence:

[(A) The Registry shall give priority to carrying out activities under this part to increase representation for such populations in order to enable a member of such a population, to the extent practicable, to have a probability of finding a suitable unrelated donor that is comparable to the probability that an individual would have.

[(B) The Registry shall consider racial and ethnic minority groups (including persons of mixed ancestry) to be populations that have been identified for purposes of this paragraph, and shall carry out subparagraph (A) with respect to such populations.

[(2) INFORMATION AND EDUCATION REGARDING RECRUITMENT; TESTING AND ENROLLMENT.—

[(A) IN GENERAL.—In carrying out the program under paragraph (1), the Registry shall carry out informational and educational activities for purposes of recruiting individuals to serve as donors of bone marrow, and shall test and enroll with the Registry potential donors. Such information and educational activities shall include the following:

[(i) Making information available to the general public, including information describing the needs of patients with respect to donors of bone marrow.

[(ii) Educating and providing information to individuals who are willing to serve as potential donors, including providing updates.

[(iii) Training individuals in requesting individuals to serve as potential donors.

[(B) PRIORITIES.—In carrying out informational and educational activities under subparagraph (A), the Registry shall give priority to recruiting individuals to serve as donors of bone marrow for populations that are identified under paragraph (1).

[(3) TRANSPLANTATION AS TREATMENT OPTION.—In addition to activities regarding recruitment, the program under paragraph (1) shall provide information to physicians, other health care professionals, and the public regarding the availability, as a potential treatment option, of receiving a transplant of bone marrow from an unrelated donor.

[(d) PATIENT ADVOCACY; CASE MANAGEMENT.—

[(1) IN GENERAL.—The Registry shall establish and maintain an office of patient advocacy (in this subsection referred to as the "Office").

[(2) GENERAL FUNCTIONS.—The Office shall meet the following requirements:

[(A) The Office shall be headed by a director.

[(B) The Office shall operate a system for patient advocacy, which shall be separate from mechanisms for donor advocacy, and which shall serve patients for whom the Registry is conducting, or has been requested to conduct, a search for an unrelated donor of bone marrow.

[(C) In the case of such a patient, the Office shall serve as an advocate for the patient by directly providing to the patient (or family members, physicians, or other individuals acting on behalf of the patient) individualized services with respect to efficiently utilizing the system under subsection (b)(1) to conduct an ongoing search for a donor.

[(D) In carrying out subparagraph (C), the Office shall monitor the system under subsection (b)(1) to determine whether the search needs of the patient involved are being met, including with respect to the following:

[(i) Periodically providing to the patient (or an individual acting on behalf of the patient) information regarding donors who are suitability matched to the patient, and other information regarding the progress being made in the search.

[(ii) Informing the patient (or such other individual) if the search has been interrupted or discontinued.

[(iii) Identifying and resolving problems in the search, to the extent practicable.

[(E) In carrying out subparagraph (C), the Office shall monitor the system under subsection (b)(1) to determine whether the Registry, donor centers, transplant centers, and other entities participating in the Registry program are complying with standards issued under subsection (e)(4) for the system for patient advocacy under this subsection.

[(F) The Office shall ensure that the following data are made available to patients:

[(i) The resources available through the Registry.

[(ii) A comparison of transplant centers regarding search and other costs that prior to transplantation are charged to patients by transplant centers.

[(iii) A list of donor registries, transplant centers, and other entities that meet the applicable standards, criteria, and procedures under subsection (e).

[(iv) The posttransplant outcomes for individual transplant centers.

[(v) Such other information as the Registry determines to be appropriate.

[(G) The Office shall conduct surveys of patients (or family members, physicians, or other individuals acting on behalf of patients) to determine the extent of satisfaction with the system for patient advocacy under this subsection, and to identify ways in which the system can be improved.

[(3) CASE MANAGEMENT.—

[(A) IN GENERAL.—In serving as an advocate for a patient under paragraph (2), the Office shall provide individualized case management services directly to the patient (or family members, physicians, or other individuals acting on behalf of the patient), including—

[(i) individualized case assessment; and

[(ii) the functions described in paragraph (2)(D) (relating to progress in the search process).

