pilot projects relating to the System for Alien Verification of Eligibility (SAVE) operated by, or through cooperative agreements with, the Immigration and Naturalization Service, and report, not later than Oct. 1, 1987, to Congress and to Commissioner of Immigration and Naturalization Service concerning the effectiveness of such projects and any problems with the implementation of such projects, particularly as they may apply to implementation of the system, with Comptroller General to monitor and analyze the implementation of such system, report to Congress and to the appropriate Secretaries, by not later than Apr. 1, 1989, on such implementation, and include in such report recommendations for appropriate changes in the system.

## § 1320b-8. Hospital protocols for organ procurement and standards for organ procurement agencies

- (a)(1) The Secretary shall provide that a hospital or critical access hospital meeting the requirements of subchapter XVIII or XIX may participate in the program established under such subchapter only if—
  - (A) the hospital or critical access hospital establishes written protocols for the identification of potential organ donors that—
    - (i) assure that families of potential organ donors are made aware of the option of organ or tissue donation and their option to decline.
    - (ii) encourage discretion and sensitivity with respect to the circumstances, views, and beliefs of such families, and
    - (iii) require that such hospital's designated organ procurement agency (as defined in paragraph (3)(B)) is notified of potential organ donors:
  - (B) in the case of a hospital in which organ transplants are performed, the hospital is a member of, and abides by the rules and requirements of, the Organ Procurement and Transplantation Network established pursuant to section 274 of this title (in this section referred to as the "Network"); and
  - (C) the hospital or critical access hospital has an agreement (as defined in paragraph (3)(A)) only with such hospital's designated organ procurement agency.
- (2)(A) The Secretary shall grant a waiver of the requirements under subparagraphs (A)(iii) and (C) of paragraph (1) to a hospital or critical access hospital desiring to enter into an agreement with an organ procurement agency other than such hospital's designated organ procurement agency if the Secretary determines that—
  - (i) the waiver is expected to increase organ donation; and
  - (ii) the waiver will assure equitable treatment of patients referred for transplants within the service area served by such hospital's designated organ procurement agency and within the service area served by the organ procurement agency with which the hospital seeks to enter into an agreement under the waiver.
- (B) In making a determination under subparagraph (A), the Secretary may consider factors that would include, but not be limited to—
  - (i) cost effectiveness;
  - (ii) improvements in quality;
  - (iii) whether there has been any change in a hospital's designated organ procurement agen-

- cy due to a change made on or after December 28, 1992, in the definitions for metropolitan statistical areas (as established by the Office of Management and Budget); and
- (iv) the length and continuity of a hospital's relationship with an organ procurement agency other than the hospital's designated organ procurement agency:

except that nothing in this subparagraph shall be construed to permit the Secretary to grant a waiver that does not meet the requirements of subparagraph (A).

- (C) Any hospital or critical access hospital seeking a waiver under subparagraph (A) shall submit an application to the Secretary containing such information as the Secretary determines appropriate.
  - (D) The Secretary shall—
  - (i) publish a public notice of any waiver application received from a hospital or critical access hospital under this paragraph within 30 days of receiving such application; and
  - (ii) prior to making a final determination on such application under subparagraph (A), offer interested parties the opportunity to submit written comments to the Secretary during the 60-day period beginning on the date such notice is published.
  - (3) For purposes of this subsection—
  - (A) the term "agreement" means an agreement described in section 273(b)(3)(A) of this title;
  - (B) the term "designated organ procurement agency" means, with respect to a hospital or critical access hospital, the organ procurement agency designated pursuant to subsection (b) for the service area in which such hospital is located; and
  - (C) the term "organ" means a human kidney, liver, heart, lung, pancreas, and any other human organ or tissue specified by the Secretary for purposes of this subsection.
- (b)(1) The Secretary shall provide that payment may be made under subchapter XVIII or XIX with respect to organ procurement costs attributable to payments made to an organ procurement agency only if the agency—
  - (A)(i) is a qualified organ procurement organization (as described in section 273(b) of this title) that is operating under a grant made under section 273(a) of this title, or (ii) has been certified or recertified by the Secretary within the previous 2 years (4 years if the Secretary determines appropriate for an organization on the basis of its past practices) as meeting the standards to be a qualified organ procurement organization (as so described);
  - (B) meets the requirements that are applicable under such subchapter for organ procurement agencies;
  - (C) meets performance-related standards prescribed by the Secretary;
  - (D) is a member of, and abides by the rules and requirements of, the Network;
  - (E) allocates organs, within its service area and nationally, in accordance with medical criteria and the policies of the Network; and
  - (F) is designated by the Secretary as an organ procurement organization payments to which may be treated as organ procurement

