''There's none better than David Carle,'' said Callahan, a former newspaper political columnist, longtime aide to former Sen. Alan Dixon, and Simon's press secretary when he was lieutenant governor.

''He's completely honest and effective in his role as press secretary,'' continued Callahan, who's dealt with myriad press aides over the last four decades. ''He's timely in returning telephone calls and would never think of misleading a reporter.''

Doug Booth, press secretary for Rep. Dennis Hastert, R-Yorkville, has known Carle since 1984 when Booth was a newsman for a radio station in Marion and Simon represented the state's southernmost House district.

''Dave always has been extremely effective in the job he has done for Paul Simon,'' Booth said. ''Pat Leahy is lucky to get him on board.''

Similar kudos come from Terri Moreland, who heads Republican Gov. Jim Edgar's office here. Moreland said Carle has been ''great to work with'' on Illinois matters.

''He's absolutely professional, and he is so highly regarded on 'the Hill,' '' Moreland said of Carle.

Indeed, Carle's ability, credibility and workaholic habits resulted in his being drafted for the thankless-but-sensitive job of spokesman for Democrats on Senate panels probing the financial dealings of President Clinton and the First Lady when Clinton was governor of Arkansas.

Although seemingly shy, Carle is the master of the soft sell. A believer in preparation, he always has been ready, responsive and reliable when reporters hit him with questions on almost any subject.

If a reporter showed even the faintest interest in a Simon issue, Carle would bombard him before day's end with a raft of material which not only supported Simon's viewpoint but also provided opposing arguments and sources.

Simon and Carle fit like hand-and-glove. Simon has kept his press secretary well posted on his activities and is comfortable talking with reporters.

Carle said he considers himself very fortunate to have worked for ''one of the finest politicians of this era or, I think, any era.''

He tends to speak of Simon as if the senator could walk on water. But Carle also would be honest enough to disclose the water-walking only happens when the pond behind Simon's rural Makanda home is frozen.●

INTERPARLIAMENTARY CONFERENCES

Mr. LOTT. Mr. President, for the information of the affected Members of the Senate, I would like to state for the record that if a Member who is precluded from travel by the provisions of rule 39 is appointed as a delegate to an official conference to be attended by Members of the Senate, then the appointment of that individual constitutes an authorization by the Senate and the Member will not be deemed in violation of rule 39.

ORGAN AND BONE MARROW TRANSPLANT PROGRAM REAUTHORIZATION ACT OF 1995

Mr. LOTT. Mr. President, I ask unanimous consent the Senate proceed to the immediate consideration of Calendar No. 377, S. 1324.

The PRESIDING OFFICER. Without objection, it is so ordered.

The clerk will report.

The legislative clerk read as follows:

A 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.

The Senate proceeded to consider the bill, which had been reported from the Committee on Labor and Human Resources, with an amendment to strike all after the enacting clause and inserting in lieu thereof the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Organ and Bone Marrow Transplant Program Reauthorization Act of 1995''.

TITLE I—SOLID-ORGAN TRANSPLANT PROGRAM

SEC. 101. SHORT TITLE.

This title may be cited as the ''Solid-Organ Transplant Program Reauthorization Act of 1995''.

SEC. 102. ORGAN PROCUREMENT ORGANIZATIONS.

(a) IN GENERAL.—Subsection (a) of section 371 of the Public Health Service Act (42 U.S.C. 273(a)) is amended to read as follows:

''(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 ORGAN PROCUREMENT ORGANIZATIONS.—Section 371(b) of such Act (42 U.S.C. 273(b)) is amended—

(1) in paragraph (1)—

(A) in the matter preceding subparagraph (A)—

(i) by striking ''for which grants may be made under subsection (a)'' and inserting ''described in this section''; and

(ii) by striking ''paragraph (2)'' and inserting ''Paragraph (3)'';

(B) by realigning the margin of subparagraph (E) so as to align with the margin of subparagraph (D); and