[(B) POSTSEARCH FUNCTIONS.—In addition to the case management services described in paragraph (1) for patients, the Office may, on behalf of patients who have completed the search for an unrelated donor, provide information and education on the process of receiving a transplant of bone marrow, including the posttransplant process.

[(e) CRITERIA, STANDARDS, AND PROCEDURES.—Not later than 180 days after the date of enactment of this part, the Secretary shall establish and enforce, for entities participating in the program, including the Registry, individual marrow donor centers, marrow donor registries, marrow collection centers, and marrow transplant centers—

[(1) quality standards and standards for tissue typing, obtaining the informed consent of donors, and providing patient advocacy;

[(2) donor selection criteria, based on established medical criteria, to protect both the donor and the recipient and to prevent the transmission of potentially harmful infectious diseases such as the viruses that cause hepatitis and the etiologic agent for Acquired Immune Deficiency Syndrome;

[(3) procedures to ensure the proper collection and transportation of the marrow;

[(4) standards for the system for patient advocacy operated under subsection (d), including standards requiring the provision of appropriate information (at the start of the search process and throughout the process) to patients and their families Physicians;

[(5) standards that—

[(A) require the establishment of a system of strict confidentiality of records relating to the identity, address, HLA type, and managing marrow donor center for marrow donors and potential marrow donors; and

[(B) prescribe the purposes for which the records described in subparagraph (A) may be disclosed, and the circumstances and extent of the disclosure; and

[(6) in the case of a marrow donor center or marrow donor registry participating in the program, procedures to ensure the establishment of a method for integrating donor files, searches, and general procedures of the center or registry with the Registry.

[(f) COMMENT PROCEDURES.—The Secretary shall establish and provide information to the public on procedures, which may include establishment of a policy advisory committee, under which the Secretary shall receive and consider comments from interested persons relating to the manner in which the Registry is carrying out the duties of the Registry under subsection (b) and complying with the criteria, standards, and procedures described in subsection (e).

[(g) CONSULTATION.—The Secretary shall consult with the board of the directors of the Registry and the bone marrow donor program of the Department of the Navy in developing policies affecting the Registry.

[(h) APPLICATION.—To be eligible to enter into a contract under section, an entity shall submit to the Secretary and obtain approval of an application at such time, in such manner, and containing such information as the Secretary shall by regulation prescribe.

[(i) ELIGIBILITY.—Entities eligible to receive a contract under this section shall include private nonprofit entities.

[(j) RECORDS.—

[(1) RECORDKEEPING.—Each recipient of a contract or subcontract under subsection (a) shall keep such records as the Secretary shall prescribe, including records that fully disclose the amount and disposition by the recipient of the proceeds of the contract, the total cost of the undertaking in connection with which the contract was made, and the amount of the portion of the cost of the undertaking supplied by other sources, and such other records as will facilitate an effective audit.

[(2) EXAMINATION OF RECORDS.—The Secretary and the Comptroller General of the United States shall have access to any books, documents, papers, and records of the recipient of a contract or subcontract entered into under this section that are pertinent to the contract, for the purpose of conducting audits and examinations.

[(k) PENALTIES FOR DISCLOSURE.—Any person who discloses the content of any record referred to in subsection (e)(5)(A) without the prior written consent of the donor or potential donor with respect to whom the record is maintained, or in violation of the standards described in subsection (e)(5)(B), shall be imprisoned for not more than 2 years or fined in accordance with title 18, United States Code or both.

[(l) ANNUAL REPORT REGARDING PRETRANSPLANT COSTS.—The Registry shall annually submit to the Secretary the data collected under subsection (b)(7) on comparisons of transplant centers regarding search and other costs that prior to transplantation are charged to patients by transplant centers. The data shall be submitted to the Secretary through inclusion in the annual report required in section 379A(c).]

SEC. 379. NATIONAL PROGRAM.