costs for purposes of reimbursement under such subchapter.

(2) The Secretary may not designate more than one organ procurement organization for service area (described in section  $273(b)(1)(E)^{1}$  of this title) under paragraph (1)(F). (Aug. 14, 1935, ch. 531, title XI, §1138, as added Pub. L. 99-509, title IX, §9318(a), Oct. 21, 1986, 100 Stat. 2009; amended Pub. L. 100-203, title IV, §4039(h)(2), Dec. 22, 1987, as added Pub. L. 100-360, title IV, §411(e)(3), July 1, 1988, 102 Stat. 775; amended Pub. L. 101-239, title VI. §6003(g)(3)(D)(iv), Dec. 19, 1989, 103 Stat. 2153; Pub. L. 103-432, title I, §155(a)(1), Oct. 31, 1994, 108 Stat. 4438; Pub. L. 105-33, title IV, §§4201(c)(1), 4642, Aug. 5, 1997, 111 Stat. 373, 487.)

## REFERENCES IN TEXT

Section 273(b)(1)(E) of this title, referred to in subsec. (b)(2), was redesignated section 273(b)(1)(F) of this title by Pub. L. 106–505, title VII,  $\S$ 701(c)(1), Nov. 13, 2000, 114 Stat. 2347 and Pub. L. 106–554,  $\S$ 1(a)(1) [title II,  $\S$ 219(b)(1)], Dec. 21, 2000, 114 Stat. 2763, 2763A–29.

## AMENDMENTS

1997—Subsec. (a). Pub. L. 105-33, §4201(c)(1), substituted "critical access" for "rural primary care" wherever appearing.

Subsec. (b)(1)(A)(ii). Pub. L. 105–33, §4642, substituted "2 years (4 years if the Secretary determines appropriate for an organization on the basis of its past practices)" for "two years".

1994—Subsec. (a)(1)(A)(iii). Pub. L. 103-432, §155(a)(1)(A), amended cl. (iii) generally. Prior to amendment, cl. (iii) read as follows: "require that an organ procurement agency designated by the Secretary pursuant to subsection (b)(1)(F) of this section be notified of potential organ donors; and".

Subsec. (a)(1)(C). Pub. L. 103-432, §155(a)(1)(B), added subpar. (C).

Subsec. (a)(2). Pub. L. 103-432, §155(a)(1)(C)(ii), added par. (2). Former par. (2) redesignated (3).

Subsec. (a)(3). Pub. L. 103–432, §155(a)(1)(D), amended par. (3) generally. Prior to amendment, par. (3) read as follows: "For purposes of this subsection, the term 'organ' means a human kidney, liver, heart, lung, pancreas, and any other human organ or tissue specified by the Secretary for purposes of this subsection."

Pub. L. 103–432,  $\S155(a)(1)(C)(i)$ , redesignated par. (2) as (3).

1989—Subsec. (a)(1). Pub. L. 101–239 substituted "hospital or rural primary care hospital" for "hospital" in two places preceding cl. (i) of subpar. (A).

1988—Subsec. (a)( $\hat{1}$ )(B). Pub. L. 100–360 added Pub. L. 100–203,  $\S4039(h)(2)$ , see 1987 Amendment note below.

1987—Subsec. (a)(1)(B). Pub. L. 100-203, \$4039(h)(2), as added by Pub. L. 100-360, substituted "in" for "In" at beginning.

