AUTHENTICATED
U.S. GOVERNMENT
INFORMATION
GPO

Calendar No. 377

104TH CONGRESS, 2d Session | SENATE | REPORT 104–256

ORGAN AND BONE MARROW TRANSPLANT PROGRAM REAUTHORIZATION ACT OF 1995

APRIL 22, 1996.—Ordered to be printed

Mrs. KASSEBAUM, from the Committee on Labor and Human Resources, submitted the following

REPORT

[To accompany S. 1324]

The Committee on Labor and Human Resources, to which was referred the bill (S. 1324), to amend the Public Health Service Act to revise and extend the solid-organ procurement and transplantation programs, and the bone marrow donor program, and for other purposes, having considered the same, report favorably thereon with an amendment in the nature of a substitute and recommend that the bill (as amended) do pass.

CONTENTS

		Page
I.	Summary of the bill	1
II.	Background and need for legislation	4
III.	Legislative history and committee action	9
IV.	Committee views	10
V.	Cost estimate	28
VI.	Regulatory impact statement	33
VII.	Section-by-section analysis	33
VIII.	Changes in existing law	40

I. SUMMARY OF THE BILL

S. 1324 extends for 5 years the Solid Organ Transplant Program, a program designed to procure and allocate lifesaving organs on an equitable basis. The bill phases out funding, authorizing $1.9 million for fiscal year 1997, $1.1 million for fiscal year 1998, and $250,000 for each of the fiscal years 1999 through 2001.

S. 1324 authorizes funds for programs that increase organ donation, especially among populations where the need for organ donations is greatest. S. 1324 recognizes that, in addition to organ procurement, the issue of organ allocation must be addressed. Currently, waiting times for organs vary greatly in different regions of the country. While a number of studies are underway to evaluate

the present allocation system, this legislation requires organs to be distributed on the basis of a single list established in an Organ Procurement Organization (OPO) region, a region encompassing at least an entire State, an approved alternative local unit, or a list that encompasses another allocation system which is approved by the Organ Procurement and Transplant Network (the Network) and the Secretary of Health and Human Services (HHS). The amendments included in this act do not interfere with Section 1138 of the Social Security Act, which prescribes the relationship between hospitals and OPO's.

The bill calls for government representation at board and committee meetings and greater patient representation on the boards of OPO's and the Network and specifies that the general public—including patients, transplant candidates, and donor families—must comprise a "reasonable balance" of each board.

To protect patients from unreasonable fee increases, the Network is required to submit all requests for patient registration fee increases to the Secretary of HHS, who is given 60 days to disapprove the proposed request. Any increases in the patient registration fee shall be limited to an increase that is reasonably required as a result of increases in the level or cost of contract tasks and other activities related to organ procurement and transplantation or decreases in expected revenue from patient registration fees available to the contractor. Fee increases must be "reasonable and customary" and may not occur more frequently than once per year.

The bill also requires OPO's to engage in public education about the need for organ donation. S. 1324 requires OPO's to be members of the Organ Procurement and Transplantion Network and abide by the Network rules.

S. 1324 authorizes the Secretary to institute and collect a "data management fee" from transplant centers and OPO's, to be phased in over the first 3 years. When fully phased in, the fee will cover the costs of operating the Scientific Registry. The fee will be set by the Network, in consultation with the Secretary, and calculated on a per-transplant basis and divided in an 80/20 split between the responsible transplant center and the OPO.

In order to track the performance of transplant centers and organ procurement organizations, the Network shall submit to the Secretary a biennial report which contains center-specific data including survival rates, waiting list time, and qualifications of transplant physicians and surgeons. Within 1 year of enactment of S. 1324, the Secretary is required to issue a "final rule" establishing Network regulations. Failure to do so will require the Secretary to issue, within 30 days of the deadline, a report to Congress describing the reasons for failure to comply with the law and steps which are being implemented to bring the Department into compliance.

The Secretary shall withhold annually $250,000, or 10 percent of the amount of the collected "data management fee" (whichever amount is larger), to be used to fund contracts to increase organ donation. No contract in excess of $25,000 may be made, using the above funds, unless an application is submitted to the Secretary, recommended by the Network, and approved by the Secretary.

The Secretary through contract shall prepare a triennial OPO-specific data report that includes an assessment of the effectiveness of OPO's in acquiring available organs. The first OPO-specific report should be completed within 18 months of enactment.

Under this bill, the Institute of Medicine (IOM) will conduct a two-part study and evaluation including: (1) the role and the impact of the Federal Government in the oversight and support of solid organ transplantation, the Network (which currently carries out its functions by government contract), and the solid organ scientific registry of transplant recipients registry; and (2) the access of all interested constituencies to membership on the Network's board of directors and all its committees. Recommendations from the second portion of the IOM study are to be considered by the contractor in consultation with the Network and the Secretary, and a plan for implementation of these recommendations is to be developed within 1 year of completion of the study.

S. 1324 extends for 3 years the Bone Marrow Transplantation Program, a program designed to increase the number of unrelated marrow donor transplants. The amounts authorized are $13,500,000 for fiscal year 1997, $12,150,000 for fiscal year 1998, and "such sums as necessary" for fiscal year 1999.

The bill clarifies the composition and limits the terms of service to three, 2-year terms for the board of directors. Composition of the board of directors and the program's committees will be composed of a "reasonable balance" of constituents, including transplant recipients and their families.The program's board of directors and committees shall include nonvoting representation from the Health Resources and Services Administration and the Naval Medical Research and Development Command.

S. 1324 mandates that the National Bone Marrow Donor Registry make it a priority to increase the number of transplants and potential donors for populations with special needs. In addition, the bill requires the contractor to compile and distribute informational materials to educate the public about the need for potential bone marrow donors and requires a compilation and distribution of updates of potential donors. The "Donor Registry" should be updated annually to account for changes in donor status.

The Bone Marrow Transplant Program, in consultation with the Secretary, using the recommendations of the ongoing Inspector General study, shall develop and implement, within 1 year of study completion, a plan to make more efficient the relationship between the donor registry and the donor centers. The Secretary may enter into contracts with public or nonprofit private entities for the purpose of increasing unrelated donor marrow transplants through: programs to provide information to educate the health community about the availability of unrelated marrow transplants; programs to inform the public about the need for marrow donations; programs to train individuals in requesting marrow donations; and programs to recruit, test, and enroll marrow donors—with the primary priority being minority populations.

S. 1324 requires the National Bone Marrow Donor Registry to establish and maintain effectively an office of patient advocacy and case management, which shall serve as an advocate for patients searching for a donor, physicians, and potential marrow donors. In

addition, the National Bone Marrow Transplant Program will provide to constituents a comparison of costs incurred by patients prior to marrow transplantation at the various transplant centers.

S. 1324 requires the Institute of Medicine to conduct a study that evaluates: (1) the role of a government-supported "National Bone Marrow Transplant Program" in facilitating the maximum number of unrelated donor marrow transplants; and (2) other possible clinical and scientific uses for the Donor Registry's potential donor pool and/or the unrelated marrow donor scientific registry.

In addition, the Secretary shall evaluate the feasibility of consolidating all federally funded scientific bone marrow transplantation registries (regardless of the type of marrow reconstitution). The bill establishes an unrelated marrow donor transplant scientific registry to be maintained on all recipients of biologically unrelated bone marrow transplants, regardless of the method of marrow reconstitution. The Donor Registry shall submit an annual report to the Secretary on the state of unrelated donor marrow transplantation, using information from the scientific registry.

II. Background and Need for Legislation

SOLID ORGAN TRANSPLANT PROGRAMS

Solid organ transplantation involves the procurement and allocation of a scarce resource. This characteristic, coupled with the widening gap between supply and demand and the role that the Medicare and the Medicaid systems play in the financing of organ transplantation ($1.6 billion yearly), necessitates a governmental role to maintain equity and to decrease the potential for abuse. It is the general view that this government-supported system is important, functions reasonably well, and provides good value for the dollars expended. However, some aspects could be improved. It may be important to develop creative and proactive approaches to compensate for the anticipated loss of Federal funds while maintaining an appropriate level of oversight for the government.

Despite the legislative efforts to increase the organ donor pool, the gap between the number of transplants performed and the number of organs needed persists. In 1994, a total of 18,270 organ transplants were performed. As of February 14, 1996, over 44,000 registrants comprised the waiting list for solid organ transplantation, indicating that the demand is more than double the supply.

LEGISLATIVE HISTORY

Public demand for organ and tissue transplants led to Federal legislation establishing a coordinated network for organ sharing and transplantation. Under the National Organ Transplant Act (NOTA), P.L. 98–507, Congress consolidated a cluster of private organ transplant programs into a federally supported entity, the Organ Procurement and Transplantation Network (the Network). The overarching objective of the Network is to increase the effectiveness of organ donation, procurement, and transplantation while ensuring equity to patients using the system. NOTA also called for: (1) the establishment of a grants program to organ procurement organizations (OPO's); (2) a bone marrow transplantation demonstration study; (3) the prohibition of human organ sales; and (4) a task

force to study and make recommendations for national organ sharing and immunosuppressive therapy usage.

The Task Force on Organ Transplantation acknowledged the growing gap between the supply of and the demand for organs and recommended, among other things, that hospitals and OPO's be better coordinated to facilitate organ donation. In response to this recommendation, Congress enacted a provision in the Omnibus Budget Reconciliation Act of 1986 (P.L. 99–509) directing OPO's to utilize policies designed to increase organ procurement and directing hospitals to notify OPO's of all potential organ donors.

The Organ Transplant Amendments Act of 1988, Title IV of the Health Omnibus Programs Extension of 1988 (P.L. 100–607), further addressed widespread concerns about the persistent organ shortage. This legislation focused heavily on consolidating OPO activities and functions with the aim of increasing organ donations. This law reauthorized the Federal grants program for OPO's, giving priority to those with special projects designed to increase the number of organ donors and requiring hospitals to design policies for routinely requesting organs from prospective donors and families. To further encourage local procurement efforts, this legislation redefined OPO service areas, required the Network to develop membership criteria for organ allocation, commissioned studies and demonstration projects which focused on improving the effectiveness of organ donation and allocation, and called for the Network to include the public, patients, and their families in its decision making. Additionally, this act authorized appropriations for the operation of the previously established national bone marrow registry for voluntary marrow donors. In the Transplant Amendments Act of 1990 (P.L. 101–616), Congress directed the General Accounting Office (GAO) to study and report on the extent to which organ procurement and allocation was equitable, efficient, and effective.

ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK

In 1986, the first contract for the federally supported Network was awarded to a private organization, the United Network for Organ Sharing (UNOS), located in Richmond. The Network is an entity supported by a private corporation in accordance with Federal organ transplant laws. The Health Resources and Services Administration (HRSA) provides oversight of the Network. HRSA is responsible for administering the Network contract and all of its components including policy development, data collection, program monitoring and increasing organ donation. Essentially, UNOS is a private contractor providing a public service. In that capacity, UNOS is responsible for carrying out the functions of the federally supported Network within the law. These functions include coordinating organ sharing and transplantation, and maintaining a patient waiting list. The Federal Government continues to provide oversight for this system because of the tensions between the supply of and demand for organs.

ORGAN PROCUREMENT ORGANIZATIONS (OPO'S)

As a member of the Network, OPO's are, by legal definition, nonprofit organizations whose staff assist with the organ transplant process by screening potential donors, discussing donation with

family members, arranging for the surgical removal of organs, and allocating organs. Federal support for OPO's is largely through the the medicare program. OPO's must operate within geographical areas designated by HCFA.

The 1986 Amendments sought to reduce the growing gap between organ supply and demand by requiring OPO's to: (1) meet organ procurement standards; (2) be members of the Network; and (3) comply with allocation rules of the Network.

The Organ Transplant Amendments of 1988 targeted funding for those organ procurement activities that sought to increase organ donations. It sought to encourage health care professionals to solicit organ donations, thus directing OPO's to assist hospitals in developing and implementing routine request policies for organ donation. Attempting to improve efficiency in the procurement structure and process, the law called for streamlining the service areas for OPO's. Also, this law required HCFA to define performance standards and do effectiveness evaluations for OPO's.

In response to the continuing organ shortage, the Transplant Amendments Act of 1990 (P.L. 101–616) allowed for the expansion of grant opportunities to nonprofit organizations, other than OPO's, for the purpose of increasing organ donations. This legislation also required the GAO to report on the extent to which organ procurement and allocation was equitable, efficient, and effective.

ORGAN ALLOCATION

Organ allocation has been an item of contention since the inception of the federally supported Network. The allocation process is controversial, largely because of the variation among regions in the level of procurement and the disparity between number of donors and size of waiting list. NOTA requires that organ allocation be based on "medical criteria."

"Waiting time" is a composite marker which may be an acceptable proxy measure for equity of allocation. There is a significant disparity among regions between patients with similar medical conditions in "waiting time" for organ transplantation. Disparity in waiting time is complicated by the lack of guidelines and standardization dealing with the placement of transplantation candidates onto "waiting lists."

Current law does not specify the types of allocation policies the Network are required to adopt, outside of medical criteria. The allocation system set forth by the Network is currently voluntary pending the development of a "final rule" by the Secretary. According to a 1993 GAO report, 25 of the 68 OPO's surveyed did not follow the standard Network guidelines for organ allocation although some were operating with approved network variances. Changes in Network policy and the behavior of the OPO's since the release of the GAO report have resulted in improvement, but some variation persists. In September 1994, HRSA, responding to a longstanding mandate to develop a "final rule", released proposed rules and requested comments. Final rules have not yet been issued.

The present system utilizes a single waiting list for each OPO. OPO's vary widely in size and geographical configuration and may not be the most appropriate allocation unit. The present Network contractor, UNOS, has initiated a study to model the available

liver allocation data and assess the outcome of a number of different allocation approaches. The University of Pittsburgh has undertaken a similar type of predictive analysis. It is expected that this modeling activity will result in a new system for allocation of livers by mid-1996 which should bring further equity to liver allocation. It is expected that over the next year, additional modeling approaches will be proposed for other solid organs.

FUNDING

Current sources of funding for organ transplant activities include the Federal Government (funding for fiscal year 1995 was $2.6 million) and patient registration fees (of approximately $9 million to $10 million per year). Federal funds are expended through a distribution of $0.8 million to the Network, $1.5 million to the Scientific Registry, and $0.3 million for donor awareness activities.

The Network and the Scientific Registry have remained as separate contracts, although both are currently held by a single contractor, UNOS. Administrative costs for HRSA ($1.4 million in fiscal year 1995) are covered under the HRSA program management fund.

Recent budgetary constraints have required Congress to review the fiscal role of the Federal Government in organ transplantation. In the 104th Congress, during consideration of the fiscal year 1995 rescission bills, (H.R. 1158 and S. 617), both the House and the Senate appropriations committees recommended reductions in funding for HRSA's solid organ transplant activities. The Senate Committee on Appropriations called its action, "a step toward the phaseout of Federal support for this activity," and said that alternative sources of financing are likely (S.Rept. 104–17). The final version of the fiscal year 1995 rescission act did not reduce organ transplant funding.

ACCOUNTABILITY

The law requires UNOS to implement policies and regulations established by the Secretary for the Network. Currently, a board of directors and a total of 11 committees set policies and procedures for the Network and also provide similar functions for the contractor, UNOS. Neither HRSA nor the Health Care Financing Administration (HCFA) are represented on the Network board of directors or on its committees. Requirements for Federal representation on the board of directors or committees are not codified.

