

“(f) REGULATIONS.—The Secretary may promulgate regulations to carry out this section.

“(g) DEFINITIONS.—In this section:

“(1) The term ‘C.W. Bill Young Cell Transplantation Program’ means the C.W. Bill Young Cell Transplantation Program under section 379 of the Public Health Service Act [this section], as amended by this Act.

“(2) The term ‘cord blood donor’ means a mother who has delivered a baby and consents to donate the neonatal blood remaining in the placenta and umbilical cord after separation from the newborn baby.

“(3) The term ‘cord blood unit’ means the neonatal blood collected from the placenta and umbilical cord of a single newborn baby.

“(4) The term ‘first-degree relative’ means a sibling or parent who is one meiosis away from a particular individual in a family.

“(5) The term ‘qualified cord blood bank’ has the meaning given to that term in section 379(d)(4) of the Public Health Service Act [subsec. (d)(4) of this section], as amended by this Act.

“(6) The term ‘Secretary’ means the Secretary of Health and Human Services.

“(h) AUTHORIZATION OF APPROPRIATIONS.—

“(1) EXISTING FUNDS.—Any amounts appropriated to the Secretary for fiscal year 2004 or 2005 for the purpose of assisting in the collection or maintenance of cord blood shall remain available to the Secretary until the end of fiscal year 2007.

“(2) SUBSEQUENT FISCAL YEARS.—There are authorized to be appropriated to the Secretary \$15,000,000 for each of fiscal years 2007, 2008, 2009, and 2010 to carry out this section.

“(3) LIMITATION.—Not to exceed 5 percent of the amount appropriated under this section in each of fiscal years 2007 through 2009 may be used to carry out the demonstration project under subsection (c).”

REPORT OF INSPECTOR GENERAL; PLAN REGARDING RELATIONSHIP BETWEEN REGISTRY AND DONOR CENTERS

Pub. L. 105–196, §2(b)(2), July 16, 1998, 112 Stat. 632, directed the Secretary of Health and Human Services to ensure that, not later than 1 year after July 16, 1998, the National Bone Marrow Donor Registry (under this section) developed, evaluated, and implemented a plan to effectuate efficiencies in the relationship between such Registry and donor centers.

STUDY BY GAO

Pub. L. 105–196, §5, July 16, 1998, 112 Stat. 636, provided that the Comptroller General was to conduct a study of the National Bone Marrow Donor Registry under this section to determine the extent to which the Registry had increased the representation of racial and ethnic minority groups among potential donors enrolled with the Registry and whether the extent of increase resulted in a level of representation that met the standard established in subsec. (c)(1)(A) of this section, the extent to which patients in need of a transplant of bone marrow from a biologically unrelated donor, and the physicians of such patients, had been utilizing the Registry, the number of patients for whom the Registry began a preliminary but not complete search process and the reasons underlying such circumstances, the extent to which the plan required in section 2(b)(2) of Pub. L. 105–196 (42 U.S.C. 274k note) had been implemented, and the extent to which the Registry, donor centers, donor registries, collection centers, transplant centers, and other appropriate entities had been complying with subsec. (e) of this section; and provided that a report describing the findings of this study was to be submitted to Congress not later than Oct. 1, 2001, and not before Jan. 1, 2001.

COMPLIANCE WITH NEW REQUIREMENTS FOR OFFICE OF PATIENT ADVOCACY

Pub. L. 105–196, §6, July 16, 1998, 112 Stat. 636, provided that with respect to requirements for the office of

patient advocacy under subsec. (d) of this section, the Secretary of Health and Human Services was to ensure that, not later than 180 days after Oct. 1, 1998, such office was in compliance with all requirements that were additional to the requirements under this section in effect with respect to patient advocacy on the day before July 16, 1998.

§ 2741. Stem cell therapeutic outcomes database

(a) Establishment

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

(b) Information

The outcomes database shall include information in a standardized electronic format with respect to patients described in subsection (a) of this section, diagnosis, transplant procedures, results, long-term follow-up, and such other information as the Secretary determines to be appropriate, to conduct an ongoing evaluation of the scientific and clinical status of transplantation involving recipients of a stem cell therapeutics product from a donor.

(c) Annual report on patient outcomes

The Secretary shall require the entity awarded a contract under this section to submit to the Secretary an annual report concerning patient outcomes with respect to each transplant center, based on data collected and maintained by the entity pursuant to this section.

(d) Publicly available data

The outcomes database shall make relevant scientific information not containing individually identifiable information available to the public in the form of summaries and data sets to encourage medical research and to provide information to transplant programs, physicians, patients, entities awarded a contract under section 274k of this title¹ donor registries, and cord blood banks.

(July 1, 1944, ch. 373, title III, §379A, as added Pub. L. 105–196, §3, July 16, 1998, 112 Stat. 635; amended Pub. L. 109–129, §3(b), Dec. 20, 2005, 119 Stat. 2561.)

PRIOR PROVISIONS

A prior section 2741, act July 1, 1944, ch. 373, title III, §379A, as added Pub. L. 101–616, title I, §101(a)(2), Nov. 16, 1990, 104 Stat. 3282, related to study by General Accounting Office, prior to repeal by Pub. L. 105–196, §§3, 7, July 16, 1998, 112 Stat. 635, 637, effective Oct. 1, 1998.

AMENDMENTS

2005—Pub. L. 109–129, amended section generally, substituting provisions relating to the stem cell therapeutic outcomes database for provisions relating to the bone marrow scientific registry.

EFFECTIVE DATE

Section effective Oct. 1, 1998, see section 7 of Pub. L. 105–196, set out as an Effective Date of 1998 Amendment note under section 274k of this title.

§ 2741–1. Definitions

In this part:

¹ So in original. Probably should be followed by a comma.