



*U.S. Department of Health and Human Services*

**Interim Report to Congress on How Federal Funds  
Are Distributed to Cord Blood Banks Participating  
In the National Cord Blood Inventory**

**Submitted to**

**The Committee on Energy and Commerce  
U.S. House of Representatives**

**and**

**The Committee on Health, Education, Labor, and Pensions  
U.S. Senate**

**July 2011**

## **Executive Summary**

Section 2(c) of the Stem Cell Therapeutic and Research Reauthorization Act of 2010 (Public Law 111-264) states:

“...The Secretary of Health and Human Services, in consultation with the Advisory Council established under such section 379, shall submit to Congress an interim report not later than 180 days after the date of enactment of this Act describing—

- (A) the methods to distribute Federal funds to cord blood banks used at the time of submission of the report;
- (B) how cord blood banks contract with collection sites for the collection of cord blood units; and
- (C) recommendations for improving the methods to distribute Federal funds described in subparagraph (A) in order to encourage the efficient collection of high-quality and diverse cord blood units.”

This Report provides background information about the Stem Cell Therapeutic and Research Reauthorization Act of 2010 and the National Cord Blood Inventory; summarizes the Health Resources and Services Administration’s approach to allocating funds to public cord blood banks; describes the relationships between cord blood banks and collection sites; and identifies potential modifications to the current methodology for allocating funds to public cord blood banks to encourage the efficient collection of high-quality and diverse cord blood units.

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## **BACKGROUND**

The Stem Cell Therapeutic and Research Act of 2005 (P.L. 109-129) authorized the establishment of a National Cord Blood Inventory (NCBI) for the purpose of creating a supply of new, high-quality and genetically diverse cord blood units to be made available for transplantation through the C.W. Bill Young Cell Transplantation Program. The NCBI and C.W. Bill Young Cell Transplantation Program are administered by the Health Resources and Services Administration (HRSA). The cord blood units comprising the NCBI are collected through Department of Health and Human Services' (HHS) contracts with qualified cord blood banks.

The Stem Cell Therapeutic and Research Reauthorization Act of 2010 (P.L. 111-264) extended the authorization for the NCBI and the C.W. Bill Young Cell Transplantation Program. Additionally, P.L. 111-264 required the Secretary of HHS, upon consultation with the Advisory Council on Blood Stem Cell Transplantation (the Council), to submit an interim report to Congress that:

1. describes HHS' current methods to distribute Federal funds to cord blood banks;
2. describes how cord blood banks contract with collection sites for the collection of cord blood units; and
3. makes recommendations for improving the methods to distribute Federal funds to encourage the efficient collection of high-quality and diverse cord blood units.

In a meeting of the Council, held by teleconference on February 4, 2011, the Council provided advice to HHS concerning the content and direction of this interim Report. Notice of the teleconference was published in the *Federal Register* and telephone lines were open to the public for comment. Several members of the public dialed in, though no comments were made by the public.

## **NCBI**

The aim of the NCBI is to build a genetically diverse inventory of at least 150,000 new units of high-quality<sup>1</sup> umbilical cord blood<sup>2</sup> to be available to patients through the C.W. Bill Young Cell Transplantation Program.

### **Status of the National Cord Blood Inventory**

The tissue types of blood stem cell donors must be closely matched with those of their recipients in order for the transplant to be successful. Since tissue types are inherited, patients are more likely to find a closely matched donor within their own racial and ethnic group. However, due to the high rate of diversity in the tissue types of racial and ethnic minorities, especially Black/African-Americans (whose tissue types are even more diverse than other minority groups),

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<sup>1</sup> The Secretary's Advisory Council on Blood Stem Cell Transplantation has formed a workgroup to identify the scientific factors necessary to define a high-quality cord blood unit, and is still deliberating. To date, it has made no recommendations to change HHS' interim criteria that define high-quality cord blood units. The interim criteria address such properties of the cord blood units as the content of nucleated cells, the viability of the cells, and the results of infectious disease marker testing performed on the cord blood units.

<sup>2</sup> In this Report, the terms "umbilical cord blood" and "cord blood" are used interchangeably.

racial and ethnic minorities are less likely to find an adequately matched adult marrow<sup>3</sup> donor on the Registry of the C.W. Bill Young Cell Transplantation Program<sup>4,5</sup>. Because cord blood can be used with a less perfect match in tissue type between donor and recipient than is the case for adult marrow donors, it offers a chance of survival for patients who lack an adequately matched relative and who cannot find an adequately matched unrelated adult donor through the Program<sup>6</sup>. Due to the diversity of tissue types among racial and ethnic minorities and the associated challenges of identifying an adequate adult marrow donor on the Registry, these patients (particularly Black/African-American patients) are especially likely to benefit from a large, diverse inventory of cord blood units. For these reasons, HHS continues to emphasize increasing the number of cord blood units collected from minority donors.