The current transplant system lacks credibility in the eyes of some patients, some professionals, and portions of the transplant community and public at large. The system is criticized for not being responsive to the needs of transplant candidates and recipients. Some in the patient community believe that it lacks adequate participation and representation on the board of directors and committees of the Network. Increased participation of the public at large and the ability of candidates, recipients, their families, and donor-family members to influence the development of policies and procedures as voting members of the Network will help to make the system more credible and more accountable and could lead to more patient-centered policies and procedures.

Also, the current system lacks consistent patient information, advocacy, and involvement in the decision-making process. This situation appears to persist despite some efforts to correct these deficiencies. There is no standardized set of information available or routinely distributed to patients which outlines the characteristics of the transplant network, the "waiting lists," the organ allocation system, and the associated patient rights and responsibilities. This is a deficiency which should be addressed.

Although improved, procurement remains inadequate among minority populations. Yet minorities make up a significant portion of those individuals with organ failure who could benefit from transplants. Increased minority representation on the Network may facilitate efforts to improve procurement rates among this portion of the population. Additional steps could be taken to acquire data from and increase procurement among minority populations.

BONE MARROW TRANSPLANTATION

Following years of successful treatments of an array of blood-related diseases utilizing allogeneic bone marrow transplantation, Congress directed the Department of Health and Human Services to hold a conference to determine the feasibility of establishing a U.S. national bone marrow donor registry. Following this 1985 conference, the Senate Committee on Appropriations (S. Rept. 98-636) directed the U.S. Navy to establish a national registry of bone marrow donors. In July 1986, the Navy awarded contracts to a consortium of organizations—the American Red Cross, the American Association of Blood Banks, and the Council of Community Blood Centers. HHS assumed responsibility for the national registry from the Navy in fiscal year 1989 (the Navy continues to provide funding to the National Marrow Donor Program). The National Bone Marrow Donor Registry was formally established in 1990 under P.L. 101-616. The National Bone Marrow Transplant Program operated under the authority of the National Heart, Lung, and Blood Institute (NHLBI) of the National Institutes of Health (NIH) until October 1994, when it moved to HRSA.

The 1990 law directed the Secretary to "increase the representation of individuals from racial and ethnic minority groups in the pool of potential donors for the registry in order to enable an individual in a minority group, to the extent practicable, to have a comparable chance of finding a suitable unrelated donor as would an individual not in a minority group."

Toward that end a contract was awarded to the National Marrow Donor Program, the contractor, to build a network which includes a coordinating center, and independent donor, collection and transplant centers. Functions of the NMDP are to: (1) collect and maintain a list of potential marrow donors; (2) coordinate searches for unrelated marrow donors; (3) expedite donor matching, workup, and collection and transport of marrow; (4) provide patient advocacy services; and (5) assess the outcomes of marrow transplants from unrelated marrow donors through maintenance of a scientific registry.

The National Bone Marrow Transplant Program is a resource which currently is being utilized by only a select portion of the population. In 1995, 5,300 patients initially searched the potential

marrow donor pool, with 1025 transplants being facilitated. Privatization and or decreases in the budgetary support for this program are being discussed. It is believed that a strong infrastructure has now been constructed, and that efforts should be focused on facilitating more transplants. Efforts to assess an appropriate Federal Government role need to be undertaken by the bone marrow transplant community and the Congress. Given the commitment of resources and the development of a national bone marrow donor pool with over 2,000,000 volunteer donors registered, new uses for this registry should be considered for the future.

FUNDING

The NMDP Coordinating Center is an umbrella organization of independently operated donor centers, whose relationship to the NMDP is contractual. Over $13 million for NMDP Donor Center contracts are provided by NMDP patient revenue and the HRSA appropriation. The financial viability of some donor centers has been questioned. However, most donor centers were started prior to the availability of NMDP financial support, by the altruism of an individual who had a family member or loved one who was in need of a donor. This type of dedication may suggest a strong likelihood for donor centers' survival. Restructuring of the NMDP could allow it to focus its revenues on those centers which are most productive and could also allow it to reconsider arrangements with centers which are less costly.

The NMDP indicates that minority donor recruitment is one of its most important goals. Last year, the minority donor pool size increased from 218,000 to 311,000 potential donors. Among African-Americans, in the period from 1994 to 1995 the donor pool rose from 71,000 to 109,000, with 42 transplants performed in 1995. In spite of progress being made in minority recruitment, insufficient minority donors and transplants present a multifactorial problem. The expansion of the donor pool size alone is unlikely to correct this problem.

MARROW TRANSPLANT RESEARCH

Biomedical research is the responsibility of the National Institutes of Health (NIH), and in 1994 the NIH expended a total of $89 million on marrow transplant research. The NMDP research dollars ($2 million) are small by comparison. The likelihood of duplication of efforts is decreased when there is a unified approach.

III. Legislative History and Committee Action

Hearings on both the solid organ and the bone marrow transplant programs were held before the committee on July 20, 1995. Testimony focused on the Federal Government's role in the oversight and funding of solid organ and unrelated donor marrow transplantation. Witnesses representing the Congress, the administration, and both professionals and patients from the solid organ and bone marrow transplant community presented testimony.

S. 1324 was introduced on October 17, 1995, by Senators Kassebaum, Kennedy, and Frist. The bill was referred to the Committee on Labor and Human Resources.

The Committee on Labor and Human Resources considered S. 1324 in an executive session held on November 8, 1995. Senator Kassebaum offered an amendment in the nature of a substitute. The bill as amended was unanimously adopted by voice vote and ordered favorably reported to the full Senate.

IV. Committee Views

The committee has approached the reauthorization of this legislation by an evaluation of the following issues: first, does the program provide equity for the program beneficiaries; second, is there a necessary government role, and if so, what are the proper present and future roles of the government in these programs; third, what measures should be taken to make the program more efficient and effective; and fourth, what is the appropriate Federal funding level for these programs.

Title I

ORGAN DONATION

There is an increasing disparity between the number of available organs and the number of patients waiting for a transplant. More than 40,000 Americans are currently waiting for transplants. Improved medical safety and effectiveness of organ transplantation have increased the demand for such procedures, but efforts to increase the supply of organs have not been particularly successful. According to recent figures from the industry, the number of organ donors remains insufficient. Yet, since 1988, the demand for organs has increased by more than 50 percent.

This legislation acknowledges the need to enhance organ donation. Various studies show that between 6,000 and 15,100 people yearly are potential organ donors, yet only 5,300 individuals donated their organs in 1995. There is potential for increasing the number of organ donors. To increase organ donation, the committee has provided authority for the Secretary of HHS to make contracts to fund projects to increase organ donation, to train health care providers to request organ donations, and to provide technical assistance. In addition to OPO's and nonprofit organizations, the committee bill would make HHS contracts available to other public entities. For example, contracts could be given to projects encouraging State divisions of motor vehicles to share information with OPO's about people who had signed organ donor cards, provided that there was no infringement on individual confidentiality. Contracts to improve cooperation between OPO's and medical examiners is another area where public entities could increase organ donation.

The committee believes that education and technical assistance have the potential for increasing the level of organ donation. Education campaigns designed to make the public aware of the good that can come from transplantation should continue. Public opinion surveys show that these campaigns have been effective—more than 95 percent of Americans are aware of transplantation, and as many as 75 percent say that they would be willing to donate an organ after death. What is not available in these data are the percentage

of individuals who have discussed their wishes with relevant family members.

The low number of procured organs, despite this apparent level of public support for donation, led researchers to the conclusion that the low procurement rate was due, in part, to the failure of health care providers to appropriately request donation from families of donor-eligible patients. Various early studies seem to support this conclusion. These data, led to the development of required request policies. Unfortunately, these policies have not resulted in the expected increase in the number of procured organs. Recent medical studies showed that families of donor-eligible patients are approached about organ donation between 73 percent to 87 percent of the time. However, only 47 percent of families of eligible donors agree to such organ donation. Although health care professionals do request that families donate, the rate of consent by families has been less than previously assumed. This suggests that empirically based education campaigns for health care workers could improve their skills in discussing this important issue with family members and could potentially increase donation. Such training must be augmented with public education focusing on the importance of the family discussion. Some success has also been found with "community based" procurement efforts in the New England region.

Better public education can also help address organ donation among populations whose donation rates are lower than that of the general population. These populations often face longer waiting times and a severe shortage of organs. Since there is a higher degree of compatible matching between members of the same ethnic group, it is critical that ethnic populations donate organs and ensure the availability of organ transplantation for these populations. We are pleased to see from recent reports a significant increase in minority population donation rates.

The committee believes that an effort should be made to categorize organ-donation approaches which have shown promise—whether developed with Federal funds or otherwise—into a central registry and that these approaches should be publicized and made available for general use. This registry would allow easy access and expedite implementation in other areas of the country, if appropriate.

The committee also expects the Division of Transplantation (DOT) in the Health Resources and Services Administration, together with the entire transplant community, including patient advocate groups, to develop a comprehensive, national approach to addressing the need for increased organ procurement. The committee believes that, while the small pilot projects typically funded through this legislation are important to providing communities with the funds to develop innovative approaches to the problem, we must take a larger, more comprehensive approach to increasing organ donation and procurement. The committee expects the funds in this legislation that are dedicated to increasing organ donation and procurement to be used effectively to maximize the available organ donation pool by the year 2001. The committee encourages all members of the transplant community to take advantage of organ donation approaches that have proven to be effective and to implement these approaches more widely.

ORGAN PROCUREMENT ORGANIZATIONS

This act is administered by the Health Resources and Services Administration of the Department of Health and Human Services. The relationship between hospitals and OPO's is directed by the Health Care Financing Administration of the Department of Health and Human Services. The dual responsibility for organ procurement organizations has posed some difficulty in the past. The committee intends to avoid discrepancies between agency regulations and legislative language. The amendments which are included in this act are not to interfere with Section 1138 of the Social Security Act, which defines the relationship between hospitals and OPO's. It is the committee's expectation that, although OPO performance standards are the responsibility of HCFA, HRSA, with its responsibility over the transplant Network, will provide the oversight of transplant centers and OPO's for organ allocation and efforts to increase organ donation. The committee would strongly encourage HCFA to consult with HRSA and the DOT in the promulgation of performance standards and in the recertification and designation of OPO's.

The committee believes that requiring OPO's to have agreements with all hospitals within their service areas which have facilities for donation will serve to increase donation, which is a major objective of this legislation. However, the committee is aware that an OPO has no control over a hospital which may choose not to enter into an agreement with the OPO serving its area. Likewise, a hospital's reluctance to participate may be indicative of a larger issue. The committee's intent is that OPO's and hospitals will make every effort possible to develop agreements that will ultimately increase organ donation.

The committee is pleased to know that HHS has developed primary performance standards for OPO's. Each OPO is expected to achieve at least 75 percent of the national mean for four of five performance categories, e.g., number of kidneys recovered per million population. Most OPO's have demonstrated their ability to fulfill these primary performance standards. However, OPO's which do not meet these primary standards should be given an opportunity to present information about unique circumstances in their service areas which impact their ability to meet the performance standards. OPO's should be given the opportunity to develop and implement a correction plan.

The committee is concerned that the threshold criterion as proposed by HCFA for an entity's eligibility as an OPO is an arbitrary qualification standard. Some OPO's are unable to meet the 24-donor rule but have demonstrated their ability to meet the primary performance standards. Therefore, the committee recommends that HHS/HCFA reevaluate the 24-donor rule for redesignating OPO's. Placing the major emphasis on OPO performance is critical, but it should focus on the primary performance measures and those OPO's which fulfill those criteria, or effectively demonstrate unique circumstances, should be redesignated as in compliance without declaring their service areas as open regions. Care should be taken to avoid abrupt or inappropriate changes in OPO service area coverages which may negatively impact organ donor recoveries.

The committee recognizes that OPO's are the backbone of the organ procurement system. The performance of individual OPO's directly affects the well-being of Americans awaiting organ transplants. Therefore, this legislation calls for a triennial data report by the Secretary assessing the effectiveness of individual OPO's in performing their role. The committee believes strongly that all OPO's should aim to maximize procurement in their service areas and that all OPO's should be required to show a plan to improve their performance and report the results from those efforts. The committee is sensitive to the needs for confidentiality of information. The committee does not expect published data to violate the confidentiality of patients.

It is critical to continue to involve transplant physicians, surgeons, and transplant centers in the OPO policy-making process. Fair representation on the OPO board is an effective way to accomplish this goal. The committee believes that OPO's should use their discretion to determine the optimal size of their boards.

The committee believes that diversification of the board of directors is critical to allow the concerns of all members of the transplant community to be represented and to create a board of directors that is responsive to the needs of the public. It is the intent of the committee that the prescribed changes in composition of both the board of directors and committees of the OPO and the Organ Procurement and Transplant Network should represent inclusion which is functional as well as numerical. It is the committee's belief that individuals should participate in the workings of the OPO's and the Network at all levels because of interest and commitment rather than because they belong to a specific constituency.

ALLOCATION OF ORGANS

The original intent of the National Organ Transplant Act was to assure patients that no matter who they were or where they lived, they would have a fair chance of receiving an organ transplant. It is the belief of the committee that the United States should adopt a consistent and fair system of allocation and move away from the persistent fragmentation and inconsistency that may have evolved despite the National Organ Transplant Act. One obstacle to achieving this consistency has been the current variation in organ donation and allocation policies. A further problem is that OPO service areas vary substantially in size, population, and donation rates. Therefore, even if all OPO's followed consistent allocation policies within their service areas, patients in one part of the country would not be guaranteed the same probability of receiving an organ transplant as patients in another OPO.

The April 1993 GAO report states that OPO allocation procedures varied drastically and that different OPO practices could account for a portion of the differences in procurement and allocation. The same report found that 25 of 68 OPO's did not follow Network allocation policies, although some of the OPO's had network approved variances. For example, certain OPO's used individual transplant center waiting lists rather than an OPO-wide list. This practice may result in less-critically ill patients receiving organs before patients with more urgent needs. Moreover, because of the wide variations in waiting times across the country, some patients

list themselves with multiple transplant centers, introducing another level of unfairness compared to those patients who are carried only on a single list.

Following the 1993 GAO report, the Network established a policy that organs should be allocated using OPO-wide waiting lists; any deviation from this policy required approval from the Network's board of directors. This policy change has resulted in a significant reduction in the use of transplant center-specific waiting lists. In 1995 at the request of the committee, the GAO reassessed OPO/transplant center waiting lists. They have noted in a preliminary report that only three OPO's employ transplant center-specific waiting lists. The exceptions to this policy, approved by the Network, are based on unique characteristics of the OPO, such as geographic size and patient demographics.

The committee believes that the Network should maintain for informational purposes a single, nationwide list of persons awaiting each type of organ transplant. These lists can provide useful information on the number of people waiting for transplants and help to assess the equity of different organ allocation policies. In order to achieve some degree of consistency among and across OPO's concerning organ allocation, the committee believes that each OPO should be required, with some notable exceptions, to have a single patient list encompassing its entire service area. The committee bill provides for three types of exceptions: a region consisting of at least an entire State; an approved alternative local unit; or another allocation system which is approved by the Network and the Secretary.