## EFFECTIVE DATE OF 1997 AMENDMENT

Amendment by section 4201(c)(1) of Pub. L. 105–33 applicable to services furnished on or after Oct. 1, 1997, see section 4201(d) of Pub. L. 105–33, set out as a note under section 1395f of this title.

# EFFECTIVE DATE OF 1994 AMENDMENT

Pub. L. 103-432, title I, \$155(a)(3), Oct. 31, 1994, 108 Stat. 4439, provided that: "The amendments made by paragraph (1) [amending this section] shall apply to hospitals and rural primary care hospitals participating in the programs under titles XVIII and XIX of the Social Security Act [42 U.S.C. 1395 et seq., 1396 et seq.] beginning January 1, 1996."

## EFFECTIVE DATE OF 1988 AMENDMENT

Except as specifically provided in section 411 of Pub. L. 100–360, amendment by Pub. L. 100–360, as it relates to a provision in the Omnibus Budget Reconciliation Act of 1987, Pub. L. 100–203, effective as if included in the enactment of that provision in Pub. L. 100–203, see section 411(a) of Pub. L. 100–360, set out as a Reference to OBRA; Effective Date note under section 106 of Title 1, General Provisions.

#### EFFECTIVE DATE

Pub. L. 99–509, title IX, \$9318(b), Oct. 21, 1986, 100 Stat. 2010, as amended by Pub. L. 100–119, title I, \$107(c), Sept. 29, 1987, 101 Stat. 784; Pub. L. 100–203, title IV, \$4009(g)(1), Dec. 22, 1987, 101 Stat. 1330–58, provided that: "(1) Section 1138(a) of the Social Security Act [42]

"(1) Section 1138(a) of the Social Security Act [42 U.S.C. 1320b-8(a)] shall apply to hospitals participating in the programs under titles XVIII and XIX of such Act [42 U.S.C. 1395 et seq., 1396 et seq.] as of November 21, 1987."

"(2) Section 1138(b) of such Act [42 U.S.C. 1320b-8(b)] shall apply to costs of organs procured on or after March 31, 1988."

[Pub. L. 100–203, title IV, §4009(g)(2), Dec. 22, 1987, 101 Stat. 1330–58, provided that: "The amendment made by paragraph (1) [amending this note] shall be effective as if included in the enactment of the Omnibus Budget Reconciliation Act of 1986 [Pub. L. 99–509]."]

# EXISTING AGREEMENTS WITH ORGAN PROCUREMENT AGENCIES

Pub. L. 103–432, title I, §155(a)(2), Oct. 31, 1994, 108 Stat. 4439, provided that: "Any hospital or rural primary care hospital which has an agreement (as defined in section 1138(a)(3)(A) of the Social Security Act [42 U.S.C. 1320b–8(a)(3)(A)]) with an organ procurement agency other than such hospital's designated organ procurement agency (as defined in section 1138(a)(3)(B) of such Act) on the date of the enactment of this section [Oct. 31, 1994] shall, if such hospital desires to continue such agreement on and after the effective date of the amendments made by paragraph (1) [see Effective Date of 1994 Amendment note above], submit an application to the Secretary for a waiver under section 1138(a)(2) of such Act not later than January 1, 1996, and such agreement may continue in effect pending the Secretary's determination with respect to such application."

## § 1320b-9. Improved access to, and delivery of, health care for Indians under subchapters XIX and XXI

(a) Agreements with States for Medicaid and CHIP outreach on or near reservations to increase the enrollment of Indians in those programs

## (1) In general

In order to improve the access of Indians residing on or near a reservation to obtain benefits under the Medicaid and State children's health insurance programs established under subchapters XIX and XXI, the Secretary shall encourage the State to take steps to provide for enrollment on or near the reservation. Such steps may include outreach efforts such as the outstationing of eligibility workers, entering into agreements with the Indian Health Service, Indian Tribes, Tribal Organizations, and Urban Indian Organizations to provide outreach, education regarding eligibility and benefits, enrollment, and translation services when such services are appropriate.

## (2) Construction

Nothing in paragraph (1) shall be construed as affecting arrangements entered into be-

<sup>&</sup>lt;sup>1</sup> See References in Text note below.