Since the first contracts with cord blood banks were signed in November 2006 through the end of fiscal year (FY) 2010, HHS contracted for the banking of nearly 50,000 cord blood units, including more than 30,000 cord blood units from minority donors. Table 1 provides a breakdown by fiscal year of the total number of cord blood units contracted for, the number of cord blood units made available to searching patients through the Cord Blood Coordinating Center (the component of the C.W. Bill Young Cell Transplantation Program responsible for facilitating cord blood transplants), and the number of cord blood units released for transplantation. Because of its emphasis on collecting genetically-diverse units, NCBI cord blood units are able to serve an increasing number of patients from populations that historically have difficulty finding a well-matched adult marrow donor.

Table 1.—*NCBI Cord Blood Unit (CBU) History*

Fiscal Year	Number of NCBI CBU Contracted For	Number of NCBI CBU Made Available for Transplant*	Number of NCBI CBU Released for Transplant
2007	22,310	2,017	4
2008	7,539	9,853	104
2009	10,207	11,050	458
2010	9,900	11,824	530
Total	49,956	34,744	1,096

\*There is a lag of several months between the date of CBU collection and when it is fully tested and available for transplant.

<sup>3</sup> In this Report, the term “marrow” refers to cells from peripheral blood as well as marrow.

<sup>4</sup> Beatty PG, Mori M, Milford E. Impact of racial genetic polymorphism on the probability of finding an HLA-matched donor. *Transplantation*. 1995 Oct 27;60(8): 778-83.

<sup>5</sup> Kollman C, Abella E, Baitty RL, et al. Assessment of optimal size and composition of the U.S. national registry of hematopoietic stem cell donors. *Transplantation*. 2004 Jul 15;78(1):89-95.

<sup>6</sup> Barker JN, Byam CE, Kernan NA, et al. Availability of cord blood extends allogeneic hematopoietic stem cell transplant access to racial and ethnic minorities. *Biol Blood Marrow Transplant*. 2010 Nov;16(11):1541-8.

Overall, umbilical cord blood as a source of blood stem cells is fulfilling its promise of improving access to transplantation, particularly for minority patients. Cord blood transplants have accounted for about half of the growth in unrelated-donor transplants facilitated through the HHS programs over the life of the NCBI program. Cord blood units serve as the source of blood stem cells for minority patients much more frequently than adult donor products<sup>7</sup>.

Approximately 30 percent of cord blood transplants are for minority patients as compared with approximately 12 percent of transplants that use adult donor products. Moreover, of the 820 minority patients who received a blood stem cell transplant in FY 2010, over 40 percent received cord blood transplants. Regional studies have shown that most of the adult minority patients who received cord blood transplants did not have an adequate adult donor available, making cord blood transplantation their only option.

### **Current Methods to Distribute Funds to Cord Blood Banks**

Cognizant of the need to quickly build and make available a diverse, high-quality inventory, HHS' current approach to funding aims to maximize progress toward the statutory charge (building a genetically diverse inventory of at least 150,000 new units of high-quality umbilical cord blood) with available funds. Specifically, the current method employed by HHS to distribute Federal funds to cord blood banks is based on the following principles:

1. Rapidly add a large number of high-quality, diverse units to the inventory;
2. Ensure that funds are distributed to banks that have demonstrated the ability to bank diverse, high-quality units (considered prior to awarding new contracts as well as prior to executing options with existing contracted banks); and
3. Ensure some geographic dispersion of federally-funded cord blood units to protect the inventory against natural and man-made disasters and to facilitate collections in areas with unique demographics.

HHS awards funds to public cord blood banks through a competitive contracting process. Contracted banks are paid through monthly invoices for each cord blood unit meeting all contract specifications. The cord blood units are made available to patients through the Cord Blood Coordinating Center. Payment under each contract is determined by unit prices negotiated at the time of contract award. HHS negotiates discounted prices to maximize the number of units to be collected. Since 2009, contract actions have included multiple reimbursement rates across different racial/ethnic targets.