Waiting times for organs do vary drastically in different parts of the country and from one OPO to another. Waiting times for kidney transplants range from 85 to 965 days. More than half of kidney transplant recipients will wait more than 600 days before a transplant becomes available. Although patients generally wait less time for liver and heart transplants, considerable variations in the time that patients wait for these organs exist among OPO's. The average waiting list time for a liver transplant is 102 days, while the average wait for a heart transplant is 219 days. These waits are affected by many factors including availability of temporary treatments such as kidney dialysis.

Variations in waiting list times among OPO's may be affected by various factors. These factors include among others, immunologic donor incompatibility, local transplant center characteristics, and local organ recovery. The GAO has recently noted that a major factor in determining waiting list time is the absence of specific criteria defining the appropriate timing for the listing of patients with organ failure. The Network is currently involved in crafting listing criteria. The committee is supportive of these critical efforts and hopes that such efforts will increase patient equity while diminishing the tendency of patients to be listed on multiple transplant lists.

This legislation does not prescribe a specific allocation approach. There are members of the transplant community who have encouraged the Congress to take such action. The committee at the present time is unclear as to what is the most equitable allocation system. The committee applauds the efforts of the transplant community to develop approaches to reevaluate the current allocation

system. We are hopeful that these efforts will go forward and evaluate all relevant solid organ transplant allocation systems. The committee believes that these efforts must be open and forthright if future allocation systems are to be rapidly embraced by the public and the transplant community and viewed with a sense of equity and fairness.

ORGAN TRANSPLANT NETWORK AND GOVERNMENT OVERSIGHT

With passage of the National Organ Transplant Act, the Congress set forth a structure which was to be composed of the Organ Procurement and Transplant Network, made up of members from the transplant community, and the public who would give voluntarily of their time and talents. The Network was described in the original law as a "private entity." The committee views the original designation as a "private entity" to represent an independent voluntary organization which would function outside of a government agency, with governmental oversight, and would represent the interests of the public and the transplant community. The committee believes that the original designation was not a legislative mandate that the Network should become a subsidiary of, and therefore synonymous with, the Network contractor.

The Network was given the responsibility for the development of policies and procedures for the transplant system. The Secretary was vested with the responsibility of providing, by contract, for the Network contractor to implement the Network policies. The contractor, a not-for-profit, private entity, would then function as the implementor of the Network-developed transplant policies and would be granted the authority to function within the constraints of good business practices. The Secretary was charged with responsibility for oversight of all aspects of the transplant system.

Over the life of the National Organ Transplant Act, the delineation between the Network and the Network contractor has been blurred by the integration of these two separate structures. At present, the Network and the Network contractor share the same committee structure and board of directors. This integration has provided some obvious benefits, but it has also led to confusion regarding the relative roles of each organization. This legislation has been crafted with the understanding that this integration already exists and does not have to be inherently detrimental. However, the Network contractor, by way of the solid organ transplant contract, has a monopoly. The integration of the policy-making body (the Network) with the Network contractor, and the absence of true competition for the contract, allows the Network contractor to function in a manner which poses a threat for a conflict of interest and could lead to a perception of distrust. It is the committee's intent that the language in this legislation clarify the relative roles of both the Network and the Network contractor.

This legislation provides for representation of the Secretary of HHS through the HRSA Division of Organ Transplantation at all meetings of the Network board of directors and committees. This representation is to be nonvoting. The Secretary, while being allowed representation in such meetings, is not expected by the committee to participate in all meetings, unless the Secretary believes that such attendance is necessary to protect the public good. It is

not the intent of the committee that the Secretary participate in the internal business of the Network contractor. However, because the organizational structures of the Network and the Network contractor have become integrated, it is the committee's intent that the Network will take all steps possible to minimize the number of meetings from which the Secretary must be excluded.

There is an increased desire by this committee and, indeed, the American people to lift the burden of unnecessary government spending and costly, ineffective government regulation. However, in the case of organ transplantation and donation, it is the committee's belief that the oversight of the transplant system represents the management of a unique resource, a resource offered by donor families at the moment of their greatest tragedy and sorrow. We believe that the actual operation of the transplant system should reside in the private sector. However, we believe that the elected government of the people should, in partnership with the private sector, be the ultimate steward of this special gift, thus ensuring that this gift is properly cared for, adequately regulated, and distributed equally to the maximum extent that is feasible.

The committee believes strongly that, for the present time, it is critical for the government to maintain its role of oversight for the solid organ transplant program. The committee believes that while the system is more mature than at its inception, the inherent concerns regarding the potential for abuse and the buying and selling of organs still exists.

Recent events at a heart transplant program exemplify the type of problem that can develop without "final rules." In this situation, qualified surgeons departed the transplant center without replacements. This action, combined with inadequate nursing support, left the center understaffed. Despite the manpower difficulties, the program continued to enroll new patients. New and existing patients were not told of the center's status and difficulties, and hearts for transplant were continually rejected for administrative rather than patient-specific reasons.

A performance audit of this problem was conducted by the legislative division of the State. Officials of the United Network for Organ Sharing (UNOS, the Network contractor), who were contacted by these investigators, informed the investigators that "they can't force members (of the Network) to comply with their policies." However, they said the voluntary compliance rate for UNOS policies is very good and that peer pressure from other members or from UNOS corrective action policies eliminate most noncompliance. The government agency responsible for monitoring the transplant program (HRSA) was unaware of this problem, although it was reported that the government had been excluded from those Network meetings in which this issue would have been discussed. The frequency of these events is reported by UNOS to be rare, but it is the committee's view that the government should not be excluded from meetings of this type.

It is the committee's belief that a portion of the public distrust is an indirect result of the failure of the government to issue final rules governing the policies and procedures for organ transplantation. The absence of final rules provides an opportunity for all parties to claim that because the policies are voluntary, they are

powerless to demand the transplant community be responsive to the needs of the public.

Because of problems of this type and the voluntary nature of the present policies, the committee, in this legislation, requires the Secretary to issue the final rule which will govern the policies and procedures of the organ transplant system. The committee believes that because the proposed rule was issued on September 8, 1994, and the period of public comment has been completed, the Secretary should be able to complete the final rule within 1 year of enactment of this legislation. The committee also believes that this is critical to the maintenance of public trust in the transplant system. The committee had considered using the proposed final rule as the final rule if the Secretary failed to meet the prescribed deadline. However, the committee chose not to pursue this course due to concerns that implementing policies as final rules which were in force in 1994, without appropriate updating, would cause significant upheaval to this dynamic system. Nevertheless, the committee believes that it is time for the final rule to be issued and that the call for final rules, which has spanned more than 6 years, needs to be brought to closure. The committee does require the Secretary to report to Congress within 30 days of the prescribed deadline if the Secretary is not in compliance with this statute. This report should explain to Congress why the Secretary is not in compliance and what steps are being taken to bring the department into compliance at the earliest date possible. The "final rule" is viewed by the committee to be of highest priority.

This legislation has also given the Secretary the responsibility to direct and to work with or work through the Network contractor to respond to new emerging issues, such as those involved in this incident. The committee's intent is that a system of prospective surveillance of policy noncompliance, the development of criteria and guidelines for the placement of patients onto organ-specific transplant waiting lists, and the development of user-friendly standardized patient information that describes the organ transplant and Network procedures will be three of the emerging issues that should be addressed immediately.

The committee believes that the appropriate number, or proportion, of members on the board of directors remains an issue. The committee believes efforts should be made to appoint to the board skilled members of the transplant community who would complement the board's responsibilities and improve the nonscientific activities (e.g., educational, procurement, financial, public relations, legal). The accountability of the Network and OPO's to transplant candidates, recipients, and families needs to be increased.

During the course of developing this legislation, the committee received a number of communications from patients and patient groups urging greater participation by transplant recipients, candidates' family members, and members of donor families in the policy-making deliberations of the Network. We believe the Network contractor has heard these concerns and has attempted to increase the involvement of recipients, candidates, and family members in its deliberations. However, the committee believes that such participation must increase. Consequently, language has been included in this bill that requires the contractor to assure a reasonable bal-

ance of such individuals on the committees and board of directors of the Network. It is the belief of the committee that the deliberations of the Network contractor, in fulfilling the requirements of the contract, should be open to the general public and that the Network contractor should do everything possible to include all interested parties in its operation. The committee's intent is for patient representatives to be chosen in an open and fair selection process because of their interest and commitment and not just because they represent a specific transplant center or advocacy group.

NEW FUNDING MECHANISM

The solid organ transplant program has always relied heavily on patient registration fees to fund the operation of the transplant Network. The collection of a patient registration fee predates the enactment of the National Organ Transplant Act (NOTA). Currently, more than 75 percent of the contractor's revenues comes from patient registration fees; the remaining 25 percent comes from Federal appropriations (funding for fiscal year 1995 was $2.6 million). The committee reconfirms that the patient registration fees are to be used to implement the requirements of the solid organ transplant contract and other activities related to organ procurement and transplantation.

Currently, the average fee collected totals $325 and goes toward maintaining the system and other activities. However, no Federal laws or regulations exist governing the collection or use of this revenue. A problem could arise if fees were charged unfairly.

The committee is aware of patient concerns that this legislation, which provides the authority to the Network to establish such fees, could be viewed as a unilateral entitlement to raise such fees whenever the contractor deemed such increases to be necessary. The committee believes that raising the patient registration fee without proper justification and input from the patient community is not appropriate and should be avoided.

This legislation allows the Network to propose reasonable and customary patient registration fee increases, but these requests must be submitted to the Secretary. The Secretary is given 60 days to disapprove the proposed fee increase. If the Secretary fails to disapprove the proposal as unreasonable, then the fee increase will go into effect. Having the Secretary participate in the determination of the patient registration fee serves to maintain a degree of integrity and fairness in charges to patients. The committee's intent is that consideration of fee increases receive the highest priority by the HHS Secretary, and that requests for increases be carefully analyzed so that the public's interest is maintained.

The committee intends to strengthen Federal oversight of the Network, but it is not the committee's intent for the Network to be a government entity. Rather the clarification of the government's oversight is intended to improve patient protection.

SCIENTIFIC REGISTRY

The Scientific Registry is a model for the best in outcome data and should continue to be developed and kept current for policy making. Data from the solid organ Scientific Registry are used for: (1) policy making, especially in the area of organ allocation; (2)

analysis of transplantation as a treatment option for the various types of end stage organ failure; (3) reporting on patient and graft survival rates as required by the Transplant Amendments of 1990 and as stipulated by this legislation; (4) supporting clinical and scientific research in areas such as immunogenetics, organ rejection, and retransplantation; (5) responding to government and non-government (e.g., media, academic) data requests; (6) providing data to the Health Care Financing Administration for the oversight of the Medicare End-stage Renal Disease Program; and (7) supplying a source of transplant center-specific data which can be used by patients, transplant centers, and third-party payers in the evaluation of transplant outcomes.

The Scientific Registry is important to the transplant centers. The registry collects and collates data on transplant recipients from which the annual, center-to-center comparative transplant statistics are generated. This type of outcome data is becoming more important as the demand for comparative outcome data by patients and managed care corporations increases.

A significant percent of the appropriated funds authorized under the National Transplant Organ Act have gone in the past to support, through competitive contract, the maintenance and expansion of the Scientific Registry. During the 104th Congress, the appropriations committees of both the Senate and the House of Representatives, in report language for the budget rescission and budget resolution legislation, called for the development of alternative measures to fund these activities. The committee has responded to this request through the creation of the ''data management fee,'' an alternative to Federal financing.

The ''data management fee'' is to be levied, on a per-transplant basis, on transplant centers and the respective OPO. The legislation stipulates that the total fee will be divided between the transplant center and the OPO in an 80/20 split. The fee will be set by the Network but approved and collected by the Secretary. It is the committee's intent that the costs be maintained at a level adequate to support the maintenance and appropriate expansion of the Scientific Registry. The committee believes that with approximately 18,000 transplants being performed yearly, the one-time, per-transplant fee of approximately $100 to $125 would provide adequate revenue to support program expenditures. It is the committee's expectation that in the case of a living relative donor, the entire data management fee would be paid by the transplant center.

The committee believes that the costs of the ''data management fee'' must be kept to a minimum. In an attempt to minimize costs to the transplant centers and OPO's, the committee intends that the Federal contract for the registry must be competitive, and that all high-quality applications be given full consideration.

The committee would like to make clear that the ''data management fee'' levied on the transplant centers and respective OPOs is not to be an additional charge levied on the patients. The committee believes strongly that the fee not increase the out-of-pocket costs for transplant patients.

The prospective implementation of such a ''data management fee'' will avoid the disruption of the functions of the Scientific Registry, should appropriated funds be rescinded in the future. To disrupt

the collection of this type of data, particularly for the area of organ allocation, would be deleterious to the Federal Government, the transplant community, and patients who could potentially benefit from a transplant.

This legislation sets aside a small portion of the "data management fee" to be used to support innovative efforts to increase organ donation. These funds, coupled with the funds authorized through this legislation, are to be used through the collective partnership between the private community and the government to increase organ donation. Programs which would increase organ donation would be beneficial to all concerned. Larger numbers of patients would receive transplants; and with more transplants to be performed, more centers' facilities, OPO services, physicians, and other health care workers would be utilized.

Funds from the "data management fee" to be utilized for contracts to support efforts to increase organ donation will be administrated by the Secretary, but all contracts which exceed $25,000 will require a recommendation by the Network and approval by the Secretary before being initiated. It is the expectation of the committee that the Secretary, the Network, and the patient community work together to encourage the effective use of these funds and to assure that all program applications for contracts and cooperative agreements be evaluated objectively.

The committee has been very concerned about the continuing controversy, over access to Scientific Registry liver allocation data, that has existed between UNOS, the Scientific Registry contractor, and the University of Pittsburgh Medical Center. These events have come about as studies to assess the most equitable approach to allocate livers have been under way. The committee recognizes the importance of the Scientific Registry contractor's obligation to the patients and members to maintain the confidentiality of patient-identified data and the need to verify center specific data prior to release. However, the committee views the Scientific Registry data collected as a consequence of administering federally funded contracts to be in the public domain and, therefore, as data which should be made available to researchers, even if the purpose of the research is the development of an alternative allocation policy.

It is the intent of the committee that there be freedom of access to the Scientific Registry data, but patient confidentiality must be maintained. It is the belief of the committee that the Secretary has and must exercise the role as final arbiter in such disputes, and the committee believes that the contractor must respond to and abide by the final judgment of the Secretary on these issues. It is also the committee's belief that the transplant community will receive greater acceptance of future allocation systems if they are constructed in an open and public manner. The transplant community must remember that many constituents have a stake in the transplant process but that the transplant recipients, candidates, and their families are the true consumers of the services of this program.

THE STUDY

This legislation requires the Secretary to request the Institute of Medicine to conduct a study of (1) the role of and the impact of the Federal Government in the oversight and support of solid organ transplantation, the Network (which carries out its functions by government contract), and the solid organ transplantation Scientific Registry; and (2) the access of all interested constituencies to membership on the Network's board of directors and all its committees.

The committee is aware of the discussion that is ongoing in the transplant community regarding the future direction of this program. One faction is of the belief that it is time to consider removing the governmental role completely and allowing the Network and the Scientific Registry to be privatized. The impact of this move at present is purely speculative. The other faction is of the belief that the potential inequities that existed in the early 1980's which led to the need for the initial legislation still exist, and that as long as there is a disparity between supply and demand, inequity will exist without governmental oversight. It is the hope that this proposed study will produce recommendations which will help the Congress respond appropriately.