(a) ESTABLISHMENT.—The Secretary, acting through the Administrator of the Health Resources and Services Administration, shall by one or more contracts establish and maintain a C.W. Bill Young Cell Transplantation Program (referred to in this section as the "Program"), successor to the National Bone Marrow Donor Registry, that has the purpose of increasing the number of transplants for recipients suitably matched to biologically unrelated donors of bone marrow and cord blood, and that meets the requirements of this section. The Secretary may award a separate contract to perform each of the major functions of the Program described in paragraphs (1) and (2) of subsection (d) if deemed necessary by the Secretary to operate an effective and efficient system that is in the best interest of patients. The Secretary shall conduct a separate competition for the initial establishment of the cord blood functions of the Program. The Program shall be under the general supervision of the Sec-

retary. The Secretary shall establish an Advisory Council to advise, assist, consult with, and make recommendations to the Secretary on matters related to the activities carried out by the Program. The members of the Advisory Council shall be appointed in accordance with the following:

(1) Each member of the Advisory Council shall serve for a term of 2 years, and each such member may serve as many as 3 consecutive 2-year terms, except that—

(A) such limitations shall not apply to the Chair of the Advisory Council (or the Chair-elect) or to the member of the Advisory Council who most recently served as the Chair; and

(B) 1 additional consecutive 2-year term may be served by any member of the Advisory Council who has no employment, governance, or financial affiliation with any donor center, recruitment organization, transplant center, or cord blood bank.

(2) A member of the Advisory Council may continue to serve after the expiration of the term of such member until a successor is appointed.

(3) In order to ensure the continuity of the Advisory Council, the Advisory Council shall be appointed so that each year the terms of approximately one-third of the members of the Advisory Council expire.

(4) The membership of the Advisory Council—

(A) shall include as voting members a balanced number of representatives including 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, and members of the general public; and

(B) shall include as nonvoting members representatives from the Department of Defense Marrow Donor Recruitment and Research Program operated by the Department of the Navy, the Division of Transplantation of the Health Resources and Services Administration, the Food and Drug Administration, and the National Institutes of Health.

(5) Members of the Advisory Council shall be chosen so as to ensure objectivity and balance and reduce the potential for conflicts of interest. The Secretary shall establish bylaws and procedures—

(A) 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 deci-

sion that materially affects the center, recruitment organization, transplant center, or cord blood bank; and

(B) to limit the number of members of the Advisory Council with any such affiliation.

(6) The Secretary, acting through the Advisory Council, shall submit to the Congress—

(A) an annual report on the activities carried out under this section; 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.

(b) ACCREDITATION.—The Secretary shall, through a public process, recognize one or more accreditation entities for the accreditation of cord blood banks.

(c) INFORMED CONSENT.—The Secretary shall, through a public process, examine issues of informed consent, including—

(1) the appropriate timing of such consent; and

(2) the information provided to the maternal donor regarding all of her medically appropriate cord blood options.

Based on such examination, the Secretary shall require that the standards used by the accreditation entities recognized under subsection (b) ensure that a cord blood unit is acquired with the informed consent of the maternal donor.

(d) FUNCTIONS.—

(1) BONE MARROW FUNCTIONS.—With respect to bone marrow, the Program shall—

(A) operate a system for identifying, matching, and facilitating the distribution of bone marrow that is suitably matched to candidate patients;

(B) consistent with paragraph (3), permit transplant physicians, other appropriate health care professionals, and patients to search by means of electronic access all available bone marrow donors listed in the Program;

(C) carry out a program for the recruitment of bone marrow donors in accordance with subsection (e), including with respect to increasing the representation of racial and ethnic minority groups (including persons of mixed ancestry) in the enrollment of the Program;

(D) maintain and expand medical contingency response capabilities, in coordination with Federal programs, to prepare for and respond effectively to biological, chemical, or radiological attacks, and other public health emergencies that can damage marrow, so that the capability of supporting patients with marrow damage from disease can be used to support casualties with marrow damage;

(E) carry out informational and educational activities in accordance with subsection (e);

(F) at least annually update information to account for changes in the status of individuals as potential donors of bone marrow;

(G) provide for a system of patient advocacy through the office established under subsection (h);

(H) provide case management services for any potential donor of bone marrow to whom the Program has provided

a notice that the potential donor may be suitably matched to a particular patient through the office established under subsection (h);

(I) with respect to searches for unrelated donors of bone marrow that are conducted through the system under subparagraph (A), collect, analyze, and publish data in a standardized electronic format on the number and percentage of patients at each of the various stages of the search process, including data regarding the furthest stage reached, the number and percentage of patients who are unable to complete the search process, and the reasons underlying such circumstances;

(J) support studies and demonstration and outreach projects for the purpose of increasing the number of individuals who are willing to be marrow donors to ensure a genetically diverse donor pool; and

(K) facilitate research with the appropriate Federal agencies to improve the availability, efficiency, safety, and cost of transplants from unrelated donors and the effectiveness of Program operations.

