

ulations prescribing the standards applicable to the notice required to be provided in connection with such offer. The Commissioner shall promulgate such final regulations within 1 year after the date of the enactment of this Act [Mar. 2, 2004].”

Pub. L. 108-203, title II, § 207(b), Mar. 2, 2004, 118 Stat. 513, provided that: “The amendments made by this section [amending this section] shall apply to items sent after 180 days after the date of the enactment of this Act [Mar. 2, 2004].”

#### EFFECTIVE DATE OF 1994 AMENDMENT

Amendment by section 108(b)(12) of Pub. L. 103-296 effective Mar. 31, 1995, see section 110(a) of Pub. L. 103-296, set out as a note under section 401 of this title.

Amendment by section 312(a)-(j) of Pub. L. 103-296 applicable with respect to violations occurring after Mar. 31, 1995, see section 312(m)(1) of Pub. L. 103-296, set out as an Effective Date note under section 333 of Title 31, Money and Finance.

#### EFFECTIVE DATE OF 1988 AMENDMENT

Amendment by Pub. L. 100-485 effective as if included in the enactment of the Medicare Catastrophic Coverage Act of 1988, Pub. L. 100-360, see section 608(g)(1) of Pub. L. 100-485, set out as a note under section 704 of this title.

#### EFFECTIVE DATE

Pub. L. 100-360, title IV, § 428(c), July 1, 1988, 102 Stat. 817, provided that: “The amendments made by this section [enacting this section and amending section 1395ss of this title] shall take effect on the date of the enactment of this Act [July 1, 1988] and shall apply only with respect to violations occurring on or after such date.”

#### REPORTS ON OPERATION OF THIS SECTION

Pub. L. 103-296, title III, § 312(k), Aug. 15, 1994, 108 Stat. 1527, required the Secretary of Health and Human Services and the Commissioner of Social Security each to submit 3 reports related to violations of this section, hearings, and penalties, due no later than Dec. 1, 1995, Dec. 1, 1997, and Dec. 1, 1999.

#### CONSULTATION BY UNITED STATES POSTAL SERVICE REGARDING PREVENTION OF DECEPTIVE MAILINGS

United States Postal Service to consult and coordinate functions of Secretary of Department of Health and Human Services in administration of this section, see section 4 of Pub. L. 101-524, set out as a Coordination of Functions With Department of Health and Human Services note under section 3001 of Title 39, Postal Service.

### § 1320b-11. Blood donor locator service

#### (a) In general

The Commissioner of Social Security shall establish and conduct a Blood Donor Locator Service, which shall be used to obtain and transmit to any authorized person (as defined in subsection (h)(1)) the most recent mailing address of any blood donor who, as indicated by the donated blood or products derived therefrom or by the history of the subsequent use of such blood or blood products, has or may have the virus for acquired immune deficiency syndrome, in order to inform such donor of the possible need for medical care and treatment.

#### (b) Provision of address information

Whenever the Commissioner of Social Security receives a request, filed by an authorized person (as defined in subsection (h)(1)), for the mailing address of a donor described in subsection (a) and the Commissioner of Social Se-

curity is reasonably satisfied that the requirements of this section have been met with respect to such request, the Commissioner of Social Security shall promptly undertake to provide the requested address information from—

(1) the files and records maintained by the Social Security Administration, and

(2) such files and records obtained pursuant to section 6103(m)(6) of the Internal Revenue Code of 1986 as the Commissioner of Social Security considers necessary to comply with such request.

#### (c) Manner and form of requests

A request for address information under this section shall be filed in such manner and form as the Commissioner of Social Security shall by regulation prescribe, shall include the blood donor's social security account number, and shall be accompanied or supported by such documents as the Commissioner of Social Security may determine to be necessary.

#### (d) Procedures and safeguards

Any authorized person shall, as a condition for receiving address information from the Blood Donor Locator Service—

(1) establish and maintain, to the satisfaction of the Commissioner of Social Security, a system for standardizing records with respect to any request, the reason for such request, and the date of such request made by or of it and any disclosure of address information made by or to it,

(2) establish and maintain, to the satisfaction of the Commissioner of Social Security, a secure area or place in which such address information and all related blood donor records shall be stored,

(3) restrict, to the satisfaction of the Commissioner of Social Security, access to the address information and related blood donor records only to persons whose duties or responsibilities require access and to whom disclosure may be made under the provisions of this section,

(4) provide such other safeguards which the Commissioner of Social Security determines (and which the Commissioner of Social Security prescribes in regulations) to be necessary or appropriate to protect the confidentiality of the address information and related blood donor records,

(5) furnish a report to the Commissioner of Social Security, at such time and containing such information as the Commissioner of Social Security may prescribe, which describes the procedures established and utilized by the authorized person for ensuring the confidentiality of address information and related blood donor records required under this subsection, and

(6) destroy such address information and related blood donor records, upon completion of their use in providing the notification for which the information was obtained, so as to make such information and records undisclosable.

