

## “(e) DURATION OF CONTRACTS.—

“(1) IN GENERAL.—Except as provided in paragraph (2), the term of each contract entered into by the Secretary under this section shall be for a period of at least 10 years beginning on the last date on which the recipient of a contract under this section receives Federal funds under this section. The Secretary shall ensure that no Federal funds shall be obligated under any such contract after the date that is 5 years after the date on which the contract is entered into, except as provided in paragraphs (2) and (3).

“(2) EXTENSIONS.—The Secretary may extend the period of funding under a contract under this section to exceed a period of 5 years if—

“(A) the Secretary finds that the inventory goal described in subsection (a) has not yet been met;

“(B) the Secretary does not receive an application for a contract under this section meeting the requirements under subsection (d) from any qualified cord blood bank that has not previously entered into a contract under this section; or

“(C) the Secretary determines that the outstanding inventory need cannot be met by the qualified cord blood banks under contract under this section.

“(3) EXTENSION ELIGIBILITY.—A qualified cord blood bank shall be eligible for a 5-year extension of a contract awarded under this section, as described in paragraph (2), provided that the qualified cord blood bank—

“(A) demonstrates a superior ability to satisfy the requirements described in subsection (b) and achieves the overall goals for which the contract was awarded;

“(B) provides a plan for how the qualified cord blood bank will increase cord blood unit collections at collection sites that exist at the time of consideration for such extension of a contract, assist with the establishment of new collection sites, or contract with new collection sites; and

“(C) annually provides to the Secretary a plan for, and demonstrates, ongoing measurable progress toward achieving self-sufficiency of cord blood unit collection and banking operations.

“(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 [42 U.S.C. 274k], 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 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 [42 U.S.C. 274k(d)(4)], as amended by this Act.

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

“(h) AUTHORIZATION OF APPROPRIATIONS.—

“(1) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to the Secretary to carry out the program under this section \$23,000,000 for each of fiscal years 2011 through 2014 and \$20,000,000 for fiscal year 2015.

“(2) LIMITATION.—Not to exceed 5 percent of the amount appropriated under this section for each of fiscal years 2011 through 2015 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.

§ 274I. 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 individ-

ually 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 title<sup>1</sup> 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 274l, 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.

#### § 274l-1. Definitions

In this part:

(1) The term “Advisory Council” means the advisory council established by the Secretary under section 274k(a)(1) of this title.

(2) The term “bone marrow” means the cells found in adult bone marrow and peripheral blood.

(3) The term “outcomes database” means the database established by the Secretary under section 274l of this title.

(4) The term “Program” means the C.W. Bill Young Cell Transplantation Program established under section 274k of this title.

(July 1, 1944, ch. 373, title III, §379A-1, as added Pub. L. 109-129, §3(c), Dec. 20, 2005, 119 Stat. 2562.)

#### § 274m. Authorization of appropriations

For the purpose of carrying out this part, there are authorized to be appropriated \$30,000,000 for each of fiscal years 2011 through 2014 and \$33,000,000 for fiscal year 2015.

(July 1, 1944, ch. 373, title III, §379B, as added Pub. L. 105-196, §4(2), July 16, 1998, 112 Stat. 636; amended Pub. L. 109-129, §3(d), Dec. 20, 2005, 119 Stat. 2562; Pub. L. 111-264, §2(d), Oct. 8, 2010, 124 Stat. 2792.)

#### AMENDMENTS

2010—Pub. L. 111-264 substituted “\$30,000,000 for each of fiscal years 2011 through 2014 and \$33,000,000 for fiscal year 2015.” for “\$34,000,000 for fiscal year 2006 and \$38,000,000 for each of fiscal years 2007 through 2010.”

2005—Pub. L. 109-129 amended section generally. Prior to amendment, section read as follows: “For the purpose of carrying out this part, there are authorized to be appropriated \$18,000,000 for fiscal year 1999, and such sums as may be necessary for each of the fiscal years 2000 through 2003.”

<sup>1</sup> So in original. Probably should be followed by a comma.

#### 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.

#### § 275. Repealed. Pub. L. 103-43, title I, § 121(a), June 10, 1993, 107 Stat. 133

Section, act July 1, 1944, ch. 373, title III, §381, as added Nov. 20, 1985, Pub. L. 99-158, §11, 99 Stat. 883; amended Nov. 4, 1988, Pub. L. 100-607, title I, §157(a), 102 Stat. 3059, established the Biomedical Ethics Board and provided for its membership, functions, reports to Congress, etc., and provided for appointment of a Biomedical Ethics Advisory Committee to assist the Biomedical Ethics Board.