(2) CORD BLOOD FUNCTIONS.—With respect to cord blood, the Program shall—

(A) operate a system for identifying, matching, and facilitating the distribution of donated cord blood units that are suitably matched to candidate patients and meet all applicable Federal and State regulations (including informed consent and Food and Drug Administration regulations) from a qualified cord blood bank;

(B) consistent with paragraph (3), allow transplant physicians, other appropriate health care professionals, and patients to search by means of electronic access all available cord blood units made available through the Program;

(C) allow transplant physicians and other appropriate health care professionals to reserve, as defined by the Secretary, a cord blood unit for transplantation;

(D) support studies and demonstration and outreach projects for the purpose of increasing cord blood donation to ensure a genetically diverse collection of cord blood units;

(E) provide for a system of patient advocacy through the office established under subsection (h);

(F) coordinate with the qualified cord blood banks to support informational and educational activities in accordance with subsection (g);

(G) maintain and expand medical contingency response capabilities; in coordination with Federal programs, to prepare for and respond effectively to biological, chemical, or radiological attacks, and other public health emergencies that can damage marrow, so that the capability of supporting patients with marrow damage from disease can be used to support causalities with marrow damage; and

(H) with respect to the system under subparagraph (A) collect, analyze, and publish data in a standardized electronic format, as required by the Secretary, on the number and percentage of patients at each of the various stages of the search process, including data regarding the furthest

stage reached, the number and percentage of patients who are unable to complete the search process, and the reasons underlying such circumstances.

(3) SINGLE POINT OF ACCESS; STANDARD DATA.—

(A) SINGLE POINT OF ACCESS.—The Secretary shall ensure that health care professionals and patients are able to search electronically for and facilitate access to, in the manner and to the extent defined by the Secretary and consistent with the functions described in paragraphs (1)(A) and (2)(A), cells from bone marrow donors and cord blood units through a single point of access.

(B) STANDARD DATA.—The Secretary shall require all recipients of contracts under this section to make available a standard dataset for purposes of subparagraph (A) in a standardized electronic format that enables transplant physicians to compare among and between bone marrow donors and cord blood units to ensure the best possible match for the patient.

(4) DEFINITION.—The term "qualified cord blood bank" means a cord blood bank that—

(A) has obtained all applicable Federal and State licenses, certifications, registrations (including pursuant to the regulations of the Food and Drug Administration), and other authorizations required to operate and maintain a cord blood bank;

(B) has implemented donor screening, cord blood collection practices, and processing methods intended to protect the health and safety of donors and transplant recipients to improve transplant outcomes, including with respect to the transmission of potentially harmful infections and other diseases;

(C) is accredited by an accreditation entity recognized by the Secretary under subsection (b);

(D) has established a system of strict confidentiality to protect the identity and privacy of patients and donors in accordance with existing Federal and State law;

(E) has established a system for encouraging donation by a genetically diverse group of donors; and

(F) has established a system to confidentially maintain linkage between a cord blood unit and a maternal donor.

(e) BONE MARROW RECRUITMENT; PRIORITIES; INFORMATION AND EDUCATION.—

(1) RECRUITMENT; PRIORITIES.—The Program shall carry out activities for the recruitment of bone marrow donors. Such recruitment program shall identify populations that are underrepresented among potential donors enrolled with the Program. In the case of populations that are identified under the preceding sentence:

(A) The Program shall give priority to carrying out activities under this part to increase representation for such populations in order to enable a member of such a population, to the extent practicable, to have a probability of finding a suitable unrelated donor that is comparable to the probability that an individual who is not a member of an underrepresented population would have.

(B) The Program shall consider racial and ethnic minority groups (including persons of mixed ancestry) to be populations that have been identified for purposes of this paragraph, and shall carry out subparagraph (A) with respect to such populations.