Contracts are detailed and include the technical characteristics of qualifying cord blood units and how banks must obtain the informed consent of donors. Contracts require cord blood banks to enter into written agreements with the facilities in which they collect cord blood units. Per law<sup>8</sup>, cord blood banks must comply with contractual obligations for at least 10 years from the last date of receipt of HHS funds. At the time of an initial contract award, funds are provided for a base year of collections with the option of up to 2 additional years of collections. The 2010 reauthorization of the Stem Cell Therapeutic and Research Act allows HHS to obligate funds to cord blood banks for up to 5 years.

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<sup>7</sup> Minority patients who are unable to find an adequately matched adult marrow donor on the Registry are often able to find an adequately matched cord blood unit for transplantation.

<sup>8</sup> P.L. 109-129, sec. 2(d)(1)

Within their established targets, cord blood banks are paid on a per-unit basis for each unit placed in inventory that meets HHS' payment criteria (which includes cord blood units containing a minimum number of nucleated cells because the ratio of blood stem cells to patient weight strongly affects transplant outcomes) and the Cord Blood Coordinating Center's eligibility rules, which address U.S. Food and Drug Administration (FDA) requirements. Payment occurs on a monthly basis after eligibility verification and notification to HHS that the units are available to searching patients through the C.W. Bill Young Cell Transplantation Program. Payment after banking and listing ensures contractual goals are attained.

In addition to HHS funds, NCBI banks and other public cord blood banks have, at times, received financial support from other sources (including the Cord Blood Coordinating Center, the National Marrow Donor Program, other public sources, philanthropic organizations, and investors).

Historically, HHS has used the following process when distributing funds to cord blood banks on an annual basis:

1. A competition is held to provide new cord blood banks and those cord blood banks with expiring contracts the ability to compete for new contracts or extensions of their expiring contracts, as applicable. A technical panel with appropriate expertise reviews proposals against evaluation criteria that include:
  - a. Technical merit;
  - b. Ability to increase the genetic diversity (especially from Black/African-American donors) of the inventory;
  - c. Ability to quickly begin collecting and banking units in accordance with HHS' criteria;
  - d. Evaluation of past performance (if applicable);
  - e. Overall cost and price per qualifying unit banked; and
  - f. Financial viability and prospects for achieving financial self-sufficiency.
2. Contract negotiations establish, for each cord blood bank, the total number of units to be banked and the racial/ethnic breakdown of those units, as well as the per-unit price to be paid, for the base year and for two possible option years.
3. Continuation funding is provided to currently-contracted cord blood banks (i.e., HHS exercises options for additional periods of collections) near completion of each cord blood bank's established targets. Evaluation criteria include assessment of cord blood bank performance as it relates to achieving existing targets, especially for minority cord blood units, and progress towards achieving financial self-sufficiency.

### **How Cord Blood Banks Contract with Collection Sites**

In general, cord blood banks establish arrangements with hospitals for the collection of cord blood units either through the execution of formal contracts or through less formal collection site

agreements (currently, HHS contracted cord blood banks are required to have written agreements with hospitals). Under either approach, some variation of the following procedure is followed:

The cord blood bank identifies a hospital of interest based on number and diversity of births. Alternatively, the hospital may initiate contact with a cord blood bank to arrange for collections at its facility.

1. The cord blood bank assesses the interest and level of commitment from hospital staff (especially registered nurses and physicians) and hospital administration.
2. Logistical feasibility is assessed, including the following:
  - a. storage space for collection materials and collected cord blood units;
  - b. suitable space for collecting cord blood units and for cord blood bank staff to work (if bank employees are used to collect units);
  - c. ability to easily obtain informed consent, maternal/family health history, and blood specimens from donor mothers; and
  - d. ability to transport collected units in a timely manner from the hospital to the cord blood bank for processing.

### **Options for Modifying the Method for Distributing Funds to Cord Blood Banks**

HHS has identified several options for modifying the existing methods of distributing funds to cord blood banks. These options are being explored to determine the extent to which they may impact HHS' ability to continue rapidly building a genetically-diverse inventory of cord blood units while decreasing the reliance on Federal funds to support public cord blood banking. HHS will consider the following options over the next year:

1. Providing, through the NCBI program, a small amount of up-front funding to cord blood banks to defray start-up costs associated with initiating collections at new sites (e.g., hiring or otherwise identifying collectors and training staff). Alternatively, modest up-front funding could be provided through the Cord Blood Coordinating Center, rather than through the NCBI program.
  - a. Cord blood banks have repeatedly reported to HHS that one barrier to their ability to initiate cord blood collections at new hospitals is the substantial up-front investment of time and money required to train cord blood collectors, staff the hospital, and establish the mechanisms necessary for transporting the cord blood units from the hospital to the cord blood bank for processing and storage.
2. Re-examining the race/ethnicity-based payment differential for cord blood units.
  - a. The race/ethnicity-based payment differential was introduced to the program in 2009 as a way of incentivizing the collection of cord blood units from minority donors and concentrating the use of Federal funds on the collection of cord blood units that cord blood banks consider to be the most difficult and expensive to collect.