It is the committee's intent that the group convened by the Institute of Medicine to study this issue will be representative of the many different factions which make up the transplant community, and that the IOM will consider the extent and impact on solid organ transplantation of privatizing all or a part of the functions and services of the Network.

The committee has also heard from patient groups, minority populations, and other nonphysician, surgeon, and transplant center groups regarding what they believe to be inadequate "true representation" on the Network's board of directors and committees. It is hoped that with the second component of this study, access and true representation will be assessed. It is the intent of the committee that within 1 year of completion of this report, the contractor, in consultation with the Network, will submit to the Secretary and the Congress a plan for implementation which would respond to recommendations of this report pertaining to access to the transplant policy-making organizations.

AUTHORIZATION OF APPROPRIATIONS

It is the committee's intent that the authorization in this legislation be a phaseout of funding for the support of the Scientific Registry, coordinated with a phase in of the "data management fee." The committee believes that the "data management fee" should be fully implemented by the third year after enactment of this legislation.

The authorization also includes $250,000 each year for the direct purpose of supporting innovative national efforts to increase organ donation. These funds, coupled with those set aside from the "data management fee," should form a major effort to increase organ donation.

Title II

The National Bone Marrow Transplant Program was developed to maximize and facilitate the number of unrelated donor bone marrow transplants. This program was separated from solid organ transplantation because marrow transplantation is quite different from solid organ transplantation. The harvest and transplantation of bone marrow is a much more controlled process. While the need for a marrow transplant can be emergent, it seldom includes the unpredictability that is inherent in a solid organ transplant.

Marrow transplantation is now used as treatment for many illnesses. Marrow transplants are of two types: autologous and allogeneic.

Autologous transplants are the most frequently performed type of marrow transplant and are associated with fewer complications than are allogeneic transplants. Autologous transplants use the patient's own bone marrow; therefore, finding an identical donor match is unnecessary.

Allogeneic transplants rely on a related or unrelated marrow donor. Unfortunately, only 25 percent of patients will have an acceptable living related donor. Careful matching of the donor and recipient is critical for success in allogeneic marrow transplants, and for those patients without a related donor, an unrelated donor must then be sought.

In this country, approximately 21,000 bone marrow transplants are performed yearly. About 13,000 transplants will utilize the patient's own bone marrow for transplant (autologous transplant), while the remaining 8,000 transplants use bone marrow from related or unrelated donors (allogeneic transplant). The National Bone Transplant Marrow Program is involved in only those allogeneic transplants in which an unrelated donor marrow is used.

The National Bone Marrow Transplant Program has facilitated 4,135 transplants since its inception. The yearly total has increased from 554 transplants in 1992 to 840 in 1994. The National Marrow Donor Program facilitated 1025 transplants in 1995. This increase in transplants has occurred at a time when the donor pool has increased from 711,696 to over 2 million. The General Accounting Office concluded in their 1992 report ("Bone Marrow Transplants: National Program Has Greatly Increased Pool of Potential Donors," GAO/HRD–93–11) that the program had been very successful in recruiting potential donors, but the success in facilitating unrelated donor marrow transplants has been more modest.

The National Marrow Donor Program had an annual budget of $63.0 million in 1995. This funding came from patient fees, a contract with the Department of Defense (Navy), and the Public Health Service authorization. Public Health Service funds are expended by the program primarily for donor center contracts, minority recruitment efforts, bone marrow transplant research, and administrative costs. Appropriated funds are used to support the infrastructure needed to facilitate the search for unrelated donor marrow. However, there are no Federal dollars in this authorization which support individual patient marrow transplants.

The contractor has expanded its focus in recent years to include the areas of patient advocacy, minority donor recruitment, marrow

procurement and storage standards, and bone marrow transplant research. This legislation intends to codify a number of the measures which the contractor has implemented during the past 2 years. The foundation for this reauthorization legislation is that of Senate bill 1994, which was passed by the Senate in the 103rd Congress.

UNRELATED MARROW DONOR REGISTRY

It is the committee's intent that this program's primary priority must be to facilitate and maximize the number of unrelated donor marrow transplants. The committee believes that, in the past, the primary focus of this program has been to increase potential marrow donors. While this has been a laudable goal, it must be stressed that unlike the case for solid organ transplantation, recruitment of a marrow donor does not automatically translate into a marrow transplant because of the need for matching.

Certain populations have been underrepresented within the potential donor pool and also among the individuals who undergo transplantation. A prime example of this problem is the transplantation of African-Americans. In 1992, only 16 African-American transplants were performed. The potential donor pool has been increased by almost 400 percent, yet the number of transplants per year increased to only 25. The committee believes that the program must target certain populations to increase the number of potential marrow donors, but it also believes that increasing the number of potential donors is only a portion of the answer to unrelated donor marrow transplantation. Barriers such as the need for donor-recipient matching, patient and physician education, genetic heterogeneity, cultural differences, and financial issues must also be overcome before unrelated donor marrow transplantation can be more universally available. The committee does not believe that the National Bone Marrow Transplant Program alone can resolve most of these latter factors.

The committee is concerned about the arrangements that the contractor has developed with the donor centers. It is the committee's belief that these arrangements have been expensive and may not have been structured in as cost-effective way as possible. The committee has also been informed that donor lists may not be updated on a regular basis and that individual donors may be listed on more than one donor center roster. The committee believes that this leads to increased cost and offers little benefit to patients seeking an acceptable marrow donor. The committee is very supportive of the ongoing Inspector General's study, "Bone Marrow Program Inspection," and hopes that recommendations from this study can be implemented to improve the present program-donor center contractual relationships.

It is the committee's intent that donor centers be retained within the program based on performance and not merely because of a historical relationship. The donor registry should undergo periodic review, with removal of potential donors that are no longer viable. The committee believes that with a substantive restructuring of the program-donor center relationship, program services can be maintained, while decreasing expenditures for the donor center contracts.

PATIENT ADVOCACY AND CASE MANAGEMENT

The committee intends with this legislation to strengthen the patient advocacy responsibilities of the National Bone Marrow Donor Registry in several respects. One of these is the explicit requirement that the patient advocacy program include case-management services for potential marrow donors and recipients. The committee is aware that the program contractor has established an office of patient advocacy and has formed a patient services committee that meets regularly. The committee looks forward to completion of the study now under way, by the Secretary, to assess these functions. The committee intends those recommendations to be seriously considered, with implementation of those suggestions which would improve such functions.

The committee believes that to achieve its mission fully, the program must be attentive not only to the needs and concerns of donors, potential and actual, but also to those of patients in need of a marrow transplant. The most significant contribution the program can make to a patient is to facilitate a successful marrow transplant. It is essential that, once a patient has been identified as a candidate, or potential candidate, for marrow transplantation, he or she receive individualized guidance, support, and assistance in fully understanding and utilizing the resources of the entire marrow transplant system. The policies and procedures of this system can seem complex and confusing, particularly to patients and families facing the pressures and anxieties that come with a fatal disease.

The principal elements of such a case-management approach should, in the committee's view, include at least the following: prompt and accurate information provided to the individual patient about the process and how to obtain access to the various resources available; periodic communications with the patient and families as well as the physician at each significant stage in the search process to make sure the patient has complete information about the status of the search and to determine whether the patient's needs and concerns are being met; monitoring of the search process and troubleshooting any problems or delays; assistance with questions about fees, insurance coverage, or program eligibility; and removal of any barriers to communications that might arise between the patient and the other participants in the transplant system.

The contractor must continue to assure that these services are being provided. It may do so through a combination of services furnished by the Office of Patient Advocacy and services furnished by a network of trained and competent individuals located at each transplant center. The committee believes that the program is to be held accountable for providing training and guidance to such individuals, for monitoring their performance, and for being prepared to intervene in individual cases where serious concerns arise with respect to the search process. In addition, physicians should be encouraged, supported, and assisted to serve as advocates on behalf of their patients. The patient, family, and physicians must know there is always a responsible person to whom they may turn whenever a problem arises.

Potential and real donors are individuals who give of themselves in an unselfish manner by providing a marrow donation to an unrelated but matched recipient. Donors are individuals who, prior to being found to be acceptable matched marrow donors, are not included in the health care system. They are then thrust into the system, and after a medical evaluation they are expected to submit themselves to a surgical procedure for the harvesting of the marrow donation gift. The completion of this procedure leaves the donor in a position without specific advocacy. Donors must be provided with donor advocacy and individual case management for services such as a leave of absence from place of employment, medical care for any initial or post-procedure residual physical complaints, and monitoring the donor's resumption to their pre-donation life style.

NATIONAL BONE MARROW DONOR PROGRAM

The committee has been concerned that, in the past, the National Marrow Donor Program has practiced a policy of routinely reappointing rather than alternating membership on its board of directors. While the committee applauds the changes to its policies of board membership recently made by the program contractor, the committee believes that it is important for the boards to be further diversified and to bring new members with varying points of view to the board and committees.

Members of the board of directors will have a term of office of 2 years, with a limit of three terms of service. The board of directors and the committees will be composed of a "reasonable balance" of constituents, including recipients and their families. The committee's intent is that there also be nonvoting representation from the Health Resources and Services Administration and the Naval Medical Research and Development Command on the board of directors and committees, as the Secretary of HHS deems it to be appropriate. The committee believes that all members of the bone marrow transplantation community, including the public, should be represented in the policy-making process of this program.

UNRELATED DONOR MARROW TRANSPLANT SCIENTIFIC REGISTRY

The committee intends that the NMDP continue to maintain the unrelated donor marrow Scientific Registry. This Scientific Registry should include information on all recipients of biologically unrelated bone marrow transplants, regardless of the method of marrow reconstitution. The committee's intent is that this scientific registry contain information including the recipient and donor demographics, characteristics of the transplant preparative regimen, and outcome data.

The National Bone Marrow Donor Registry contractor shall submit an annual report to the Secretary of HHS on the state of unrelated donor marrow transplantation, using information from the Scientific Registry. It is the intent of the committee that this registry provide public information and that within the confines of maintenance of patient confidentiality, this information be made available to the biomedical scientific community for use in furthering medical science.

STUDIES AND EVALUATIONS

The committee is interested in receiving recommendations from the bone marrow transplant community on the future role of the Federal Government in the area of unrelated donor marrow. The committee is proud of the infrastructure which has been built through the partnership between private efforts and governmental support. The success of the program to date is a testimony to the strength and credibility of the infrastructure that has been developed. It is also the committee's belief that the National Bone Marrow Transplant Program contractor has performed well in the delivery of the important services to program beneficiaries and has responded to the emerging needs of the transplant community.

The committee is aware of the findings of the General Accounting Office's 1992 report ''Bone Marrow Transplants: National Program Has Greatly Increased the Pool of Potential Donors,'' GAO/HRD–93–11). Noting these conclusions, it is the intent of the committee that the proposed Institute of Medicine study focus primarily on issues which are global in nature and programmatic and not on the performance of the contractor.

Debate exists about the appropriate governmental role in many of the national programs that receive governmental support, including the National Bone Marrow Transplant Program. The need for a matched donor for an individual with an illness which may be responsive to allogeneic marrow transplant is obviously critical, but members of the committee believe that the benefits to the Nation as a whole of this government-supported program need to be evaluated. The question which the committee has considered is: With the infrastructure now in place, would a change in the Federal Government's role have a positive or negative effect on the delivery of potentially lifesaving marrow transplant services to those patients in need?

The committee expects the Secretary of HHS to request the Institute of Medicine to conduct a study to evaluate the role of a government-supported National Bone Marrow Transplant Program in facilitating the maximum number of unrelated marrow donor transplants. The committee believes this study should consider the magnitude of the potential need for unrelated marrow transplants that are reasonably feasible based on the present state of the art of patient-donor matching, the optimal potential donor pool size that would maximize the number of unrelated donor marrow transplants, the dependence of donor centers on the financial support provided to them through the HRSA appropriation, and other potential uses of the large registry of Human Leukocyte Antigen (HLA) matched marrow donors. It is also the committee's intent that the Institute of Medicine assess the present and future optimum capacity of the National Bone Marrow Program to provide equity of opportunity for finding matched unrelated donors for all ethnic groups. The optimal balance between the expected numbers of facilitated unrelated transplants, donor pool size and the HLA diversity of potential donors and the population should be considered. For the purposes of the IOM study, an optimum number of transplants facilitated by the National Bone Marrow Program is a number that can be reasonably achieved among all racial groups

and among diverse HLA types given the present state of patient-donor matching, the diversity of HLA types among the population and potential rates of increase in potential donor pool size and racial diversity.

The committee expects the Institute of Medicine to use the expertise of the marrow transplant community in developing the recommendations of this study. The committee believes that in defining the marrow transplant community, the Institute of Medicine should include not only scientists, but also marrow transplant physicians, transplant and donor center representatives, unrelated donor marrow transplant recipients and their families, and the appropriate research community.

The committee believes that a study which examines need, scientific and technology limitations of unrelated donor marrow transplantation, other potential uses of such a large registry of HLA-typed donors, and the present limit on Federal Government resources would produce recommendations to Congress which could help define the future role for the government in this program. It is the hope of the committee that this study will also provide for the program contractor a blueprint of options that could be considered for the future.

OTHER EVALUATIONS

The committee also intends for the Secretary of HHS to conduct an evaluation of the feasibility of consolidating all federally funded bone marrow transplant scientific registries. The committee believes that the consolidation of these registries would make this information both clinically and scientifically more valuable. The committee anticipates that the consolidated scientific registry data will become the foundation for the development of transplant policies and procedures, while helping to chart the future of marrow transplantation.

The Federal Government currently funds the unrelated donor marrow transplant Scientific Registry as part of the National Bone Marrow Transplant Program, the International Bone Marrow Transplant Registry, the Autologous Bone Marrow Transplant Registry, and the soon-to-be-funded Scientific Registry to track marrow reconstitution with the use of umbilical cord blood cells. These data could then be used to develop policies and procedures to chart the future of marrow transplantation.

The committee remains committed to the importance of biomedical research. The committee expects the Secretary to conduct an evaluation of the feasibility of consolidating all federally funded bone marrow research under the direction of the National Institutes of Health.

The Federal Government through the National Institutes of Health provided more than $110 million for bone marrow research in fiscal year 1995. The committee does not intend for the National Bone Marrow Transplant Program to administer and direct an independent marrow transplant research program which has the potential to be duplicative of other government-funded bone marrow efforts. While the committee is not opposed the National Bone Marrow Transplant Program developing a research presence, the committee believes that the National Bone Marrow Transplant Pro-

gram should compete through the peer-reviewed system of the National Institutes of Health.

AUTHORIZATION OF APPROPRIATIONS

The committee has decreased the authorized funding for this program during the first 2 years of this legislation. The committee believes that the decrease in funding is quite modest (approximately 10 percent of authorization or 2.5 percent of the program's total budget) and is consistent with the amount of funding which the program has devoted to bone marrow transplant research. Because the decrease in authorization is modest, the committee intends for the level of services for program beneficiaries, including the funds devoted to increase minority transplants, to be maintained at the present level.

The legislation authorizes funding in the third year at a level of "such sums as necessary." The committee intends with this authorization to allow for the recommendations of the Institute of Medicine study to be evaluated for possible implementation.

V. COST ESTIMATE

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, DC, March 14, 1996.

Hon. NANCY LANDON KASSEBAUM,
Chairman, Committee on Labor and Human Resources,
U.S. Senate, Washington, DC.