(2) INFORMATION AND EDUCATION REGARDING RECRUITMENT; TESTING AND ENROLLMENT.—

(A) IN GENERAL.—The Program shall carry out informational and educational activities, in coordination with organ donation public awareness campaigns operated through the Department of Health and Human Services, for purposes of recruiting individuals to serve as donors of bone marrow, and shall test and enroll with the Program potential bone marrow donors. Such information and educational activities shall included the following:

(i) Making information available to the general public, including information describing the needs of patients with respect to donors of bone marrow.

(ii) Educating and providing information to individuals who are willing to serve as potential bone marrow donors.

(iii) Training individuals in requesting individuals to serve as potential bone marrow donors.

(B) PRIORITIES.—In carrying out informational and educational activities under subparagraph (A), the Program shall give priority to recruiting individuals to serve as donors of bone marrow for populations that are identified under paragraph (1).

(3) TRANSPLANTATION AS TREATMENT OPTION.—In addition to activities regarding recruitment, the recruitment program under paragraph (1) shall provide information to physicians, other health care professionals, and the public regarding bone marrow transplants from unrelated donors as a treatment option.

(4) IMPLEMENTATION OF SUBSECTION.—The requirements of this subsection shall be carried out by the entity that has been awarded a contract by the Secretary under subsection (a) to carry out the functions described in subsection (d)(1).

(f) BONE MARROW CRITERIA, STANDARDS, AND PROCEDURES.—The Secretary shall enforce, for participating entities, including the Program, individual marrow donor centers, marrow donor registries, marrow collection centers, and marrow transplant centers—

(1) quality standards and standards for tissue typing, obtaining the informed consent of donors, and providing patient advocacy;

(2) donor selection criteria, based on established medical criteria, to protect both the donor and the recipient and to prevent the transmission of potentially harmful infectious diseases such as the viruses that cause hepatitis and the etiologic agent for Acquired Immune Deficiency Syndrome;

(3) procedures to ensure the proper collection and transportation of the marrow;

(4) standards for the system for patient advocacy operated under subsection (h), including standards requiring the provision of appropriate information (at the start of the search proc-

ess and throughout the process) to patients and their families and physicians;

(5) standards that—

(A) require the established of a system of strict confidentiality of records relating to the identity, address, HLA type, and managing marrow donor center for marrow donors and potential marrow donors; and

(B) prescribe the purposes for which the records described in subparagraph (A) may be disclosed, and the circumstances and extent of the disclosure; and

(6) in the case of a marrow donor center or marrow donor registry participating in the program, procedures to ensure the establishment of a method for integrating donor files, searches, and general procedures of the center or registry with the Program.

(g) CORD BLOOD RECRUITMENT; PRIORITIES; INFORMATION AND EDUCATION.—

(1) RECRUITMENT; PRIORITIES.—The Program shall support activities, in cooperation with qualified cord blood banks, for the recruitment of cord blood donors. Such recruitment program shall identify populations that are underrepresented among cord blood donors. In the case of populations that are identified under the preceding sentence:

(A) The Program shall give priority to supporting activities under this part to increase representation for such populations in order to enable a member of such a population, to the extent practicable, to have a probability of finding a suitable cord blood unit that is comparable to the probability that an individual who is not a member of an underrepresented population would have.

(B) The Program shall consider racial and ethnic minority groups (including persons of mixed ancestry) to be populations that have been identified for purposes of this paragraph, and shall support activities under subparagraph (A) with respect to such populations.

(2) INFORMATION AND EDUCATION REGARDING RECRUITMENT; TESTING AND DONATION.—

(A) IN GENERAL.—In carrying out the recruitment program under paragraph (1), the Program shall support informational and educational activities in coordination with qualified cord blood banks and organ donation public awareness campaigns operated through the Department of Health and Human Services, for purposes of recruiting pregnant women to serve as donors of cord blood. Such information and educational activities shall include the following:

(i) Making information available to the general public, including information describing the needs of patients with respect to cord blood units.

(ii) Educating and providing information to pregnant women who are willing to donate cord blood units.

(iii) Training individuals in requesting pregnant women to serve as cord blood donors.

(B) PRIORITIES.—In carrying out informational and educational activities under subparagraph (A), the Program shall give priority to supporting the recruitment of pregnant women to serve as donors of cord blood for populations that are identified under paragraph (1).