(C) in subparagraph (G)—

(i) in the matter preceding clause (i), by striking ''directors or an advisory board'' and inserting ''directors (or an advisory board, in the case of a hospital-based organ procurement organization established prior to September 1, 1993)''; and

(ii) in clause (i)—

(I) by striking ''composed of'' in the matter preceding subclause (I) and inserting ''composed of a reasonable balance of'';

(II) by inserting before the comma in subclause (II) the following: '', 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'';

(III) by striking subclause (IV) and inserting the following new subclause:

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

(IV) in subclause (V), by striking ''a member'' and all that follows through the comma and insert the following: ''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) by striking paragraph (2);

(3) by redesignating paragraph (3) as paragraph (2);

(4) in paragraph (2) (as so redesignated)—

(A) in subparagraph (A)—

(i) by striking ''a substantial majority'' and inserting ''all'';

(ii) by striking ''donations,'' and inserting ''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''; and

(iii) by adding at the end thereof the following: ''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) by redesignating subparagraphs (B) through (K) as subparagraphs (D) through (M), respectively,

(C) by inserting after subparagraph (A) the following new subparagraphs:

''(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,'';

(D) by inserting before the comma in subparagraph (G) (as so redesignated) the following: '', 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 in 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;'';

(E) by inserting before the comma in subparagraph (I) (as so redesignated) the following: ''and work with local transplant centers to ensure that such centers are actively involved with organ donation efforts''; and

(F) by inserting after ''evaluate annually'' in subparagraph (L) (as so redesignated) the following ''and submit data to the Network contractor on'' the effectiveness of the organization,''; and

(5) by adding at the end thereof the following new paragraph:

''(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.''.

(c) AFFECT OF AMENDMENTS.—The amendments made by subsection (b) shall not be construed to affect the provisions of section 1138(a) of the Social Security Act (42 U.S.C. 1320b-8(a)).

(d) EFFECTIVE DATE.—The amendments made by subsection (b) shall apply to organ procurement organizations and the Organ Procurement and Transplantation Network beginning January 1, 1996.

SEC. 103. ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK.

(a) OPERATION.—Subsection (a) of section 372 of the Public Health Service Act (42 U.S.C. 274(a)) is amended to read as follows:

''(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 stills 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 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 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 fee 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 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 under this section and section 373.''.

(b) REQUIREMENTS.—Section 372(b) of the Public Health Service Act (42 U.S.C. 274(b)) is amended—

(1) in paragraph (1)(B)—

(A) in clause (i)—

(i) by striking ''(including organizations that have received grants under section 371)''; and

(ii) by striking ''; and'' at the end thereof and inserting ''(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;'';

(B) in clause (ii)—

(i) by inserting ''including a patient affairs committee and a minority affairs committee'' after ''committees,''; and

(ii) by striking the period; and

(C) by adding at the end thereof the following new clauses:

''(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).''; and

(2) in paragraph (2)—

(A) in subparagraph (A)—

(i) in the matter preceding clause (i), by striking ''or through regional centers'' and inserting ''and at each Organ Procurement Organization''; and

(ii) by striking clause (i) and inserting the following new clause:

''(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) in subparagraph (B), by inserting '', including requirements under section 371(b),'' after ''membership criteria'';

(C) by redesignating subparagraphs (E) through (L), as subparagraphs (F) through (M), respectively;

(D) by inserting after subparagraph (D), the following new subparagraph:

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

(E) in subparagraph (K) (as so redesignated), by striking ''and'' at the end thereof;

(F) in subparagraph (L) (as so redesignated), by striking the period and inserting '', including making recommendations to organ procurements organizations and the Secretary based on data submitted to the Network under section 371(b)(2)(L),'';

(G) in subparagraph (M) (as so redesignated)—

(i) by striking ''annual'' and inserting ''biennial'';

(ii) by striking ''the comparative costs and'';

(iii) by striking the period and inserting the following: '', 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,''; and

(H) by adding at the end thereof the following new subparagraphs:

''(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 if 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 transplantation, and

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

(c) PROCEDURES.—Section 372(c) of the Public Health Service Act (42 U.S.C. 274(c)) is amended—

(1) in paragraph (1), by striking ''and'' at the end thereof;

(2) in paragraph (2), by striking the period and inserting a semicolon; and

(3) by adding at the end thereof the following new paragraphs:

''(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.—Section 372 of the Public Health Service Act (42 U.S.C. 274) is amended by adding at the end thereof the following new subsection:

''(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.''.