DEAR MADAM CHAIRMAN: The Congressional Budget Office has reviewed S. 1324, the Organ and Bone Marrow Transplant Program Reauthorization Act of 1995, as ordered reported by the Senate Committee on Labor and Human Resources on November 8, 1995.

The bill would affect direct spending and receipts and therefore would be subject to the pay-as-you-go procedures of the Balanced Budget Act.

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

Sincerely,

JUNE E. O'NEILL,
Director.

CONGRESSIONAL BUDGET OFFICE COST ESTIMATE

1. Bill number: S. 1324.

2. Bill title: Organ and Bone Marrow Transplant Program Reauthorization Act of 1995.

3. Bill status: As ordered reported by the Senate Committee on Labor and Human Resources on November 8, 1995.

4. Bill purpose: S. 1324 would reauthorize the Solid Organ Transplant Program and the Bone Barrow Transplantation Program. It would modify the programs to improve public information and access to their services, increase participation of those directly affected by the programs, and require evaluative studies and reports. In addition, the bill would permit the Secretary of Health and Human Service and the Organ Procurement and Transplan-

tation Network to collect fees to cover the costs of providing certain services in the Solid Organ Transplant Program.

5. Estimated cost to the Federal Government: For the Solid Organ Transplant Program, the bill would authorize $1.95 million for 1997, $1.1 million for 1998, and $0.25 million each year from 1999 through 2001. For the Bone Barrow Transplantation Program, it would be authorize $13.5 million for 1997, $12.15 million for 1998, and such sums as may be necessary for 1999. For the purpose of this estimate, CBO assumes that all funds authorized by the bill would be appropriated. Since the bill does not contain any authorization for fiscal year 1996, the spending shown for that year reflects only the amounts appropriated in the continuing resolutions through March 15, 1996. Estimated outlays are based on historical spending patterns of existing programs administered by the Health Resources and Services Administration (HRSA).

The bill would also continue the patient registration fee, establish a data management fee, and authorize the spending of their proceeds without further Congressional action. These provisions would increase offsetting receipts and direct spending but have no significant effect on total outlays.

The following table summarizes the estimated authorizations and outlays that would result from S. 1324 under two different sets of assumptions. The first set of assumptions adjusts the estimated authorizations for projected inflation after 1996. The second set of assumptions makes no allowance for projected inflation.

[By fiscal year, in millions of dollars]

	1995	1996	1997	1998	1999	2000
AUTHORIZATIONS OF APPROPRIATIONS						
Spending under current law:						
Budget authority	18.0	7.6	.....	.....	.....	.....
Estimated outlays	16.4	12.5	5.1	0.8	.....	.....
WITH ADJUSTMENT FOR INFLATION						
Proposed changes:						
Estimated Authorization	.....	.....	15.5	13.3	12.8	0.3
Estimated outlays	.....	.....	7.4	12.7	13.3	6.8
Projected spending under S. 1324:						
Estimated Authorization	.....	.....	15.5	13.3	12.8	0.3
Estimated outlays	.....	.....	12.5	13.5	13.3	6.8
WITHOUT ADJUSTMENT FOR INFLATION						
Proposed changes:						
Estimated Authorization	.....	.....	15.5	13.3	12.4	0.3
Estimated outlays	.....	.....	7.4	12.7	13.1	6.7
Projected spending under S. 1324:						
Estimated Authorization	.....	.....	15.5	13.3	12.4	0.3
Estimated outlays	.....	.....	12.5	13.5	13.1	6.7
DIRECT SPENDING						
Total	.....	.....	(1)	(1)	(1)	(1)

[1] Less than $500,000.

The costs of this bill fall within budget function 550.

6. Basis of the estimate: The Organ Procurement and Transplantation Program provides funds to support the National Organ Procurement and Transplantation Network (Network). The Network is an organization established by the Federal Government to maintain a 24-hour telephone service that aids in matching donor or-

gans with potential recipients and in coordinating placement efforts with transplant centers. The program also funds the Scientific Registry of Transplant Recipients (Scientific Registry). The Scientific Registry provides information on transplant recipients and outcomes of organ transplants which may be used for research and policy making.

The National Bone Marrow Donor Program provides funds to support the National Bone Marrow Donor Registry (Donor Registry). The Donor Registry maintains a list of potential bone marrow donors and matches patients in need of a transplant with a biologically unrelated donor of the same issue type. This registry increases the chances of a patient without a suitably matched relative to receive a transplant. The Health Resources and Services Administration has authority over the Donor Registry to allow for coordination between the solid organ and bone marrow transplantation programs.

Solid Organ Transplant Program

S. 1324 would permit the Secretary to enter into cooperative agreements and contracts for the purpose of increasing organ donation through approaches such as planning and conducting educational programs for the public, training individuals in requesting organ donations from the public, providing technical assistance to entities that can contribute to organ donation, and increasing organ donation and access to transplantation for populations experiencing organ shortages.

The bill would require organ procurement organizations (OPO's) to conduct and participate in systematic efforts to increase the number of potential donors, including populations for which there is a greater degree of organ shortage than that of the general population. OPO's would have agreements with all of the health care entities with facilities for organ donation in their service areas to identify potential organ donors.

In addition, OPO's would allocate donated organs on the basis of lists that identify individuals medically referred to a transplant center in their service areas and who are on a waiting list for that organ. The list would encompass an entire service area, an entire state, an approved alternative local unit, or another allocation system that has been approved by the Network and the Secretary. The bill would also require OPO's to be members of the Network and abide by its rules and requirements.

Finally, S. 1324 would require the Board of Directors for the Network and the Boards of Directors for qualified OPO's to be composed of a reasonable balance of constituents, including transplant recipients, members of their families, medical providers, and others directly involved in providing organ transplant services.

Fees.—S. 1324 would permit the Network to continue assessing a patient registration fee for listing potential transplant recipients on its national organ matching system to cover the reasonable costs of operation. The proceeds of this fee could be spent without further Congressional action. Fee increases, however, would require approval by the Secretary, and spending would be subject to an annual audit.

The bill also would permit the Secretary to collect a new data management fee from transplant hospitals and OPO's. This fee would cover the costs of the operation and administration of the Scientific Registry and the costs of contracts and cooperative agreements that support efforts to increase organ donation. The data management fee would be set annually by the Network based on the number of transplants performed. CBO estimates that these fees would be about $1.8 million in 1997. The transplant center would pay 80 percent of the fee, and the OPO would pay the remaining 20 percent. Again, the proceeds from this fee could be spent without further Congressional action, but the expenditure of such funds would be subject to an annual audit.

The Secretary would annually withhold the larger of $250,000 or 10 percent of the receipts from the data management fee to be used to fund the contracts with qualified OPO's and other public or nonprofit private entities to increase organ donation. No contract in excess of $25,000 would be made unless approved by the Secretary.

Studies and Reports.—S. 1324 would require the Secretary to issue a final rule to establish the regulations for criteria under the Solid Organ Transplant Program within 1 year of the enactment of this act.

The Public Health Service would be directed to contract for a triennial report on each organ procurement organization that would include: information on the effectiveness of each OPO in acquiring potentially available organs, particularly among minority populations; data on the variation of procurement across hospitals within the OPO's region; a plan to increase procurement, particularly among populations for which there is a greater degree of organ shortage relative to the general population; and a plan to increase procurement at hospitals with low rates of procurement.

The Network would submit to the Secretary an annual report concerning the scientific and clinical status of organ donation and transplantation.

The bill also would require the Institute of Medicine to study the role and impact of the Federal Government in the oversight and support of solid organ transplantation. This study would be completed within 2 years after the date of enactment of this proposal.

Bone Marrow Transplant Program

S. 1324 specifies that the recruitment efforts for potential bone marrow donors would include the priority to increase potential marrow donors for which there is a greater degree of marrow donor shortage than that of the general population and the compilation and distribution of informational materials to educate and update potential donors.

The bill would permit the Secretary to enter into contracts with entities for the purpose of increasing unrelated allogeneic marrow transplants. This would enable such entities to: provide information and education on the availability of such transplants as a potential treatment option; provide information and education to the public on their availability and the need for donations of bone marrow; train individuals in requesting bone marrrow donations; and recruit, test, and enroll marrow donors with the priority being

groups for which there is a great degree of marrow donor shortage than that of the general population.

It would require the Donor Registry to provide information to physicians, other health care professionals, and the public regarding the availability of unrelated allogeneic marrow transplantation as a potential treatment option.

The Donor Registry would establish and maintain an office of patient advocacy and case management to assist patients and their physicians in a search for an unrelated donor and provide services as appropriate to assist individuals and physicians involved with the Donor Registry. The office would also collect and analyze data and perform patient surveys. The bill would require the Donor Registry to be updated annually to account for changes in potential donor status.

Finally, S. 1324 would require the board of directors of the Donor Registry and its committees to be composed of a reasonable balance of constituents including transplant recipients, members of their families, medical providers, and others directly involved in providing bone marrow transplant services.

Bone Marrow Scientific Registry.—S. 1324 would require the Secretary to establish and maintain a bone marrow scientific registry of all recipients of biologic unrelated allogeneic marrow donors. It would include information on these transplant recipients, transplant procedures, pre-transplant and transplant costs, and other information the Secretary determined to be necessary for evaluation of the scientific and clinical status of unrelated allogeneic marrow transplantation.

Studies and Reports.—S. 1324 would require the Institute of Medicine (IOM) to study the role of a national bone marrow transplant program supported by the Federal Government in facilitating the maximum number of unrelated marrow donor transplants. The IOM would also be directed to study other possible clinical or scientific uses of the potential donor pool or the accompanying information maintained by the Donor Registry or the unrelated marrow donor scientific registry. This study would be completed within two years after the date of enactment of the bill.

The bill would require the Secretary to evaluate the feasibility of integrating or consolidating all federally funded bone marrow transplantation scientific registries, regardless of the type of marrow reconstitution used. It would also require the Secretary to evaluate all federally funded bone marrow transplantation research to be conducted under the direction and administration of the peer review system of the National Institutes of Health.

Finally, within one year of the completion of the Bone Marrow Donor Inspection, performed by the Inspector General, the bill would require the marrow donor program to develop, evaluate, and implement a plan to streamline and make more efficient the relationship between the Donor Registry and donor centers based on the recommendations of the study.

7. Estimated cost to State and local governments: S. 1324 would impose a mandate on public hospitals with transplant centers by requiring them to pay a data management fee (discussed in section 6 of the cost estimate). In total, we expect that $1.8 million would be collected each year from this fee. Because payments from public

hospitals would represent a small percentage of these fees, the costs of complying with this mandate would not exceed the $50 million threshold. The bill would impose no other direct costs on state and local governments.

8. Estimated costs to the private sector: Title I, section 103, would impose two mandates on private sector entities. The patient registration fee (which the Network already collects) would impose costs on potential transplant recipients, and the new data management fee would impose costs on organ procurement organizations (OPO's) and transplant centers.

With respect to the patient registration fee, the bill would continue current practice. The Network already collects a one-time patient registration fee of $315, intended to cover its listing costs. In 1995, collections from this fee totaled about $10 million. The bill would not increase the costs of the private sector compared to the costs of carrying out Federal laws and regulations currently in effect.

The estimated cost of the newly imposed data management fee would be $1.8 million per year. Because part of the fee would be paid by public hospitals (who are not in the private sector), the cost of this mandate to private-sector entities would be somewhat less than $1.8 million per year.

9. Estimate comparison: None.

10. Previous estimate: None.

11. Estimate prepared by: Cyndi S. Dudzinski, Marc Nicole, Sandra Christensen.

12. Estimate approved by: Paul N. Van de Water, Assistant Director for Budget Analysis.

VI. Regulatory Impact Statement

The committee has determined that there will be no increase in the regulatory burden of paperwork as the result of this bill.

VII. Section-by-Section Analysis

Title I—Solid-Organ Transplant Program

Section 101 of the bill cites the short title as the "Solid-Organ Transplantation Program Act of 1995."

Section 102(a) of the bill amends section 371(a) of the Public Health Service Act (Organ Procurement Organizations) to authorize the Secretary of the Department of Health and Human Services (HHS) to enter into agreements or contracts with organ procurement organizations (OPO's) for the purpose of increasing organ donations through activities that include the following:

(a) planning and conducting programs designed to educate the public about the need for organ donations;

(b) training for individuals to request organ donations;

(c) providing technical assistance to OPO's and other groups that can contribute to organ donations;

(d) support for research and demonstration programs designed to increase organ donations;

(e) voluntary consolidation of OPO's and tissue banks; or

(f) increasing organ donation and access to transplantation among minority populations for which there is a greater degree of organ shortages relative to the general population. Under the new section 371, the Secretary shall give priority to increasing donations and improving consent rates among prospective donors as well as increasing donations from both OPO's and hospitals.

For purposes of this act, "tissue banks" shall not include eye banks.

Section 102(b)(1)(A) of the bill amends section 371(b) of existing law to modify the descriptor for an OPO.

Section 102(b)(1)(B) of the bill makes a technical amendment concerning paragraph alignment for subparagraph (E) of existing law.

Section 102(b)(1)(C) of the bill modifies section 371(b)(1)(G) of existing law specifying that hospital-based OPO's established before September 1993 may be directed by an advisory board. The bill requires that a "reasonable balance" of representatives sit on the OPO's board of directors and that transplant patients and/or family members of transplant donors sit on this board. The bill provides the following as examples of health care professionals who are qualified to be OPO board members, adding to the existing list: physicians or other health care professionals with knowledge and skill in the field of neurology, emergency medicine, or trauma surgery. In addition, physicians who are actively and directly involved in caring for the transplant patient would be qualified to become members of the OPO board of directors.

Section 102(b)(2) of the bill eliminates paragraph (2) in existing law that directed the Secretary to publish rules to establish criteria for determining whether an entity meets the requirements of an OPO, as set forth in the legislation.

Section 102(b)(3) of the bill redesignates (3) in existing law as paragraph (2).

Section 102(b)(4)(A) of the bill revises agreements required between OPO's and hospitals. Consequently, OPO's must have agreements with all hospitals in their service areas, unless they have been granted waivers by the Secretary.

Section 102(b)(4)(B) of the bill makes technical amendments, redesignating the order of paragraphs.

Section 102(b)(4)(C) of the bill adds new sections to existing law requiring OPO's to conduct and participate in systematic efforts to increase the number of potential donors, including minority populations (for which there is a greater degree of organ shortage than in of the general population). Also, OPO's will be required to abide by the rules of the federally supported Network.

Section 102(b)(4)(D) of the bill amends section 371(G) (as so redesignated) to require OPO's to adhere to an allocation system that utilizes:

(a) a single list that encompasses an entire service area;

(b) a list that encompasses at least an entire State;

(c) a list that encompasses an approved alternative local unit; or

(d) a list that encompasses another allocation system which has been approved by the Network and the Secretary.

Section 102(b)(4)(E) of the bill modifies the requirement for transplant center and OPO coordination, calling for increased involvement in activities to promote organ donation.

Section 102(b)(4)(F) of the bill directs OPO's to submit data to the Network concerning their effectiveness in organ procurement.

Section 102(b)(5) of the bill defines the term "alternative local unit" (as referred to in paragraph 371(b)(2)(G) of the amended law), and specifies the terms under which the Secretary may assign this classification. A local unit is:

(a) a unit composed of two or more OPO's; or

(b) a subdivision of an OPO that operates as a result of special geographic, rural, or minority population concerns but is not composed of any subunit of a metropolitan statistical area.