If the Commissioner of Social Security determines that any authorized person has failed to, or does not, meet the requirements of this sub-

section, the Commissioner of Social Security may, after any proceedings for review established under subsection (f), take such actions as are necessary to ensure such requirements are met, including refusing to disclose address information to such authorized person until the Commissioner of Social Security determines that such requirements have been or will be met. In the case of any authorized person who discloses any address information received pursuant to this section or any related blood donor records to any agent, this subsection shall apply to such authorized person and each such agent (except that, in the case of an agent, any report to the Commissioner of Social Security or other action with respect to the Commissioner of Social Security shall be made or taken through such authorized person). The Commissioner of Social Security shall destroy all related blood donor records in the possession of the Social Security Administration upon completion of their use in transmitting mailing addresses as required under subsection (a), so as to make such records undisclosable.

**(e) Arrangements with State agencies and authorized persons**

The Commissioner of Social Security, in carrying out the Commissioner's duties and functions under this section, shall enter into arrangements—

(1) with State agencies to accept and to transmit to the Commissioner of Social Security requests for address information under this section and to accept and to transmit such information to authorized persons, and

(2) with State agencies and authorized persons otherwise to cooperate with the Commissioner of Social Security in carrying out the purposes of this section.

**(f) Procedures for administrative review**

The Commissioner of Social Security shall by regulation prescribe procedures which provide for administrative review of any determination that any authorized person has failed to meet the requirements of this section.

**(g) Unauthorized disclosure of information**

Paragraphs (1), (2), and (3) of section 7213(a) of the Internal Revenue Code of 1986 shall apply with respect to the unauthorized willful disclosure to any person of address information or related blood donor records acquired or maintained by or under the Commissioner of Social Security, or pursuant to this section by any authorized person, or of information derived from any such address information or related blood donor records, in the same manner and to the same extent as such paragraphs apply with respect to unauthorized disclosures of return and return information described in such paragraphs. Paragraph (4) of section 7213(a) of such Code shall apply with respect to the willful offer of any item of material value in exchange for any such address information or related blood donor record in the same manner and to the same extent as such paragraph applies with respect to offers (in exchange for any return or return information) described in such paragraph.

**(h) Definitions**

For purposes of this section—

**(1) Authorized person**

The term “authorized person” means—

(A) any agency of a State (or of a political subdivision of a State) which has duties or authority under State law relating to the public health or otherwise has the duty or authority under State law to regulate blood donations, and

(B) any entity engaged in the acceptance of blood donations which is licensed or registered by the Food and Drug Administration in connection with the acceptance of such blood donations, and which, in accordance with such regulations as may be prescribed by the Commissioner of Social Security, provides for—

(i) the confidentiality of any address information received pursuant to this section and related blood donor records,

(ii) blood donor notification procedures for individuals with respect to whom such information is requested and a finding has been made that they have or may have the virus for acquired immune deficiency syndrome, and

(iii) counseling services for such individuals who have been found to have such virus.

**(2) Related blood donor record**

The term “related blood donor record” means any record, list, or compilation which indicates, directly or indirectly, the identity of any individual with respect to whom a request for address information has been made pursuant to this section.

**(3) State**

The term “State” includes the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, the Commonwealth of the Northern Marianas, and the Trust Territory of the Pacific Islands.

(Aug. 14, 1935, ch. 531, title XI, §1141, as added Pub. L. 100-647, title VIII, §8008(b)(1), Nov. 10, 1988, 102 Stat. 3784; amended Pub. L. 103-296, title I, §108(b)(13), Aug. 15, 1994, 108 Stat. 1484.)

**Editorial Notes**

**REFERENCES IN TEXT**

The Internal Revenue Code of 1986, referred to in subsecs. (b)(2) and (g), is classified generally to Title 26, Internal Revenue Code.

**AMENDMENTS**

1994—Subsec. (a). Pub. L. 103-296, §108(b)(13)(A), (C), substituted “The Commissioner of Social Security” for “The Secretary” and struck out “under the direction of the Commissioner of Social Security,” before “which shall be used”.

Subsec. (b), (c). Pub. L. 103-296, §108(b)(13)(A), substituted “Commissioner of Social Security” for “Secretary” wherever appearing.

Subsec. (d). Pub. L. 103-296, §108(b)(13)(D), which directed amendment of par. (6) by substituting “Social Security Administration” for “Department of Health Services”, was executed by substituting “Social Security Administration” for “Department of Health and Human Services” in closing provisions to reflect the probable intent of Congress.

Pub. L. 103-296, §108(b)(13)(A), substituted “Commissioner of Social Security” for “Secretary” wherever appearing.