(e) REGULATIONS.—

(1) IN GENERAL.—Not later than the expiration of the 1-year period beginning on the date of enactment of this Act, the Secretary of Health and Human Services shall issue a final rule to establish the regulations for criteria under part H of title III of the Public Health Service Act (42 U.S.C. 273 et seq.).

(2) CONSIDERATION OF CERTAIN BYLAWS AND POLICIES.—In developing regulations under paragraph (1), the Secretary shall consider the bylaws and policies of the Network.

(3) FAILURE TO ISSUE REGULATIONS BY DATE CERTAIN.—If the Secretary fails to issue a final rule under paragraph (1) prior to the expiration of the period referred to in such paragraph, the Secretary shall, not later than 30 days after the expiration of such period, prepare and submit to the appropriate committees of Congress a report describing the reasons why the Secretary is not in compliance with paragraph (1) and the plans that will be implemented to provide for the issuance of the final rule under such paragraph.

SEC. 104. TERMS AND CONDITIONS OF CONTRACTS.

Section 374 of the Public Health Service Act (42 U.S.C. 274b) is amended—

(1) in subsection (b)(2), by striking ''two years'' and inserting ''(three years)'';

(2) in subsection (c)—

(A) by redesignating paragraph (1) and (2) as paragraphs (2) and (3), respectively; and

(B) by inserting before paragraph (2) (as so redesignated) the following new paragraph:

''(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.'';

(3) by redesignating subsection (d) as subsection (e); and

(4) by adding at the end thereof the following new subsection:

''(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.''.

SEC. 105. ADMINISTRATION.

Section 375 of the Public Health Service Act (42 U.S.C. 274c) is amended—

(1) in section 375 (42 U.S.C. 274c), by inserting before the dash the following: ''oversee the Network, the Scientific Registry and to'';

(2) in paragraph (3)—

(A) by striking ''in the health care system''; and

(B) by striking ''and'' at the end thereof;

(3) in paragraph (4), by striking the period and inserting ''; and''; and

(4) by adding at the end thereof the following new paragraph:

''(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. 106. STUDY AND REPORT.

Section 377 of the Public Health Service Act (42 U.S.C. 274f) is amended to read as follows:

''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. 107. GENERAL PROVISIONS.

(a) CONTRACTS.—Section 374 of the Public Health Service Act (42 U.S.C. 274b) is amended—

(1) in the section heading, by striking ''GRANTS AND'';

(2) in subsection (a), by striking ''grant may be made under this part or contract'' and inserting ''contract may be'';

(3) in subsection (b)—

(A) in paragraph (1)—

(i) by striking ''grant'' and inserting ''contract''; and

(ii) by striking ''and may not exceed $100,000'';

(B) by striking paragraph (2);

(C) by redesignating paragraph (3) as paragraph (2); and

(D) in paragraph (2) (as so redesignated)—

(i) by striking ''Grants or contracts'' and inserting ''Contracts''; and

(ii) by striking ''371(a)(3)'' and inserting ''371(a)(2)'';

(4) in subsection (c)—

(A) by striking ''grant or'' each place that such appears; and

(B) in paragraph (1), by striking ''grants and''; and

(5) in subsection (d)(2), by striking ''and for purposes of section 373, such term includes bone marrow''.

(b) REPEAL.—Sections 376 and 378 of the Public Health Service Act (42 U.S.C. 274d and 274g) are repealed.

SEC. 108. AUTHORIZATION OF APPROPRIATION.

Part H of title III of the Public Health Service Act (42 U.S.C. 273 et seq.) is amended by adding at the end thereof the following new section:

''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. 109. EFFECTIVE DATES.