Section 102(c) of the bill indicates that current amendments to OPO requirements shall not affect provisions of section 1138(a) of the Social Security Act (42 U.S.C. 1320b–8(a)).

Section 102(d) of the bill establishes January 1, 1996, as the effective date for amendments to section 371(b) of the law as it applies to OPO's and the Network.

Section 103(a)(1) of the bill amends section 372(a) of the PHSA to assert findings by Congress. Congress finds that:

(a) it is in the public interest to maintain and improve the Federal network for organ sharing (the Network) and to assist OPOs with the distribution of organs for human transplantation;

(b) there should be a private-public partnership with a continued role for the Federal Government in providing oversight and assistance for services provided by the Network; and

(c) the Federal Government should actively oversee activities of the Network to ensure that its policies and procedures for procuring and distributing organs are fair, efficient, and in compliance with all applicable laws and standards. However, primary responsibility for establishing medical criteria and standards for organ procurement and transplantation reside with the Network.

Section 103(a)(2) of the bill directs the Secretary to provide contracts for operation of the Network as stipulated in Section 372(b) of the PHSA (Organ Procurement and Transplantation Network).

Section 103(a)(3) of the bill establishes the Network as a private entity that has experience in organ procurement and transplantation whose main purpose is to encourage organ donation, maintain a waiting list, and operate and monitor an equitable and effective system for allocating organs to transplant recipients.

Section 103(a)(4) of the bill directs the Network to assess a patient registration fee (to be collected by the contractor), in an amount that is reasonable, customary, and determined by the Network, and approved by the Secretary of HHS. The fees are to be calculated so that they may cover the Network's reasonable cost of operation. The Secretary will have 60 days to respond to a proposed patient registration fee schedule.

Section 103(a)(5) of the bill requires that increases in the patient registration fees be limited to:

(a) increases in the level or cost of contract tasks and other activities related to organ procurement and transplantation; or

(b) decreases in expected revenue from patient registration fees available to the contractor.

Section 103(a)(6) of the bill requires that fees collected by the Network be available as needed, without fiscal year limitation. Fees are subject to annual audit under the provisions of the Office of Management and Budget Circular No. A–133, entitled "Audits of Institutions of Higher Learning and Other Nonprofit Institutions." A report concerning the audit and recommendations regarding expenditures will be submitted to the Network, the contractor, and the Secretary.

Section 103(a)(7) of the bill directs the Secretary to collect a data management fee from transplant hospitals and OPO's. Data management fees are intended to cover:

(a) the costs of operating and administering the Scientific Registry; and

(b) the costs of contracts and cooperative agreements to support efforts to increase organ donation. The data management fees will be set annually by the Network in an amount determined by the Network in consultation with the Secretary. These fees will be calculated so that the per-transplant data management fee is divided into two: the patient-specific transplant center will pay 80 percent, and the procuring organ procurement organization will pay 20 percent of the transplant data management fee. These fees will be available to the Secretary and the contractor operating the Scientific Registry without fiscal year limitation. Expenditures of the data management fees by the contractor are subject to annual independent audit and reported along with recommendations to the Network, the contractor, and the Secretary.

Section 103(a)(8) of the bill authorizes the Secretary and the Comptroller General to have access to all data collected by the contractor in carrying out its responsibilities under the contract.

Section 103(b)(1) of the bill amends section 372(b)(1)(B) of the current law by stipulating additional requirements for the Network. The Network must include on its board of directors the following:

(a) "a reasonable portion" of individuals who have received an organ transplant; individuals who are part of the family of organ transplant patients or transplant candidates; and individuals who are part of the family of those who have been organ donors or recipients; and

(b) the Division of Transplantation of the Bureau of Health Resources Development (the Health Resources and Services Administration) shall be represented at all meetings except for those pertaining to the Network contractor's internal business.

Also, the Network is required to have a patient affairs committee and a minority affairs committee. Section 372(b)(1)(B) is also amended to require representation by a member of the Division of Organ Transplantation of the Bureau of Health Resources Development (the Health Resources and Services Administration) at all meetings of all committees of the Network. The board of directors may also include members from OPO's and physicians or other health care professionals with knowledge about organ transplantation.

Section 103(b)(2) of the bill states requirements for operation of the Network. It directs the Network to establish within all OPO's (with respect to each type of transplant) a national list of individ-

uals who have been medically referred to receive a transplant, including the names of patients on the lists in effect under section 371(b)(2)(G). The Network is further directed to establish membership criteria and medical criteria for organ allocation and to provide members of the public an opportunity for public comment. The Network is charged with assisting and monitoring OPO's in the equitable distribution of organs among transplant patients. A new requirement directs the Network to make recommendations to OPO's and the Secretary for increasing organ donations based on effectiveness data submitted by OPO's, under new section 371(b)(2)(L). Other new responsibilities for the Network are to: (1) submit biennial reports to the Secretary containing information on patient outcomes at each transplant center affiliated with the Network, including survival information, waiting list information, and information pertaining to the qualifications and experience of transplant surgeons and physicians affiliated with the Network program; (2) submit to the Secretary justification for any proposed increase in patient registration fees; (3) make available to the Secretary information about the Network; (4) submit to the Secretary an annual report on the scientific and clinical status of organ donation and transplantation; and (5) comply with other requirements established by the Secretary.

Section 103(c) of the bill amends section 372(c) of the PHSA authorizing the Secretary to work through, work with, and direct the Network contractor to define priorities and respond to new emerging issues and problems.

Section 103(d) instructs the Network contractor, in consultation with the Network, within 1 year of completion of the study, to implement the IOM study recommendation with respect to the expansion of public access to Network committees and board of directors.

Section 103(e) instructs the Secretary to publish a final rule establishing regulations for criteria under part H of title III of the PHSA within one year of enactment, with consideration of the policies and bylaws of the Network. Failure to issue regulations by the statutory date will require the Secretary to issue, within 30 days of the deadline, a report to the Congress describing the reasons for failure to comply with the law and the steps which are being implemented to bring the Department into compliance.

Section 104 amends section 374 of the PHSA to establish terms and conditions for contracts entered into under section 371 of the PHSA. A limit of $250,000 (or 10 percent of the amount) of data management fees collected under section 372 (whichever is greater) is to be used to fund contracts described in section 371. No contract in excess of $25,000 is to be made using funds withheld under subsection (c)(1) unless an application has been submitted to the Secretary, recommended by the Network, and approved by the Secretary.

Section 105 of the bill amends section 375 of the PHSA (Administration) by assigning the Secretary responsibility to oversee the Network in carrying out its administrative function. The Secretary will prepare, through contract, a triennial report on OPO-specific data that includes:

(a) data about the effectiveness of OPO's in procuring organs, particularly among minority populations;

(b) data concerning the variation of procurement across hospitals within the OPO region;

(c) a plan to increase organ procurement, particularly among minority populations, for which there is a greater degree of organ shortage relative to the general population; and

(d) a plan to increase procurement at hospitals with low rates of procurement.

Section 106 of the bill amends section 377 of the PHSA and calls for the Institute of Medicine to conduct a study and an evaluation of:

(a) the role and impact of the Federal Government in the oversight and support of solid-organ transplantation, the Network, and the solid-organ Scientific Registry; and

(b) the access of all interested constituencies and organizations to membership on the Network's board of directors and all committees.

If the IOM declines to conduct this study and evaluation, the Secretary shall appoint another public or nonprofit group to do it. Within 2 years of enactment of the bill, the completed study shall be submitted to the Senate Committee on Labor and Human Resources.

Section 107(a) of the bill further amends section 374 of the PHSA and replaces in all parts of section 374, the word "contracts" for "grants." The monetary limit of $100,000 for which OPO grants may be awarded is removed.

Section 107(b) of the bill repeals sections 376 (Report) and 378 (Authorization of Appropriations) of the PHSA.

Section 108 of the bill amends part H of title III of the PHSA by adding "Sec. 378. Authorization of Appropriations." There are authorized to be appropriated to carry out sections 371, 372, and 373, $1,950,000 for fiscal year 1997, and $1,100,000 for fiscal year 1998, and to carry out section 371, $250,000 for each of the fiscal years 1999 through 2001.

Section 109 of the bill specifies that the amendments made by this title are effective on the date of enactment.

Title II—Bone Marrow Donor Program

Section 201 of the bill cites the short title as the "Bone Marrow Transplantation Program Reauthorization Act of 1995."

Section 202(a) of the bill amends section 379(b) of the PHSA (National Marrow Donor Registry) to reauthorize the National Bone Marrow Donor Registry. Section 202(a)(1) amends 379(a) to establish that the primary purpose of the Donor Registry is to increase the number of unrelated donor marrow transplants, as specified by the bill. Section 379(a) of the Public Health Service Act (PHSA) is amended to set term limits for those serving as members of the board of directors for the National Marrow Donor Registry. Members may serve for 2-year terms, for as many as three consecutive terms. To ensure continuity of the composition of the board, the maximum number of newly appointed members in any given year is limited such that not more than one-third are selected in any given year. Board-appointed members of committees are limited to 2 years, with one-third of the members of each committee subject each year to replacement and with no member serving more than

three consecutive 2-year terms. The board and committees are required to be composed of a reasonable balance of representatives of donor centers, transplant centers, blood banks, marrow transplant recipients, and individuals who are family members of an individual who has required, received, or is registered with the Donor Registry to become a recipient of a bone marrow transplant. In addition, the bill requires board representation from the Naval Medical Research and Development Command and the Division of Organ Transplantation of the Bureau of Health Resources Development (of the Health Resources and Services Administration).

Section 202(b) of the bill amends the functions of the Federal program for the Donor Registry, under section 379(b) of the existing law, requiring that patients and physicians thoroughly integrate resources available to the Donor Registry Program (i.e., patient advocacy and case management office, and other marrow donor registries). The bill requires the Donor Registry to establish a program for recruiting new bone marrow donors that will focus on: (1) increasing minority donors, since there is a greater degree of marrow donor shortage among this group than among the general population, and (2) compiling and distributing information and materials to increase awareness among the general population. This new section amends PHSA to require the Donor Registry to update annually donor listings and to require the Secretary of the Department of Health and Human Services (HHS) to develop, evaluate, and implement a plan to streamline and enhance the efficiency of the relationship between the Donor Registry and donor centers upon completion of the "Bone Marrow Program Inspection."

Section 202(c) of the bill amends section 379 to create an information and education program calling for the Secretary to award contracts to public or nonprofit private groups to engage in education and training activities in the community for the purpose of increasing unrelated allogeneic marrow transplants. Priorities for award distribution will be given to those projects aimed at increasing marrow donations among minority populations.

Section 202(d) of the bill further amends Section 379 of the current law to direct the Donor Registry to establish a new Office of Patient Advocacy and Case Management. Functions include: (1) leadership by a director-advocate serving in the interest of patients, physicians, and potential marrow donors; (2) creation and maintenance of a system for patient advocacy that assists patients, their families, and physicians in search of an unrelated marrow donor; (3) provision of individual case management services to patients, their families, and physicians; (4) collection and analysis of data about the search process (from search to transplantation), including costs incurred by patients prior to transplantation; (5) evaluations of patient satisfaction with the search process; and (6) provision of individual case-management services to marrow donors. The Secretary is directed to evaluate the office of patient advocacy and case management and make recommendations concerning the success or failure of this new office and its impact on the assistance to individuals in proceeding to marrow transplantation. Subsequently, the Secretary shall release a report on the foregoing evaluation by April 1, 1996.

Section 202(e) of the bill amends section 379A to read: "Sec. 379A. Studies, Evaluations, and Reports."

The new section 379A(a) authorizes the Secretary of HHS to enter into a contract with a public or nonprofit private organization to do a study and evaluation of: (1) the role of the federally supported bone marrow transplant program in facilitating the maximum number of unrelated marrow donor transplants; and (2) other uses for the potential donor pool or accompanying information maintained by the Donor Registry. In addition, at the request of the Secretary, the Institute of Medicine (IOM) of the Academy of Sciences shall conduct the aforementioned study. If the IOM refuses, the Secretary shall arrange for another group to conduct the study as specified by law. Upon completion of the study, either the IOM or (other entity as the case may be) is required to submit a report to the Senate Committee on Labor and Human Resources.

Section 379A(b) directs the Secretary to conduct a study on: (1) the evaluation of the feasibility of consolidating all federally funded bone marrow transplantation scientific registries; and (2) the evaluation of all federally funded bone marrow transplantation research conducted by the National Institutes of Health. The term "marrow reconstitution" is defined as encompassing all sources of blood cells, including marrow (autologous, related or unrelated allogeneic, syngeneic), autologous marrow, allogeneic marrow (biologically related or unrelated), umbilical cord blood cells, peripheral blood progenitor cells, or other approaches that may be utilized.

Section 202(f) of the bill amends part I of title III of the PHSA by adding the following new section: "Sec. 379B. Bone Marrow Scientific Registry."

The new section 379B(a) directs the Secretary of HHS to establish and maintain a Scientific Registry of all recipients of biologically unrelated allogeneic marrow donors.

Section 379B(b) defines the type of information the newly created Bone Marrow Scientific Registry is obligated to maintain. The Scientific Registry must collect information about biologically unrelated allogeneic marrow transplants, transplant procedures, pretransplant and transplant costs, and other information the Secretary deems necessary.

Section 379B(c) requires the Donor Registry to submit to the Secretary on an annual basis a report using data collected and maintained by the marrow transplantation Scientific Registry containing information about patient outcomes with respect to each transplant center, and pretransplant comparative costs involved.

Section 379B(g) of the bill amends part I of title III of the PHSA by adding the following new section: "Sec. 379C. Authorization of Appropriations." This section authorizes to be appropriated, for activities specified under section 379, totals of $13,500,000 for fiscal year 1997, $12,150,000 for fiscal year 1998, and such sums as may be necessary for fiscal year 1999.

VIII. 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 mat-

ter is printed in italic, existing law in which no change is proposed is shown in roman):

* * * * * * *

PUBLIC HEALTH SERVICE ACT

ORGAN AND BONE MARROW TRANSPLANT PROGRAM REAUTHORIZATION ACT OF 1995

* * * * * * *

ORGAN PROCUREMENT ORGANIZATIONS

SEC. 371. [(a)(1) The Secretary may make grants for the planning of qualified organ procurement organizations described in subsection (b).

[(2) The Secretary may make grants for the establishment, initial operation, consolidation, and expansion of qualified organ procurement organizations described in subsection (b).

[(3) The Secretary may make grants to, and enter into contracts with, qualified organ procurement organizations described in subsection (b) and other nonprofit private entities for the purpose of carrying out special projects designed to increase the number of organ donors.]

(a)(1) The Secretary may enter into cooperative agreements and contracts with qualified organ procurement organizations described in subsection (b) and other public or nonprofit private entities for the purpose of increasing organ donation through approaches such as—

(A) the planning and conducting of programs to provide information and education to the public on the need for organ donations:

(B) the training of individuals in requesting such donations:

(C) the provision of technical assistance to organ procurement organizations and other entities that can contribute to organ donation;

(D) the performance of research and the performance of demonstration programs by organ procurement organizations and other entities that may increase organ donation;

(E) the voluntary consolidation of organ procurement organizations and tissue banks or

(F) increasing organ donation and access to transplantation with respect to populations for which there is a greater degree of organ shortages relative to the general population.