Subsec. (e). Pub. L. 103-296, §108(b)(13)(A), (B), substituted “Commissioner of Social Security” for “Secretary” wherever appearing and “Commissioner’s” for “Secretary’s” in introductory provisions.

Subsecs. (f), (g), (h)(1)(B). Pub. L. 103-296, §108(b)(13)(A), substituted “Commissioner of Social Security” for “Secretary”.

#### Statutory Notes and Related Subsidiaries

##### EFFECTIVE DATE OF 1994 AMENDMENT

Amendment by Pub. L. 103-296 effective Mar. 31, 1995, see section 110(a) of Pub. L. 103-296, set out as a note under section 401 of this title.

##### TIME LIMIT FOR ESTABLISHMENT OF BLOOD DONOR LOCATOR SERVICE

Pub. L. 100-647, title VIII, §8008(b)(2), Nov. 10, 1988, 102 Stat. 3786, required the Secretary of Health and Human Services to establish the Blood Donor Locator Service pursuant to this section no later than 180 days after Nov. 10, 1988.

#### Executive Documents

##### TERMINATION OF TRUST TERRITORY OF THE PACIFIC ISLANDS

For termination of Trust Territory of the Pacific Islands, see note set out preceding section 1681 of Title 48, Territories and Insular Possessions.

### § 1320b-12. Research on outcomes of health care services and procedures

#### (a) Establishment of program

##### (1) In general

The Secretary, acting through the Director of the Agency for Healthcare Research and Quality, shall—

(A) conduct and support research with respect to the outcomes, effectiveness, and appropriateness of health care services and procedures in order to identify the manner in which diseases, disorders, and other health conditions can most effectively and appropriately be prevented, diagnosed, treated, and managed clinically; and

(B) assure that the needs and priorities of the program under subchapter XVIII are appropriately reflected in the development and periodic review and updating (through the process set forth in section 299b-2<sup>1</sup> of this title) of treatment-specific or condition-specific practice guidelines for clinical treatments and conditions in forms appropriate for use in clinical practice, for use in educational programs, and for use in reviewing quality and appropriateness of medical care.

##### (2) Evaluations of alternative services and procedures

In carrying out paragraph (1), the Secretary shall conduct or support evaluations of the comparative effects, on health and functional capacity, of alternative services and procedures utilized in preventing, diagnosing, treating, and clinically managing diseases, disorders, and other health conditions.

##### (3) Initial guidelines

(A) In carrying out paragraph (1)(B) of this subsection, and section 299b-1(d)<sup>1</sup> of this title,

the Secretary shall, by not later than January 1, 1991, assure the development of an initial set of the guidelines specified in paragraph (1)(B) that shall include not less than 3 clinical treatments or conditions that—

(i)(I) account for a significant portion of expenditures under subchapter XVIII; and

(II) have a significant variation in the frequency or the type of treatment provided; or

(ii) otherwise meet the needs and priorities of the program under subchapter XVIII, as set forth under subsection (b)(3).

(B)(i) The Secretary shall provide for the use of guidelines developed under subparagraph<sup>2</sup> (A) to improve the quality, effectiveness, and appropriateness of care provided under subchapter XVIII. The Secretary shall determine the impact of such use on the quality, appropriateness, effectiveness, and cost of medical care provided under such subchapter and shall report to the Congress on such determination by not later than January 1, 1993.

(ii) For the purpose of carrying out clause (i), the Secretary shall expend, from the amounts specified in clause (iii), \$1,000,000 for fiscal year 1990 and \$1,500,000 for each of the fiscal years 1991 and 1992.

(iii) For each fiscal year, for purposes of expenditures required in clause (ii)—

(I) 60 percent of an amount equal to the expenditure involved is appropriated from the Federal Hospital Insurance Trust Fund (established under section 1395i of this title); and

(II) 40 percent of an amount equal to the expenditure involved is appropriated from the Federal Supplementary Medical Insurance Trust Fund (established under section 1395t of this title).

#### (b) Priorities

##### (1) In general

The Secretary shall establish priorities with respect to the diseases, disorders, and other health conditions for which research and evaluations are to be conducted or supported under subsection (a). In establishing such priorities, the Secretary shall, with respect to a disease, disorder, or other health condition, consider the extent to which—

(A) improved methods of prevention, diagnosis, treatment, and clinical management can benefit a significant number of individuals;

(B) there is significant variation among physicians in the particular services and procedures utilized in making diagnoses and providing treatments or there is significant variation in the outcomes of health care services or procedures due to different patterns of diagnosis or treatment;

(C) the services and procedures utilized for diagnosis and treatment result in relatively substantial expenditures; and

(D) the data necessary for such evaluations are readily available or can readily be developed.

##### (2) Preliminary assessments

For the purpose of establishing priorities under paragraph (1), the Secretary may, with

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

<sup>2</sup> So in original. Probably should be “subparagraph”.