The amendments made by this title shall become effective on the date of enactment of this Act.

TITLE II—BONE MARROW DONOR PROGRAM

SEC. 201. SHORT TITLE.

This title may be cited as the ''Bone Marrow Transplantation Program Reauthorization Act of 1995''.

SEC. 202. REAUTHORIZATION.

(a) ESTABLISHMENT OF DONOR REGISTRY.—Section 379(a) of the Public Health Service Act (42 U.S.C. 274k(a)) is amended—

(1) by striking '''Registry''' and inserting '''Donor Registry''';

(2) by inserting after the end parenthesis the following: ''the primary purpose of which shall be increasing unrelated donor marrow transplants,''; and

(3) by adding at the end thereof the following: ''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) PROGRAM FOR UNRELATED MARROW TRANSPLANTS.—Section 379(b) of such Act (42 U.S.C. 274k(b)) is amended—

(1) in paragraph (4) to read as follows:

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

(2) in paragraph (5) to read as follows:

''(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;'';

(3) by redesignating paragraphs (6) and (7) as paragraphs (8) and (9), respectively; and

(4) by inserting after paragraph (5), the following new paragraphs:

''(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;''.

(c) INFORMATION AND EDUCATION PROGRAM.—Section 379 of such Act (42 U.S.C. 274k) is amended by striking subsection (j), and inserting the following new subsection:

''(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 in such paragraph with respect to population groups with such shortages.''.

(d) PATIENT ADVOCACY AND CASE MANAGEMENT.—

(1) IN GENERAL.—Section 379 of such Act (42 U.S.C. 274k), as amended by subsection (c), is amended by adding at the end thereof the following new subsection:

''(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 number 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.''.

(2) DONOR REGISTRY FUNCTIONS.—Section 379(b)(2) of such Act (42 U.S.C. 274k(b)(2)) is amended by striking ''establish'' and all that follows through ''directly assists'' and inserting ''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''.

(e) STUDY AND REPORTS.—Section 379A of such Act (42 U.S.C. 274l) is amended to read as follows:

''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 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.''.

(f) BONE MARROW TRANSPLANTATION SCIENTIFIC REGISTRY.—Part I of title III of such Act (42 U.S.C. 274k et seq.) is amended by adding at the end thereof the following new section:

''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.''.

(g) AUTHORIZATION OF APPROPRIATIONS.—Part I of title III of such Act (42 U.S.C. 274k et seq.) as amended by subsection (f), is further amended by adding at the end thereof the following new section:

''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.''.

AMENDMENT NO. 5205

(Purpose: To restore and modify certain qualified organ procurement organization board of director provisions)

Mr. LOTT. Mr. President, I understand Senator KASSEBAUM has an amendment at the desk. I ask for its immediate consideration.

The PRESIDING OFFICER. The clerk will report.

The legislative clerk read as follows:

The Senator from Mississippi [Mr. LOTT], for Mrs. KASSEBAUM, proposes an amendment numbered 5205.

The amendment is as follows:

Beginning on page 41, strike line 23, and all that follows through line 4 on page 42, and insert the following:

''(i) in clause (i)—''.

On page 43, between lines 6 and 7, insert the following:

''(ii) in clause (ii), by inserting ', administrative functions of the organ procurement organization, ' after 'organs'; and

''(iii) in clause (iii), to read as follows:

'(iii) in the case of a hospital-based organ procurement organization, has no authority over any non-transplant-related activity of the organization.';''.

Mr. LOTT. Mr. President, I ask unanimous that the amendment be considered read and agreed to, the bill be deemed read a third time, passed, the motion to reconsider be laid upon the table, and that any statements relating to the bill be printed at the appropriate place in the RECORD.

The PRESIDING OFFICER. Without objection, it is so ordered.

The amendment (No. 5205) was agreed to.

The bill (S. 1324) was deemed read for a third time and passed, as follows:

S. 1324

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Organ and Bone Marrow Transplant Program Reauthorization Act of 1996''.