(2)(A) In entering into cooperative agreements and contracts under subparagraphs (A) and (B) of paragraph (1), the Secretary shall give priority to increasing donations and improving consent rates for the purpose described in such paragraph.

(B) In entering into cooperative agreements and contracts under paragraph (1)(C), the Secretary shall give priority to carrying out the purpose described in such paragraph with respect to increasing donations from both organ procurement organizations and hospitals.

(b) QUALIFIED ORGANIZATIONS.

(1) A qualified organ procurement organization [for which grants may be made under subsection (a)] *described in this section* is an organization which, as determined by the Secretary, will carry out the functions described in [paragraph (2)] *Paragraph (3)* and—

* * * * * * *

[(E)]
(*E*) * * *

* * * * * * *

(G) has a board of [directors or an advisory board] *directors (or an advisory board, in the case of a hospital-based organ procurement organization established prior to September 1, 1993)* which—

(i) is [composed of] *composed of a reasonable balance of—*

* * * * * * *

(II) members who represent the public residing in such area *including individuals who have received a transplant of an organ (or transplant candidates), and individuals who are part of the family of an individual who has donated or received an organ or who is a transplant candidate,*

* * * * * * *

[(IV)] a physician with knowledge or skill in the field of neurology, and]

(IV) physicians or other health care professionals with knowledge and skill in the field of neurology, emergency medicine, or trauma surgery

(V) from each transplant center in its service area which has arrangements described in paragraph (2)(G) with the organization, [a member who is a surgeon who has practicing privileges in such center and who performs organ transplant surgery,] *a member who is a surgeon or physician who has privileges to practice in such centers and who is actively and directly involved in caring for transplant patients,*

* * * * * * *

[(2)(A) Not later than 90 days after the date of enactment of this paragraph, the Secretary shall publish in the Federal Register a notice of proposed rulemaking to establish criteria for determining whether an entity meets the requirement established in paragraph (1)(E).

(B) Not later than 1 year after the date of enactment of this paragraph, the Secretary shall publish in the Federal Register a final rule to establish the criteria described in subparagraph (A).]

[(3)] *(2)* An organ procurement organization shall—

(A) have effective agreements, to identify potential organ donors, with [a substantial majority] *all* of the hospitals and other health care entities in its service area which

have facilities for organ [donations] *donation,unless they have been previously granted by the Secretary a waiver from paragraph (1)(A) or have waivers pending under section 1138 of the Social Security Act, except that the Secretary may waive the requirements of this subparagraph upon the request of the organ procurement organization if the Secretary determines that such an agreement would not be helpful in promoting organ donation,*

(B) conduct and participate in systematic efforts including public education, to increase the number of potential donors, including populations for which there is a greater degree of organ shortage than that of the general population,

(C) be a member of and abide by the rules and requirements of the Organ Procurement and Transplantation Network (referred to in this part as the 'Network') established under section 372,

[(B)] *(D)* conduct and participate in systematic efforts, including professional education, to acquire all useable organs from potential donors,

[(C)] *(E)* arrange for the acquisition and preservation of donated organs and provide quality standards for the acquisition of organs which are consistent with the standards adopted by the Organ Procurement and Transplantation Network under section 372(b)(2)(E), including arranging for testing with respect to preventing the acquisition of organs that are infected with the etiologic agent for acquired immune deficiency syndrome,

[(D)] *(F)* arrange for the appropriate tissue typing of donated organs,

[(E)] *(G)* have a system to allocate donated organs equitably among transplant patients according to established medical criteria, *which system shall, at a minimum, allocate each type of organ on the basis of—*

(i) a single list encompassing the entire service area;

(ii) a list that encompasses at least an entire State;

(iii) a list that encompasses an approved alternative local unit (as defined in paragraph (3)) that is approved by the Network and the Secretary, or

(iv) a list that encompasses another allocation system which has been approved by the Network and the Secretary,

of individuals who have been medically referred to a transplant center the service area of the organization in order to receive a transplant of the type of organ with respect to which the list is maintained and had been placed on an organ specific waiting list;

[(F)] *(H)* provide or arrange for the transportation of donated organs to transplant centers,

[(G)] *(I)* have arrangements to coordinate its activities with transplant centers in its service area *and work with local transplant centers to ensure that such centers are actively involved with organ donation efforts,*

[(H)] *(J)* participate in the Organ Procurement Transplantation Network established under section 372,

[(I)] *(K)* have arrangements to cooperate with tissue banks for the retrieval, processing, preservation, storage, and distribution of tissues as may be appropriate to assure that all useable tissues are obtained from potential donors,

[(J)] *(L)* evaluate annually *and submit data to the Network contractor on the effectiveness of the organization,* the effectiveness of the organization in acquiring potentially available organs, and

[(K)] *(M)* assist hospitals in establishing and implementing protocols for making routine inquiries about organ donation by potential doors.

(3)(A) As used in paragraph (2)(G), the term 'alternative local unit' means—

(i) a unit composed of two or more organ procurement organizations; or

(ii) a subdivision of an organ procurement organization that operates as a distinct procurement and distribution unit as a result of special geographic, rural, or population concerns but that is not composed of any subunit of a metropolitan statistical area.

(B) The Network shall make recommendations to the Secretary concerning the approval or denial of alternative local units. The Network shall assess whether the alternative local units will better promote organ donation and the equitable allocation of organs.

(C) The Secretary shall approve or deny any alternative local unit designation recommended by the Network. The Secretary shall have 60 days, beginning on the date on which the application is submitted to the Secretary, to approve or deny the recommendations of the Network under subparagraph (B) with respect to the application of the alternative local unit.

ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK

SEC. 372. [(a) The Secretary shall by contract provide for the establishment and operation of an Organ Procurement and Transplantation Network which meets the requirements of subsection (b). The amount provided under such contract in any fiscal year may not exceed $2,000,000. Funds for such contracts shall be made available from funds available to the Public Health Service from appropriations for fiscal years beginning after fiscal year 1984.]

(a) (1) Congress finds that—

(A) it is in the public interest to maintain and improve a durable system for promoting and supporting a central network to assist organ procurement organizations in the nationwide distribution of organs among transplant patients;

(B) it is desirable to continue the partnership between public and private enterprise, by continuing to provide Federal Government oversight and assistance for services performed by the Network; and

(C) the Federal Government should actively oversee Network activities to ensure that the policies and procedures of the Network for serving patient and donor families and procuring and

distributing organs are fair, efficient and in compliance with all applicable legal rules and standards; however, the initiative and primary responsibility for establishing medical criteria and standards for organ procurement and transplantation still resides with the Network.

(2) The Secretary shall provide by contract for the operation of the Network which shall meet the requirements of subsection (b).

(3) The Network shall be recognized as a private entity that has an expertise in organ procurement and transplantation with the primary purposes of encouraging organ donation, maintaining a 'wait list', and operating and monitoring an equitable and effective system for allocating organs to transplant recipients, and shall report to the Secretary instances of continuing noncompliance with policies (or when promulgated, rules) and requirements of the Network.

(4) The Network may assess a fee (to be known as the 'patient registration fee'), to be collected by the contractor for listing each potential transplant recipient on its national organ matching system, in an amount which is reasonable and customary and determined by the Network and approved as such by the Secretary. The patient registration fee shall be calculated so as to be sufficient to cover the Network's reasonable costs of operation in accordance with this section. The Secretary shall have 60 days, beginning on the date on which the written application justifying the proposed fee as reasonable is submitted to the Secretary, to provide the Network with a written determination and rationale for such determination that the proposed increase is not reasonable and customary and that the Secretary disapproves the recommendation of the Network under this paragraph with respect to the change in fee for listing each potential transplant recipient.

(5) Any increase in the patient registration fee shall be limited to an increase that is reasonably required as a result of—

(A) increases in the level or cost of contract tasks and other activities related to organ procurement and transplantation; or

(B) decreases in expected revenue from patient registration fees available to the contractor.

The patient registration fees shall not be increased more than once during each year.

(6) All fees collected by the Network contractor under paragraph (4) shall be available to the Network without fiscal year limitation. The contract with the Network contractor shall provide that expenditures of such funds (including patient registration fees collected by the contractor and or contract funds) are subject to an annual audit under the provisions of the Office of Management and Budget Circular No. A–133 entitled 'Audits of Institutions of Higher Learning and Other Nonprofit Institutions' to be performed by the Secretary or an authorized auditor at the discretion of the Secretary. A report concerning the audit and recommendations regarding expenditures shall be submitted to the Network, the contractor, and the Secretary.

(7) The Secretary may institute and collect a data management fee from transplant hospitals and organ procurement organizations. Such fees shall be directed to and shall be sufficient to cover—

(A) the costs of the operation and administration of the Scientific Registry in accordance with the contract under section 373; and

(B) the costs of contracts and cooperative agreements to support efforts to increase organ donation under section 371.

Such data management fees shall be set annually by the Network in an amount determined by the Network, in consultation with the Secretary, and approved by the Secretary. Such data management fee shall be calculated to be sufficient to cover the reasonable costs of operation in accordance with section 373. Such data management fee shall be calculated based on the number of transplants performed or facilitated by each transplant hospital or center, or organ procurement organization. The per transplant data management fee shall be divided so that the patient specific transplant center will pay 80 percent and the procuring organ procurement organization will pay 20 percent of the per transplant data management fee. Such fees shall be available to the Secretary and the contractor operating the Scientific Registry without fiscal year limitation. The expenditure (including fees or contract funds) of such fees by the contractor shall be subject to an annual independent audit (performed by the Secretary or an authorized auditor at the discretion of the Secretary) and reported along with recommendations regarding such expenditures, to the Network, the contractor and the Secretary.

(8) The Secretary and the Comptroller General shall have access to all data collected by the contractor or contractors in carrying out its responsibilities under the contract this section and section 373.

(b)(1)(B)(i) that includes representatives of organ procurement organizations **[**(including organizations that have received grants under section 371)**]**, transplant centers, voluntary health associations, and the general public**[**; and**]** *(including both individuals who have received a transplant of an organ (or transplant candidates), individuals who are part of the family of individuals who have donated or received an organ, the number of whom shall make up a reasonable portion of the total number of board members), and the Division of Organ Transplantation of the Bureau of Health Resources Development (the Health Resources and Services Administration) shall be represented at all meetings except for those pertaining to the Network contractor's internal business;*

(ii) that shall establish an executive committee and other committees *including a patient affairs committee and a minority affairs committee,* whose chairpersons shall be selected to ensure continuity of leadership for the board**[**.**]***;*

(iii) that shall include representation by a member of the Division of Organ Transplantation of the Bureau of Health Resources Development (the Health Resources and Services Administration) as a representative at all meetings (except for those portions of committee meetings pertaining to the Network contractor's internal business) of all committees (including the executive committee, finance committee, nominating committee, and membership and professional standards committee) under clause (ii);

(iv) that may include a member from an organ procurement organization on all committees under clause (ii); and

(v) that may include physicians or other health care professionals with knowledge and skill in the field of neurology, emergency medicine, and trauma surgery on all committees under clause (ii).

(2) The Organ Procurement and Transplantation Network shall—

(A) establish in one location [or through regional centers] *and at each Organ Procurement Organization—*

[(i) a national list of individuals who need organs, and]

(i) with respect to each type of transplant, a national list of individuals who have been medically referred to receive a transplant of the type of organs with respect to which the list is maintained (which list shall include the names of all individuals included on lists in effect under section 371(b)(2)(G)), and

* * * * * * *

(B) establish membership criteria, *including requirements under section 371(b),* and medical criteria for allocating organs and provide to members of the public an opportunity to comment with respect to such criteria,

* * * * * * *

(E) assist and monitor organ procurement organizations in the equitable distribution of organs among transplant patients,

[(E)] *(F)* adopt and use standards of quality for the acquisition and transportation of donated organs, including standards for preventing the acquisition of organs that are infected with the etiologic agent for acquired immune deficiency syndrome,

[(F)] *(G)* prepare and distribute, on a regionalized basis (and, to the extent practicable, among regions or on a national basis), samples of blood sera from individuals who are included on the list and whose immune system makes it difficult for them to receive organs, in order to facilitate matching the compatibility of such individuals with organ donors,

[(G)] *(H)* coordinate, as appropriate, the transportation of organs from organ procurement organizations to transplant centers,

[(H)] *(I)* provide information to physicians and other health professionals regarding organ donation,

[(I)] *(J)* collect, analyze, and publish data concerning organ donation and transplants,

[(J)] *(K)* carry out studies and demonstration projects for the purpose of improving procedures for organ procurement and allocation, [and]

[(K)] *(L)* work actively to increase the supply of donated organs[.]*, including making recommendations to organ procurements organizations and the Secretary based on data submitted to the network under section 371(b)(2)(L),*

[(L)] *(M)* submit to the Secretary an [annual] *biennial* report containing information on [the comparative costs and] patient outcomes at each transplant center affiliated with the organ procurement and transplantation network[.]*, including survival information, waiting list information, and information pertaining to the qualifications and experience of transplant surgeons and physicians affiliated with the specific Network programs,*

(N) submit to the Secretary for approval a written notice containing a justification, as reasonable and customary, of any proposed increase in the patient registration fees as maintained under subparagraph (A)(i), such change to be considered as so

approved in the Secretary does not provide written notification otherwise prior to the expiration of the 60-day period beginning on the date on which the notice of proposed change is submitted to the Secretary,

(O) make available to the Secretary such information, books, and records regarding the Network as the Secretary may require,

(P) submit to the Secretary, in a manner prescribed by the Secretary, an annual report concerning the scientific and clinical status of organ donation and transplantion, and

(Q) meet such other criteria regarding compliance with this part as the Secretary may establish.

(c) The Secretary shall establish procedures for—

(1) receiving for interested persons critical comments relating to the manner in which the Organ Procurement and Transplantation Network is carrying out the duties of the Network under subsection (b); [and]

(2) the consideration by the Secretary of such critical comments[.]*;*

(3) working through and with, the Network contractor to define priorities; and

(4) working through, working with, and directing the Network contractor to respond to new emerging issues and problems.

(d) Expansion of Access to Committees and Board of Directors.—Not later than 1 year after the completion of the Institute of Medicine report required under section 377, the Network contractor, in consultation with the Network and the Secretary, shall present to the Secretary and the appropriate committees of Congress, a plan to implement the study recommendations relating to the access of all interested constituencies and organizations to membership on the Network Board of Directors and all of its committees. Ensuring the reasonable mix of all populations shall be a priority of the plan for implementation.

* * * * * * *

GENERAL PROVISIONS RESPECTING [GRANTS AND] CONTRACTS

SEC. 374. (a) No [grant may be made under this part or contract] *contract may be* entered into under section 372 or 373 unless an application therefore has been submitted to, and approved by, the Secretary. Such an application shall be in such form and shall be submitted in such manner as the Secretary shall by regulation prescribe.

(b)(1) A [grant] *contract* for planning section 371(a)(1) may be made for one year with respect to any organ procurement organization [and may not exceed $100,000].

[(2) Grants under section 371(a)(2) may be made for [two years] *three years.* No such grant may exceed $500,000 for any year and no organ procurement organization may receive more than $800,000 for initial operation or expansion.]

[(3)] *(2)* [Grants or contracts] *Contracts* under section [371(a)(3)] *371(a)(2)* may be mode for not more than 3 years.

