

conducted by the Department of Health and Human Services has created a level of uncertainty that is interfering with the effectiveness of organ procurement organizations in raising the level of organ donation.

“(3) The General Accounting Office [now Government Accountability Office], the Institute of Medicine, and the Harvard School of Public Health have identified substantial limitations in the organ procurement organization certification and recertification process and have recommended changes in that process.

“(4) The limitations in the recertification process include:

“(A) An exclusive reliance on population-based measures of performance that do not account for the potential in the population for organ donation and do not permit consideration of other outcome and process standards that would more accurately reflect the relative capability and performance of each organ procurement organization.

“(B) A lack of due process to appeal to the Secretary of Health and Human Services for recertification on either substantive or procedural grounds.

“(5) The Secretary of Health and Human Services has the authority under section 1138(b)(1)(A)(i) of the Social Security Act (42 U.S.C. 1320b-8(b)(1)(A)(i)) to extend the period for recertification of an organ procurement organization from 2 to 4 years on the basis of its past practices in order to avoid the inappropriate disruption of the nation’s organ system.

“(6) The Secretary of Health and Human Services can use the extended period described in paragraph (5) for recertification of all organ procurement organizations to—

“(A) develop improved performance measures that would reflect organ donor potential and interim outcomes, and to test these measures to ensure that they accurately measure performance differences among the organ procurement organizations; and

“(B) improve the overall certification process by incorporating process as well as outcome performance measures, and developing equitable processes for appeals.”

STUDY REGARDING IMMUNOSUPPRESSIVE DRUGS

Pub. L. 106-310, div. A, title XXI, §2101(b), Oct. 17, 2000, 114 Stat. 1156, provided that:

“(1) IN GENERAL.—The Secretary of Health and Human Services (referred to in this subsection as the ‘Secretary’) shall provide for a study to determine the costs of immunosuppressive drugs that are provided to children pursuant to organ transplants and to determine the extent to which health plans and health insurance cover such costs. The Secretary may carry out the study directly or through a grant to the Institute of Medicine (or other public or nonprofit private entity).

“(2) RECOMMENDATIONS REGARDING CERTAIN ISSUES.—The Secretary shall ensure that, in addition to making determinations under paragraph (1), the study under such paragraph makes recommendations regarding the following issues:

“(A) The costs of immunosuppressive drugs that are provided to children pursuant to organ transplants and to determine the extent to which health plans, health insurance and government programs cover such costs.

“(B) The extent of denial of organs to be released for transplant by coroners and medical examiners.

“(C) The special growth and developmental issues that children have pre- and post-organ transplantation.

“(D) Other issues that are particular to the special health and transplantation needs of children.

“(3) REPORT.—The Secretary shall ensure that, not later than December 31, 2001, the study under paragraph (1) is completed and a report describing the findings of the study is submitted to the Congress.”

STUDY ON HOSPITAL AGREEMENTS WITH ORGAN PROCUREMENT AGENCIES

Pub. L. 103-432, title I, §155(b), Oct. 31, 1994, 108 Stat. 4439, directed Office of Technology Assessment to conduct study to determine efficacy and fairness of requiring a hospital to enter into agreement under subsec. (b)(3)(A) of this section with organ procurement agency for service area in which such hospital is located and impact of such requirement on efficacy and fairness of organ procurement and distribution, and to submit to Congress, not later than 2 years after Oct. 31, 1994, report containing findings of such study and implications of such findings with respect to policies affecting organ procurement and distribution.

TASK FORCE ON ORGAN PROCUREMENT AND TRANSPLANTATION

Pub. L. 98-507, title I, §§101-105, Oct. 19, 1984, 98 Stat. 2339-2342, directed Secretary of Health and Human Services, not later than 90 days after Oct. 19, 1984, to establish a Task Force on Organ Transplantation to conduct comprehensive examinations, prepare an assessment and report, and submit advice as to regulation of the medical, legal, ethical, economic, and social issues presented by human organ procurement and transplantation, with the final report due not later than 12 months after the Task Force is established and the Task Force to terminate 3 months thereafter.

BONE MARROW REGISTRY DEMONSTRATION AND STUDY

Section 401 of Pub. L. 98-507 directed Secretary of Health and Human Services to hold a conference on the feasibility of establishing and the effectiveness of a national registry of voluntary bone marrow donors not later than 9 months after Oct. 19, 1984, and if the conference found that it was feasible to establish a national registry of voluntary donors of bone marrow and that such a registry was likely to be effective in matching donors with recipients, the Secretary was to establish a registry of voluntary donors of bone marrow not later than six months after the completion of the conference, and further directed the Secretary, acting through the Assistant Secretary for Health, to study the establishment and implementation of the registry to identify the issues presented by the establishment of such a registry, to evaluate participation of bone marrow donors, to assess the implementation of the informed consent and confidentiality requirements, and to determine if the establishment of a permanent bone marrow registry was needed and appropriate, and to report the results of the study to Congress not later than two years after the date the registry was established.

§ 273a. National living donor mechanisms

The Secretary may establish and maintain mechanisms to evaluate the long-term effects associated with living organ donations by individuals who have served as living donors.

(July 1, 1944, ch. 373, title III, §371A, as added Pub. L. 108-216, §7, Apr. 5, 2004, 118 Stat. 589.)

§ 273b. Report on the long-term health effects of living organ donation

Not later than 1 year after December 21, 2007, and annually thereafter, the Secretary of Health and Human Services shall submit to the appropriate committees of Congress a report that details the progress made towards understanding the long-term health effects of living organ donation.

(Pub. L. 110-144, §3, Dec. 21, 2007, 121 Stat. 1814.)

CODIFICATION

Section was enacted as part of the Charlie W. Norwood Living Organ Donation Act, and not as part of the