TITLE I—SOLID-ORGAN TRANSPLANT PROGRAM

SEC. 101. SHORT TITLE.

This title may be cited as the ''Solid-Organ Transplant Program Reauthorization Act of 1996''.

SEC. 102. ORGAN PROCUREMENT ORGANIZATIONS.

(a) IN GENERAL.—Subsection (a) of section 371 of the Public Health Service Act (42 U.S.C. 273(a)) is amended to read as follows:

''(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 ORGAN PROCUREMENT ORGANIZATIONS.—Section 371(b) of such Act (42 U.S.C. 273(b)) is amended—

(1) in paragraph (1)—

(A) in the matter preceding subparagraph (A)—

(i) by striking ''for which grants may be made under subsection (a)'' and inserting ''described in this section''; and

(ii) by striking ''paragraph (2)'' and inserting ''Paragraph (3)'';

(B) by realigning the margin of subparagraph (E) so as to align with the margin of subparagraph (D); and

(C) in subparagraph (G)—

(i) in clause (i)—

(I) by striking ''composed of'' in the matter preceding subclause (I) and inserting ''composed of a reasonable balance of'';

(II) by inserting before the comma in subclause (II) the following: '', 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'';

(III) by striking subclause (IV) and inserting the following new subclause:

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

(IV) in subclause (V), by striking ''a member'' and all that follows through the comma and insert the following: ''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,'';

(ii) in clause (ii), by inserting '', administrative functions of the organ procurement organization,'' after ''organs''; and

(iii) in clause (iii), to read as follows:

''(iii) in the case of a hospital-based organ procurement organization, has no authority over any non-transplant-related activity of the organization.'';

(2) by striking paragraph (2);

(3) by redesignating paragraph (3) as paragraph (2);

(4) in paragraph (2) (as so redesignated)—

(A) in subparagraph (A)—

(i) by striking ''a substantial majority'' and inserting ''all'';

(ii) by striking ''donations,'' and inserting ''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''; and

(iii) by adding at the end thereof the following: ''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) by redesignating subparagraphs (B) through (K) as subparagraphs (D) through (M), respectively,

(C) by inserting after subparagraph (A) the following new subparagraphs:

''(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,'';

(D) by inserting before the comma in subparagraph (G) (as so redesignated) the following: '', 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 in 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;'';

(E) by inserting before the comma in subparagraph (I) (as so redesignated) the following: ''and work with local transplant centers to ensure that such centers are actively involved with organ donation efforts''; and

(F) by inserting after ''evaluate annually'' in subparagraph (L) (as so redesignated) the following ''and submit data to the Network contractor on'' the effectiveness of the organization,''; and

(5) by adding at the end thereof the following new paragraph:

''(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.''.

(c) AFFECT OF AMENDMENTS.—The amendments made by subsection (b) shall not be construed to affect the provisions of section 1138(a) of the Social Security Act (42 U.S.C. 1320b-8(a)).

(d) EFFECTIVE DATE.—The amendments made by subsection (b) shall apply to organ procurement organizations and the Organ Procurement and Transplantation Network beginning January 1, 1996.

SEC. 103. ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK.

(a) OPERATION.—Subsection (a) of section 372 of the Public Health Service Act (42 U.S.C. 274(a)) is amended to read as follows:

''(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 stills 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 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 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 fee 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 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 under this section and section 373.''.

(b) REQUIREMENTS.—Section 372(b) of the Public Health Service Act (42 U.S.C. 274(b)) is amended—

(1) in paragraph (1)(B)—

(A) in clause (i)—

(i) by striking ''(including organizations that have received grants under section 371)''; and

(ii) by striking ''; and'' at the end thereof and inserting ''(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;'';

(B) in clause (ii)—

(i) by inserting ''including a patient affairs committee and a minority affairs committee'' after ''committees,''; and

(ii) by striking the period; and

(C) by adding at the end thereof the following new clauses:

''(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).''; and

(2) in paragraph (2)—

(A) in subparagraph (A)—

(i) in the matter preceding clause (i), by striking ''or through regional centers'' and inserting ''and at each Organ Procurement Organization''; and

(ii) by striking clause (i) and inserting the following new clause:

''(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) in subparagraph (B), by inserting '', including requirements under section 371(b),'' after ''membership criteria'';

(C) by redesignating subparagraphs (E) through (L), as subparagraphs (F) through (M), respectively;

(D) by inserting after subparagraph (D), the following new subparagraph:

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

(E) in subparagraph (K) (as so redesignated), by striking ''and'' at the end thereof;

(F) in subparagraph (L) (as so redesignated), by striking the period and inserting '', including making recommendations to organ procurements organizations and the Secretary based on data submitted to the Network under section 371(b)(2)(L),'';

(G) in subparagraph (M) (as so redesignated)—

(i) by striking ''annual'' and inserting ''biennial'';

(ii) by striking ''the comparative costs and'';

(iii) by striking the period and inserting the following: '', 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,''; and

(H) by adding at the end thereof the following new subparagraphs:

''(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 if 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 transplantation, and

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

(c) PROCEDURES.—Section 372(c) of the Public Health Service Act (42 U.S.C. 274(c)) is amended—

(1) in paragraph (1), by striking ''and'' at the end thereof;

(2) in paragraph (2), by striking the period and inserting a semicolon; and

(3) by adding at the end thereof the following new paragraphs:

''(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.—Section 372 of the Public Health Service Act (42 U.S.C. 274) is amended by adding at the end thereof the following new subsection:

''(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.''.

(e) REGULATIONS.—

(1) IN GENERAL.—Not later than the expiration of the 1-year period beginning on the date of enactment of this Act, the Secretary of Health and Human Services shall issue a final rule to establish the regulations for criteria under part H of title III of the Public Health Service Act (42 U.S.C. 273 et seq.).

(2) CONSIDERATION OF CERTAIN BYLAWS AND POLICIES.—In developing regulations under paragraph (1), the Secretary shall consider the bylaws and policies of the Network.

(3) FAILURE TO ISSUE REGULATIONS BY DATE CERTAIN.—If the Secretary fails to issue a final rule under paragraph (1) prior to the expiration of the period referred to in such paragraph, the Secretary shall, not later than 30 days after the expiration of such period, prepare and submit to the appropriate committees of Congress a report describing the reasons why the Secretary is not in compliance with paragraph (1) and the plans that will be implemented to provide for the issuance of the final rule under such paragraph.

SEC. 104. TERMS AND CONDITIONS OF CONTRACTS.

Section 374 of the Public Health Service Act (42 U.S.C. 274b) is amended—

(1) in subsection (b)(2), by striking ''two years'' and inserting ''(three years)'';

(2) in subsection (c)—

(A) by redesignating paragraph (1) and (2) as paragraphs (2) and (3), respectively; and

(B) by inserting before paragraph (2) (as so redesignated) the following new paragraph:

''(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.'';

(3) by redesignating subsection (d) as subsection (e); and

(4) by adding at the end thereof the following new subsection:

''(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.''.

SEC. 105. ADMINISTRATION.

Section 375 of the Public Health Service Act (42 U.S.C. 274c) is amended—

(1) in section 375 (42 U.S.C. 274c), by inserting before the dash the following: ''oversee the Network, the Scientific Registry and to'';

(2) in paragraph (3)—

(A) by striking ''in the health care system''; and

(B) by striking ''and'' at the end thereof;

(3) in paragraph (4), by striking the period and inserting ''; and''; and

(4) by adding at the end thereof the following new paragraph:

''(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. 106. STUDY AND REPORT.

Section 377 of the Public Health Service Act (42 U.S.C. 274f) is amended to read as follows:

''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. 107. GENERAL PROVISIONS.