(c)*(1) The Secretary shall annually withhold not to exceed $250,000 or 10 percent of the amount of the data management fees collected under section 372 (whichever is greater) to be used to fund contracts as described in section 371.*

[(1)**]** *(2)* The Secretary shall determine the amount of a **[**grant or**]** contract made under section 371 or 373. Payments under such **[**grants and**]** contracts may be made in advance on the basis of estimates or by the way of reimbursement, with necessary adjustments on account of underpayments or overpayments, and in such installments and on such terms and conditions as the Secretary finds necessary to carry out the purposes of such grants and contracts.

[(2)**]** *(3)* (A) Each recipient of a **[**grant or**]** contract under section 371 or 373 shall keep such records as the Secretary shall prescribe, including records which fully disclose the amount and disposition by such recipient of the proceeds of such **[**grant or**]** contract, the total cost of the undertaking in connection with which such **[**grant or**]** contract was made, and the amount of that portion of the cost of the undertaking supplied by other sources, and such other records as will facilitate an effective audit.

(B) The Secretary and the Comptroller General of the United States, or any of their duly authorized representatives, shall have access for the purpose of audit and examination to any books, documents, papers, and records of the recipient of a **[**grant or**]** contract under section 371 or 373 that are pertinent to such **[**grant or**]** contract.

[(d)**]** *(e)* * * *

(d) No contract in excess of $25,000 may be made under this part using funds withheld under subsection (c)(1) unless an application for such contract has been submitted to the Secretary, recommended by the Network and approved by the Secretary. Such an application shall be in such form and be submitted in such a manner as the Secretary shall prescribe.

* * * * * * *

(2) The term "organ" means the human kidney, liver, heart, lung, pancreas, and any other human organ (other than corneas and eyes) specified by the Secretary by regulation **[**and for purposes of section 373, such term includes bone marrow**]**.

* * * * * * *

SEC. 375. The Secretary shall designate and maintain an identifiable administrative unit in the Public Health Service to *oversee the Network, the Scientific Registry and to—*

* * * * * * *

(3) provide technical assistance to organ procurement organizations, the Organ Procurement and Transplantation Network established under section 372, and other entities **[**in the health care system**]** involved in organ donations, procurement, and transplants, **[**and**]**

(4)(ii) to patients and their families about the resources available nationally and in each State, and the comparative costs and patient outcomes at each transplant center affiliated with the organ procurement and transplantation network, in

order to assist the patients and families with the costs associated with transplantation[.]*; and*

(5) through contract, prepare a triennial organ procurement organization specific data report (the initial report to be completed not later than 18 months after the date of enactment of this paragraph) that includes—

(A) data concerning the effectiveness of each organ procurement organization in acquiring potentially available organs, particularly among minority populations;

(B) data concerning the variation of procurement across hospitals within the organ procurement organization region;

(C) a plan to increase procurement, particularly among populations for which there is a greater degree of organ shortages relative to the general population; and

(D) a plan to increase procurement at hospitals with low rates of procurement.

* * * * * * *

[SEC. 376. Not later than February 10 of 1991 and of each second year thereafter, the Secretary shall publish, and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate, a report on the scientific and clinical status of organ transplantation. The Secretary shall consult with the Director of the National Institutes of Health and the Commissioner of the Food and Drug Administration in the preparation of the report.]

[SEC. 377. STUDY BY GENERAL ACCOUNTING OFFICE.

[(a) IN GENERAL.—The Comptroller General of the United States shall conduct a study for the purpose of determining—

[(1) the extent to which the procurement and allocation of organs have been equitable, efficient, and effective;

[(2) the problems encountered in the procurement and allocation; and

[(3) the effect of State required-request laws.

[(b) REPORT.—Not later than January 7, 1992, the Comptroller General of the United States shall complete the study required in subsection (a) and submit to the Committee on Energy and Commerce of the House of Representatives, and to the Committee on Labor and Human Resources of the Senate, a report describing the findings made as a result of the study.]

SEC. 377. STUDY AND REPORT.

(a) EVALUATION BY THE INSTITUTE OF MEDICINE.—

(1) IN GENERAL.—The Secretary shall enter into a contract with a public or nonprofit private entity to conduct a study and evaluation of—

(A) the role of and the impact of the Federal Government in the oversight and support of solid-organ transplantation, the Network (which on the date of enactment of this section carries out its functions by government contract) and the solid organ transplantation scientific registry; and

(B) the access of all interested constituencies and organizations to membership on the Network board of directors and all Network committees.

(2) INSTITUTE OF MEDICINE.—The Secretary shall request the Institute of Medicine of the National Academy of Sciences to enter into the contract under paragraph (1) to conduct the study and evaluation described in such paragraph. If the Institute declines to conduct the study and evaluation under such paragraph, the Secretary shall carry out such activities through another public or nonprofit private entity.

(b) REPORT.—Not later than 2 years after the date of enactment of this section, the Institute of Medicine (or other entity as the case may be) shall complete the study required under subsection (a)(1) and prepare and submit to the Committee on Labor and Human Resources of the Senate, a report describing the findings made as a result of the study.

[Sec. 378. For the purpose of carrying out this part, there are authorized to be appropriated $8,000,000 for fiscal year 1991, and such sums as may be necessary for each of the fiscal years 1992 and 1993.]

SEC. 378. AUTHORIZATION OF APPROPRIATIONS

There are authorized to be appropriated to carry out sections 371, 372, 375 and 377, $1,950,000 for fiscal year 1997, and $1,100,000 for fiscal year 1998, and to carry out section 371, $250,000 for each of the fiscal years 1999 through 2001.

* * * * * * *

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''] *'Donor Registry'*) *the primary purpose of which shall be increasing unrelated donor marrow transplants,* 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 that shall include representatives of marrow donor centers, marrow transplant centers, persons with expertise in the social science, and the general public. *With respect to the board of directors—*

(1) each member of the board shall serve for a term of 2 years, and each such member may serve as many as three consecutive 2-year terms;

(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) to ensure the continuity of the board, not more than one-third of the board shall be composed of members newly appointed each year;

(4) all appointed and elected positions within committees established by the board shall be for 2-year periods;

(5) the terms of approximately one-third of the members of each such committee will be subject each year to reappointment or replacement;

(6) no individual shall serve more than three consecutive 2-year terms on any such committee; and

(7) the board and committees shall be composed of a reasonable balance of representatives of donor centers, transplant centers, blood banks, marrow transplant recipients, individuals

who are family members of an individual who has required, received, or is registered with the Donor Registry to become a recipient of a transplant from a biologically unrelated marrow donor, with nonvoting representatives from the Naval Medical Research and Development Command and the Division of Organ Transplantation of the Bureau of Health Resources Development (of the Health Resources and Services Administration).

* * * * * * *

(b)(2) [establish a system for patient advocacy, separate from mechanisms for donor advocacy, that directly assists] *integrate the activities of the patient advocacy and case management office established under subsection (k) with the remaining Donor Registry functions by making available information on (A) the resources available through the Donor Registry Program, (B) the comparative costs incurred by patients prior to transplant, and (C) the marrow donor registries that meet the standards described in paragraphs (3) and (4) of subsection (c), to assist* patients, their families, and their physicians in the search for an unrelated marrow donor.

* * * * * * *

[(4) provide information to physicians, other health care professionals, and the public regarding bone marrow transplantation;]

(4) provide information to physicians, other health care professionals and the public regarding the availability of unrelated marrow transplantation as a potential treatment option;]

[(5) recruit bone marrow donors;]

(5) establish a program for the recruitment of new bone marrow donors that includes—

(A) the priority to increase potential marrow donors for which there is a greater degree of marrow donor shortage than that of the general population; and

(B) the compilation and distribution of informational materials to educate and update potential donors;

(6) annually update the Donor Registry to account for changes in potential donor status;

(7) not later than 1 year after the date on which the 'Bone Marrow Program Inspection' (hereafter referred to in this part as the 'Inspection') that is being conducted by the Office of the Inspector General on the date of enactment of this paragraph is completed, in consultation with the Secretary, and based on the findings and recommendations of the Inspection, the marrow donor program shall develop, evaluate, and implement a plan to streamline and make more efficient the relationship between the Donor Registry and donor centers;

[(6)] *(8)* collect, analyze, and publish data concerning bone marrow donation and transplantation; and

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

* * * * * * *

[(j) Authorization of appropriations. There are authorized to be appropriated to carry out this section $15,000,000 for fiscal year

1991 and such sums as may be necessary for each of fiscal years 1992 and 1993.]

(j) INFORMATION AND EDUCATION PROGRAM.—

(1) IN GENERAL.—The Secretary may enter into contracts with, public or nonprofit private entities for the purpose of increasing unrelated allogeneic marrow transplants, by enabling such entities to—

(A) plan and conduct programs to provide information and education to the professional health care community on the availability of unrelated allogeneic marrow transplants as a potential treatment option;

(B) plan and conduct programs to provide information and education to the public on the availability of unrelated donor marrow transplants and the need for donations of bone marrow;

(C) train individuals in requesting bone marrow donations; and

(D) recruit, test and enroll marrow donors with the priority being groups for which there is a greater degree of marrow donor shortage than that of the general population.

(2) PRIORITIES.—In awarding contracts under paragraph (1), the Secretary shall give priority to carrying out the purposes described with respect to population groups with such shortages.

(k) PATIENT ADVOCACY AND CASE MANAGEMENT.—

(1) ESTABLISHMENT.—The Donor Registry shall establish and maintain an office of patient advocacy and case management that meets the requirements of this subsection.

(2) FUNCTIONS.—The office established under paragraph (1) shall—

(A) be headed by a director who shall serve as an advocate on behalf of—

(i) individuals who are registered with the Donor Registry to search for a biologically unrelated bone marrow donor;

(ii) the physicians involved; and

(iii) individuals who are included in the Donor Registry as potential marrow donors;

(B) establish and maintain a system for patient advocacy that directly assists patients, their families, and their physicians in a search for an unrelated donor;

(C) provide individual case management services as appropriate to directly assist individuals and physicians referred to in subparagraph (A), including—

(i) individualized case assessment and tracking of preliminary search through activation (including when the search process is interrupted or discontinued);

(ii) informing individuals and physicians on regular intervals of progress made in searching for appropriate donors; and

(iii) identifying and resolving individual search problems or concerns;

(D) collect and analyze data concerning the number and percentage of individuals proceeding from preliminary to formal search, formal search to transplantation, the num-

ber and percentage of patients unable to complete the search process, and the comparative costs incurred by patients prior to transplant;

(E) survey patients to evaluate how well such patients are being served and make recommendations for expediting the search process; and

(F) provide individual case management services to individual marrow donors.

(3) EVALUATION.—

(A) IN GENERAL.—The Secretary shall evaluate the system established under paragraph (1) and make recommendations concerning the success or failure of such system in improving patient satisfaction, and any impact the system has had on assisting individuals in proceeding to transplant.

(B) REPORT.—Not later than April 1, 1996, the Secretary shall prepare and make available a report concerning the evaluation conducted under subparagraph (A), including the recommendations developed under such subparagraph.

* * * * * * *

[SEC. 379A. STUDY BY GENERAL ACCOUNTING OFFICE

[(a) IN GENERAL. The Comptroller General of the United States shall conduct a study that evaluates—

[(1) the costs and benefits of the search process for an unrelated bone marrow donor among different marrow donor registries;

[(2) the extent to which marrow donor registries protect donor confidentiality;

[(3) the relationship between the Registry, individual marrow donor centers, and other marrow donor registries;

[(4) the effectiveness and appropriateness of policies and procedures of marrow donor centers, marrow transplant centers, and marrow donor registries, including—

[(A) the process of donor recruitment, including the policy of asking each donor whether the donor would want to donate more than one time;

[(B) the maintenance and updating of donor files; and

[(C) the policy of initially typing donors for A/B antigens only instead of initially typing for both A/B and D/R antigens;

[(5) the ability of the marrow donor registries to incorporate changes in medical research and clinical practice; and

[(6) the costs associated with tissue typing.

[(b) REPORT.—Not later than 1 year after the date of enactment of this part, the Comptroller General shall complete the study required under subsection (a) and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate a report describing the findings made by the study and recommendations for legislative reform.]

SEC. 379A. STUDIES, EVALUATIONS AND REPORTS.

(a) EVALUATION BY THE INSTITUTE OF MEDICINE.—

(1) IN GENERAL.—The Secretary shall enter into a contract with a public or nonprofit private entity to conduct a study and evaluation of—

(A) the role of a national bone marrow transplant program supported by the Federal Government in facilitating the maximum number of unrelated marrow donor transplants; and

(B) other possible clinical or scientific uses of the potential donor pool or accompanying information maintained by the Donor Registry or the unrelated marrow donor scientific registry.

(2) INSTITUTE OF MEDICINE.—The Secretary shall request the Institute of Medicine of the National Academy of Sciences to enter into the contract under paragraph (1) to conduct the study and evaluation described in such paragraph. If the Institute declines to conduct the study and evaluation under such paragraph, the Secretary shall carry out such activities through another public or nonprofit private entity.

(3) REPORT.—Not later than 2 years after the date of enactment of this section, the Institute of Medicine (or other entity as the case may be) shall complete the study required under paragraph (1) and prepare and submit to the Committee on Labor and Human Resources of the Senate, a report describing the findings made as a result of the study.

(b) BONE MARROW CONSOLIDATION.—

(1) IN GENERAL.—The Secretary shall conduct—

(A) an evaluation of the feasibility of integrating or consolidating all federally funded bone marrow transplantation scientific registries, regardless of the type of marrow reconstitution utilized; and

(B) an evaluation of all federally funded bone marrow transplantation research to be conducted under the direction and administration of the peer review system of the National Institutes of Health.

(2) REPORT.—Not later than 1 year after the date of enactment of this section, the Secretary shall prepare and submit to the Committee on Labor and Human Resources of the Senate a report concerning the evaluations conducted under paragraph (1).

(3) DEFINITION.—As used in paragraph (1), the term 'marrow reconstitution' shall encompass all sources of hematopoietic cells including marrow (autologous, related and unrelated allogeneic, syngeneic), autologous marrow, allogeneic marrow (biologically related or unrelated), umbilical cord blood cells, peripheral blood progenitor cells, or other approaches that may be utilized.

SEC. 379B. BONE MARROW SCIENTIFIC REGISTRY.

(a) ESTABLISHMENT.—The Secretary, acting through the Donor Registry, shall establish and maintain a bone marrow scientific registry of all recipients of biologic unrelated allogeneic marrow donors.

(b) INFORMATION.—The bone marrow transplantation scientific registry established under subsection (a) shall include information with respect to patients who have received biologic unrelated

allogeneic marrow transplant, transplant procedures, pretransplant and transplant costs, and other information the Secretary determines to be necessary to conduct an ongoing evaluation of the scientific and clinic status of unrelated allogeneic marrow transplantation.

(c) REPORT.—The Donor Registry shall submit to the Secretary on an annual basis a report using data collected and maintained by the bone marrow transplantation scientific registry established under subsection (a) concerning patient outcomes with respect to each transplant center and the pretransplant comparative costs involved at such transplant centers.

SEC. 379C. AUTHORIZATION OF APPROPRIATIONS.

There are authorized to be appropriated to carry out section 379, $13,500,000 for fiscal year 1997, $12,150,000 for fiscal year 1998, and such sums as may be necessary for fiscal year 1999.

○