(3) TRANSPLANTATION AS TREATMENT OPTION.—In addition to activities regarding recruitment, the recruitment program under paragraph (1) shall provide information to physicians, other health care professionals, and the public regarding cord blood transplants from donors as a treatment option.

(4) IMPLEMENTATION OF SUBSECTION.—The requirements of this subsection shall be carried out by the entity that has been awarded a contract by the Secretary under subsection (a) to carry out the functions described in subsection (d)(2).

(h) PATIENT ADVOCACY AND CASE MANAGEMENT FOR BONE MARROW AND CORD BLOOD.—

(1) IN GENERAL.—The Secretary shall establish and maintain, through a contract or other means determined appropriate by the Secretary, an office of patient advocacy (in this subsection referred to as the "Office").

(2) GENERAL FUNCTIONS.—The Office shall meet the following requirements:

(A) The Office shall be headed by a director.

(B) The Office shall be staffed by individuals with expertise in bone marrow and cord blood therapy covered under the Program.

(C) The Office shall operate a system for patient advocacy, which shall be separate from mechanisms for donor advocacy, and which shall serve patients for whom the Program is conducting, or has been requested to conduct a search for a bone marrow donor or cord blood unit.

(D) In the case of such a patient, the Office shall serve as an advocate for the patient by directly providing to the patient (or family members, physicians, or other individuals acting on behalf of the patient) individualized services with respect to efficiently utilizing the system under paragraphs (1) and (2) of subsection (d) to conduct an ongoing search for a bone marrow donor or cord blood unit and assist with information regarding third party payor matters.

(E) In carrying out subparagraph (D), the Office shall monitor the system under paragraphs (1) and (2) of subsection (d) to determine whether the search needs of the patient involved are being met, including with respect to the following:

(i) Periodically providing to the patient (or an individual acting on behalf of the patient) information regarding bone marrow donors or cord blood units that are suitably matched to the patient, and other information regarding the progress being made in the search.

(ii) Informing the patient (or such other individual) if the search has been interrupted or discontinued.

(iii) Identifying and resolving problems in the search, to the extent practicable.

(F) The Office shall ensure that the following data are made available to patients:

(i) The resources available through the Program.

(ii) A comparison of transplant centers regarding search and other costs that prior to transplantation are charged to patients by transplant centers.

(iii) The post-transplant outcomes for individual transplant centers.

(iv) Information concerning issues that patients may face after a transplant.

(v) Such other information as the Program determines to be appropriate.

(G) The Office shall conduct surveys of patients (or family members, physicians, or other individuals acting on behalf of patients) to determine the extent of satisfaction with the system for patient advocacy under this subsection, and to identify ways in which the system can be improved to best meet the needs of patients.

(3) CASE MANAGEMENT.—

(A) IN GENERAL.—In serving as an advocate for a patient under paragraph (2), the Office shall provide individualized case management services directly to the patient (or family members, physicians, or other individuals acting on behalf of the patient), including—

(i) individualized case assessment; and

(ii) the functions described in paragraph (2)(D) (relating to progress in the search process).

(B) POSTSEARCH FUNCTIONS.—In addition to the case management services described in paragraph (1) for patients, the Office shall, on behalf of patients who have completed the search for a bone marrow donor or cord blood unit, provide information and education on the process of receiving a transplant, including the post-transplant process.

(i) COMMENT PROCEDURES.—The Secretary shall establish and provide information to the public on procedures under which the Secretary shall receive and consider comments from interested persons relating to the manner in which the Program is carrying out the duties of the Program. The Secretary may promulgate regulations under this section.

(j) CONSULTATION.—In developing policies affecting the Program, the Secretary shall consult with the Advisory Council, the Department of Defense Marrow Donor Recruitment and Research Program operated by the Department of the Navy, and the board of directors of each entity awarded a contract under this section.

(k) CONTRACTS.—

(1) APPLICATION.—To be eligible to enter into a contract under this section, an entity shall submit to the Secretary and obtain approval of an application at such time, in such manner, and containing such information as the Secretary shall by regulation prescribe.

(2) CONSIDERATIONS.—In awarding contracts under this section, the Secretary shall give consideration to the continued safety of donors and patients and other factors deemed appropriate by the Secretary.