A prior section 275, act July 1, 1944, ch. 373, title III, §381, formerly §371, as added Aug. 3, 1956, ch. 907, §1, 70 Stat. 960; renumbered §381, Mar. 13, 1970, Pub. L. 91-212, §10(a)(3), 84 Stat. 66, established a National Library of Medicine in the Public Health Service and stated the congressional purposes for such establishment, prior to repeal by Pub. L. 99-158, §3(b), Nov. 20, 1985, 99 Stat. 879.

#### §§ 276 to 280a-1. Repealed. Pub. L. 99-158, § 3(b), Nov. 20, 1985, 99 Stat. 879

Section 276, act July 1, 1944, ch. 373, title III, §382, formerly §372, as added Aug. 3, 1956, ch. 907, §1, 70 Stat. 960; renumbered §382 and amended Mar. 13, 1970, Pub. L. 91-212, §10(a)(3), (b)(1), (d)(1), 84 Stat. 66, 67; Nov. 18, 1971, Pub. L. 92-157, title III, §301(d)(1), 85 Stat. 463, related to functions of Secretary with regard to acquisition, etc., of materials and rules for public access to materials.

Section 277, act July 1, 1944, ch. 373, title III, §383, formerly §373, as added Aug. 3, 1956, ch. 907, §1, 70 Stat. 960; amended Oct. 22, 1965, Pub. L. 89-291, §4, 79 Stat. 1067; renumbered §383 and amended Mar. 13, 1970, Pub. L. 91-212, §10(a)(3), (d)(1), 84 Stat. 66, 67; Oct. 30, 1970, Pub. L. 91-515, title VI, §601(b)(2), 84 Stat. 1311; Nov. 18, 1971, Pub. L. 92-157, title III, §301(d)(2), 85 Stat. 464; Nov. 9, 1978, Pub. L. 95-622, title II, §212, 92 Stat. 3421, related to establishment, etc., of Board of Regents.

Section 278, act July 1, 1944, ch. 373, title III, §384, formerly §374, as added Aug. 3, 1956, ch. 907, §1, 70 Stat. 961; renumbered §384 and amended Mar. 13, 1970, Pub. L. 91-212, §10(a)(3), (d)(1), 84 Stat. 66, 67; Oct. 17, 1979, Pub. L. 96-88, title V, §509(b), 93 Stat. 695; Apr. 26, 1983, Pub. L. 98-24, §2(a)(2), 97 Stat. 176, related to acceptance and administration of gifts and establishment of memorials to donors.

Section 279, act July 1, 1944, ch. 373, title III, §385, formerly §375, as added Aug. 3, 1956, ch. 907 §1, 70 Stat. 962; renumbered §385 and amended Mar. 13, 1970, Pub. L. 91-212, §10(a)(3), (b)(2), 84 Stat. 66, defined “medicine” and “medical”.

Section 280, act July 1, 1944, ch. 373, title III, §386, formerly §376, as added Aug. 3, 1956, ch. 907, §1, 70 Stat. 962; renumbered §386 and amended Mar. 13, 1970, Pub. L. 91-212, §10(a)(3), (d)(1), 84 Stat. 66, 67; Nov. 18, 1971, Pub. L. 92-157, title III, §301(d)(3), 85 Stat. 464, authorized appropriations for erection and equipment of Library.

Section 280a, act July 1, 1944, ch. 373, title III, §387, formerly §377, as added Aug. 3, 1956, ch. 907, §1, 70 Stat. 962; amended 1970 Reorg. Plan No. 2 §102, eff. July 1, 1970, 35 F.R. 7959, 84 Stat. 2085; renumbered §387, Mar. 13, 1970, Pub. L. 91-212, §10(a)(3), 84 Stat. 66, related to transfer of Armed Forces Medical Library to Public Health Service for use in administration of part I.

Section 280a-1, act July 1, 1944, ch. 373, title III, §388, formerly §378, as added Oct. 22, 1965, Pub. L. 89-291, §3, 79 Stat. 1067; renumbered §388 and amended Mar. 13, 1970, Pub. L. 91-212, §10(a)(3), (d)(1), 84 Stat. 66, 67; Nov. 18, 1971, Pub. L. 92-157, title III, §301(d)(4), 85 Stat. 464, related to establishment of regional branches.