3. Reducing emphasis on discounted prices negotiated with cord blood banks during contract negotiations.
  - a. Such an approach may increase the rate at which banks are able to achieve financial self-sufficiency. However, higher per unit reimbursement rates would result in fewer overall units being added to the inventory each year.
4. Providing payment for cord blood units collected remotely at hospitals in which the cord blood bank does not have a written agreement. (A HHS-funded pilot project testing this model is currently being conducted by three NCBI cord blood banks and the Cord Blood Coordinating Center.)
  - a. Such collection models could be valuable for reaching small populations with unique diversity and may help banks obtain funding from states or other sources to supplement HHS funding. However, the cost-effectiveness of this model of collections has not yet been established.
5. Raising the minimum total nucleated cell threshold for payment in view of transplant centers' strong tendency to select the largest (greatest number of cells) cord blood units or devising an adjustable payment model that provides escalating funds based upon the cellular content of cord blood units such that larger units are paid for at a higher rate.
  - a. These options may improve the financial situation of cord blood banks as they would incentivize cord blood banks to store only those units with a higher likelihood of being selected for transplant (i.e., those units containing the greatest number of cells). Additionally, these options place an emphasis on use of Federal funds to pay for higher-demand cord blood units. However, with present collection technologies, these approaches would result in substantially fewer overall units being added to the inventory each year. Also, smaller units that represent rare tissue types are still of value, especially to minority patients. HHS would not necessarily want to disincentivize the banking of those units.

In addition to the options presented herein, there may be other innovative contractual and financial models for distributing Federal funds to cord blood banks. All possibilities must be considered within the legal framework and statutory authorities. Ultimately, any modifications to the existing arrangements between the government and cord blood banks or between banks and their collection sites must allow cord blood banks to conform to FDA and other regulatory requirements as well as accreditation standards.

## **RECOMMENDATION**

HHS continues to work with the Council, the contractor for the Cord Blood Coordinating Center (the National Marrow Donor Program), and the NCBI cord blood banks to identify and explore ways to increase the number of public cord blood collection sites (including through remote collections of cord blood), to increase the efficiency of cord blood collections, to ensure progress toward a financially feasible and sustainable cord blood banking model, and to improve upon existing NCBI contracting methods.

HHS must ensure that Federal funds are invested in a way that maximizes the number, quality, and diversity of units available to patients and minimizes the risk of failure to deliver by contracted cord blood banks. With this in mind, HHS has sought advice from the Council concerning the advisability of changing HHS' approach to NCBI funding, including whether HHS should provide up-front funding to cord blood banks to enable expanded collections at hospitals with especially large numbers of births from minority mothers. As of its most recent meeting (May 2011), the Council has not finalized recommendations specific to how HHS pays for cord blood units, though several of the options outlined in this Report have been discussed. The Council is currently considering the definition that HHS should use in assessing cord blood bank progress toward financial self-sufficiency. At the November 2010 meeting, the Council recommended that ...“HRSA, in providing guidance to banks regarding self-sufficiency, define financial self-sufficiency in a way that incorporates continued, rapid progress toward building the cord blood inventory urgently needed by patients.”

HHS plans to finalize specific recommendations relating to the NCBI funding pending the outcome of ongoing work of several Council workgroups. HHS is also actively examining alternate ways of providing up-front funding to cord blood banks, including through the Cord Blood Coordinating Center. Finally, HHS provided support for a Cord Blood Financial Summit that was convened by the Cord Blood Coordinating Center and held March 17-18, 2011. Several of the agenda topics related directly to the financial viability of cord blood banks. Information from this Summit will further inform HHS' approach to distributing Federal funds to cord blood banks. As required by the 2010 Reauthorization Act<sup>9</sup>, the Government Accountability Office (GAO) is currently conducting a study examining similar issues related to the National Cord Blood Inventory and how Federal funds are distributed through contracts to cord blood banks. Once HHS has formulated further views on these issues, and upon consideration of applicable recommendations from the Council and GAO, HHS will include such recommendations in the Report to Congress required on an annual basis by section 379(a)(6) of the Public Health Service Act (42 U.S.C. 274k(a)(6)).

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<sup>9</sup> P.L. 111-264 sec. 2(e)(1)