(l) ELIGIBILITY.—Entities eligible to receive a contract under this section shall include private nonprofit entities.

(m) RECORDS.—

(1) RECORDKEEPING.—Each recipient of a contract or subcontract under subsection (a) shall keep such records as the Secretary shall prescribe, including records that fully disclose the amount and disposition by the recipient of the proceeds of the contract, the total cost of the undertaking in connection with which the contract was made, and the amount of the portion of the cost of the undertaking supplied by other sources, and such other records as will facilitate an effective audit.

(2) EXAMINATION OF RECORDS.—The Secretary and the Comptroller General of the United States shall have access to any books, documents, papers, and records of the recipient of a contract or subcontract entered into under this section that are pertinent to the contract, for the purpose of conducting audits and examinations.

(n) PENALTIES FOR DISCLOSURE.—Any person who discloses the content of any record referred to in subsection (d)(4)(D) or (f)(5)(A) without the prior written consent of the donor or potential donor with respect to whom the record is maintained, or in violation of the standards described in subsection (f)(5)(B), shall be imprisoned for not more than 2 years or fined in accordance with title 18, United States Code, or both.

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[SEC. 379A. BONE MARROW SCIENTIFIC REGISTRY.

[(a) ESTABLISHMENT OF RECIPIENT REGISTRY.—The Secretary, acting through the Registry under section 379 (in this section referred to as the "Registry"), shall establish and maintain a scientific registry of information relating to patients who have been recipients of a transplant of bone marrow from a biologically unrelated donor.

[(b) INFORMATION.—The scientific registry under subsection (a) shall include information with respect to patients described in subsection (a), transplant procedures and such other information as the Secretary determines to be appropriate to conduct an ongoing evaluation of the scientific and clinical status of transplantation involving recipients of bone marrow from biologically unrelated donors.

[(c) ANNUAL REPORT ON PATIENT OUTCOMES.—The Registry shall annually submit to the Secretary a report concerning patient outcomes with respect to each transplant center. Each such report shall use data collected and maintained by the scientific registry under subsection (a). Each such report shall in addition include the data required in section 379(l) (relating to pretransplant costs).]

SEC. 379A. STEM CELL THERAPEUTIC OUTCOMES DATABASE.

(a) ESTABLISHMENT.—The Secretary shall by contract establish and maintain a scientific database of information relating to patients who have been recipients of a stem cell therapeutics product (including bone marrow, cord blood, or other such product) from a donor.

(b) INFORMATION.—The outcomes database shall include information in a standardized electronic format with respect to patients described in subsection (a), diagnosis, transplant procedures, results, long-term follow-up, and such other information as the Secretary determines to be appropriate, to conduct an ongoing evaluation of

the scientific and clinical status of transplantation involving recipients of a stem cell therapeutics product from a donor.

(c) ANNUAL REPORT ON PATIENT OUTCOMES.—The Secretary shall require the entity awarded a contract under this section to submit to the Secretary an annual report concerning patient outcomes with respect to each transplant center, based on data collected and maintained by the entity pursuant to this section.

(d) PUBLICLY AVAILABLE DATA.—The outcomes database shall make relevant scientific information not containing individually identifiable information available to the public in the form of summaries and data sets to encourage medical research and to provide information to transplant programs, physicians, patients, and entities awarded a contract under section 379 donor registries, and cord blood banks.

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SEC. 379A–1. DEFINITIONS.

In this part:

(1) The term "Advisory Council" means the advisory council established by the Secretary under section 379(a)(1).

(2) The term "bone marrow" means the cells found in adult bone marrow and peripheral blood.

(3) The term "outcomes database" means the database established by the Secretary under section 379A.

(4) The term "Program" means the C.W. Bill Young Cell Transplantation Program established under section 379.

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[SEC. 379B. AUTHORIZATION OF APPROPRIATIONS.

[For the purpose of carrying out this part, there are authorized to be appropriated $18,000,000 for fiscal year 1999, and such sums as may be necessary for each of the fiscal years 2000 through 2003.]

SEC. 379B. AUTHORIZATION OF APPROPRIATIONS.

For the purpose of carrying out this part, there are authorized to be appropriated $34,000,000 for fiscal year 2006 and $38,000,000 for each of fiscal years 2007 through 2010.

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