(a) CONTRACTS.—Section 374 of the Public Health Service Act (42 U.S.C. 274b) is amended—

(1) in the section heading, by striking ''GRANTS AND'';

(2) in subsection (a), by striking ''grant may be made under this part or contract'' and inserting ''contract may be'';

(3) in subsection (b)—

(A) in paragraph (1)—

(i) by striking ''grant'' and inserting ''contract''; and

(ii) by striking ''and may not exceed $100,000'';

(B) by striking paragraph (2);

(C) by redesignating paragraph (3) as paragraph (2); and

(D) in paragraph (2) (as so redesignated)—

(i) by striking ''Grants or contracts'' and inserting ''Contracts''; and

(ii) by striking ''371(a)(3)'' and inserting ''371(a)(2)'';

(4) in subsection (c)—

(A) by striking ''grant or'' each place that such appears; and

(B) in paragraph (1), by striking ''grants and''; and

(5) in subsection (d)(2), by striking ''and for purposes of section 373, such term includes bone marrow''.

(b) REPEAL.—Sections 376 and 378 of the Public Health Service Act (42 U.S.C. 274d and 274g) are repealed.

SEC. 108. AUTHORIZATION OF APPROPRIATION.

Part H of title III of the Public Health Service Act (42 U.S.C. 273 et seq.) is amended by adding at the end thereof the following new section:

''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. 109. EFFECTIVE DATES.

The amendments made by this title shall become effective on the date of enactment of this Act.

TITLE II—BONE MARROW DONOR PROGRAM

SEC. 201. SHORT TITLE.

This title may be cited as the ''Bone Marrow Transplantation Program Reauthorization Act of 1996''.

SEC. 202. REAUTHORIZATION.

(a) ESTABLISHMENT OF DONOR REGISTRY.—Section 379(a) of the Public Health Service Act (42 U.S.C. 274k(a)) is amended—

(1) by striking '' 'Registry' '' and inserting '' 'Donor Registry' '';

(2) by inserting after the end parenthesis the following: ''the primary purpose of which shall be increasing unrelated donor marrow transplants,''; and

(3) by adding at the end thereof the following: ''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) PROGRAM FOR UNRELATED MARROW TRANSPLANTS.—Section 379(b) of such Act (42 U.S.C. 274k(b)) is amended—

(1) in paragraph (4) to read as follows:

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

(2) in paragraph (5) to read as follows:

''(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;'';

(3) by redesignating paragraphs (6) and (7) as paragraphs (8) and (9), respectively; and

(4) by inserting after paragraph (5), the following new paragraphs:

''(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;''.

(c) INFORMATION AND EDUCATION PROGRAM.—Section 379 of such Act (42 U.S.C. 274k) is amended by striking subsection (j), and inserting the following new subsection:

''(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 in such paragraph with respect to population groups with such shortages.''.

(d) PATIENT ADVOCACY AND CASE MANAGEMENT.—

(1) IN GENERAL.—Section 379 of such Act (42 U.S.C. 274k), as amended by subsection (c), is amended by adding at the end thereof the following new subsection:

''(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 number 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.''.

(2) DONOR REGISTRY FUNCTIONS.—Section 379(b)(2) of such Act (42 U.S.C. 274k(b)(2)) is amended by striking ''establish'' and all that follows through ''directly assists'' and inserting ''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''.

(e) STUDY AND REPORTS.—Section 379A of such Act (42 U.S.C. 274l) is amended to read as follows:

''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 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.''.

(f) BONE MARROW TRANSPLANTATION SCIENTIFIC REGISTRY.—Part I of title III of such Act (42 U.S.C. 274k et seq.) is amended by adding at the end thereof the following new section:

''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.''.

(g) AUTHORIZATION OF APPROPRIATIONS.—Part I of title III of such Act (42 U.S.C. 274k et seq.) as amended by subsection (f), is further amended by adding at the end thereof the following new section:

''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.''.

MAKING TECHNICAL CORRECTIONS IN THE FEDERAL OIL AND GAS ROYALTY MANAGEMENT ACT OF 1982

Mr. LOTT. Mr. President, I ask unanimous consent the Senate proceed to the immediate consideration of H.R. 4018.

The PRESIDING OFFICER. The clerk will report.