

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

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

(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 respect to services and procedures utilized in preventing, diagnosing, treating, and clinically managing diseases, disorders, and other health conditions, conduct or support assessments of the extent to which—

(A) rates of utilization vary among similar populations for particular diseases, disorders, and other health conditions;

(B) uncertainties exist on the effect of utilizing a particular service or procedure; or

(C) inappropriate services and procedures are provided.

### **(3) Relationship with medicare program**

In establishing priorities under paragraph (1) for research and evaluation, and under section 299b-3(a)<sup>1</sup> of this title for the agenda under such section, the Secretary shall assure that such priorities appropriately reflect the needs and priorities of the program under subchapter XVIII, as set forth by the Administrator of the Centers for Medicare & Medicaid Services.

### **(c) Methodologies and criteria for evaluations**

For the purpose of facilitating research under subsection (a), the Secretary shall—

(1) conduct and support research with respect to the improvement of methodologies and criteria utilized in conducting research with respect to outcomes of health care services and procedures;

(2) conduct and support reviews and evaluations of existing research findings with respect to such treatment or conditions;

(3) conduct and support reviews and evaluations of the existing methodologies that use large data bases in conducting such research and shall develop new research methodologies, including data-based methods of advancing knowledge and methodologies that measure clinical and functional status of patients, with respect to such research;

(4) provide grants and contracts to research centers, and contracts to other entities, to conduct such research on such treatment or conditions, including research on the appropriate use of prescription drugs;

(5) conduct and support research and demonstrations on the use of claims data and data on clinical and functional status of patients in determining the outcomes, effectiveness, and appropriateness of such treatment; and

(6) conduct and support supplementation of existing data bases, including the collection of new information, to enhance data bases for research purposes, and the design and development of new data bases that would be used in outcomes and effectiveness research.

### **(d) Standards for data bases**

In carrying out this section, the Secretary shall develop—

(1) uniform definitions of data to be collected and used in describing a patient's clinical and functional status;

(2) common reporting formats and linkages for such data; and

(3) standards to assure the security, confidentiality, accuracy, and appropriate maintenance of such data.

### **(e) Dissemination of research findings and guidelines**

#### **(1) In general**

The Secretary shall provide for the dissemination of the findings of research and the

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

guidelines described in subsection (a), and for the education of providers and others in the application of such research findings and guidelines.

**(2) Cooperative educational activities**

In disseminating findings and guidelines under paragraph (1), and in providing for education under such paragraph, the Secretary shall work with professional associations, medical specialty and subspecialty organizations, and other relevant groups to identify and implement effective means to educate physicians, other providers, consumers, and others in using such findings and guidelines, including training for physician managers within provider organizations.

**(f) Evaluations**

The Secretary shall conduct and support evaluations of the activities carried out under this section to determine the extent to which such activities have had an effect on the practices of physicians in providing medical treatment, the delivery of health care, and the outcomes of health care services and procedures.

**(g) Research with respect to dissemination**

The Secretary may conduct or support research with respect to improving methods of disseminating information on the effectiveness and appropriateness of health care services and procedures.

**(h) Omitted**

**(i) Authorization of appropriations**

**(1) In general**

There are authorized to be appropriated to carry out this section—

- (A) \$50,000,000 for fiscal year 1990;
- (B) \$75,000,000 for fiscal year 1991;
- (C) \$110,000,000 for fiscal year 1992;
- (D) \$148,000,000 for fiscal year 1993; and
- (E) \$185,000,000 for fiscal year 1994.

**(2) Specifications**

For the purpose of carrying out this section, for each of the fiscal years 1990 through 1992 an amount equal to two-thirds of the amounts authorized to be appropriated under paragraph (1), and for each of the fiscal years 1993 and 1994 an amount equal to 70 percent of such amounts, are to be appropriated in the following proportions from the following trust funds:

- (A) 60 percent from the Federal Hospital Insurance Trust Fund (established under section 1395i of this title).
- (B) 40 percent from the Federal Supplementary Medical Insurance Trust Fund (established under section 1395t of this title).

**(3) Allocations**

(A) For each fiscal year, of the amounts transferred or otherwise appropriated to carry out this section, the Secretary shall reserve appropriate amounts for each of the purposes specified in clauses (i) through (iv) of subparagraph (B).

(B) The purposes referred to in subparagraph (A) are—

- (i) the development of guidelines, standards, performance measures, and review criteria;

- (ii) research and evaluation;
- (iii) data-base standards and development; and
- (iv) education and information dissemination.

(Aug. 14, 1935, ch. 531, title XI, § 1142, as added Pub. L. 101-239, title VI, § 6103(b)(1), Dec. 19, 1989, 103 Stat. 2195; amended Pub. L. 106-129, § 2(b)(2), Dec. 6, 1999, 113 Stat. 1670; Pub. L. 108-173, title IX, § 900(e)(1)(C), Dec. 8, 2003, 117 Stat. 2371.)

**Editorial Notes**

REFERENCES IN TEXT

Sections 299b-1 to 299b-3 of this title, referred to in subsecs. (a) and (b), were in the original references to sections 912 to 914 of act July 1, 1944, which were omitted in the general amendment of subchapter VII of chapter 6A of this title by Pub. L. 106-129, § 2(a), Dec. 6, 1999, 113 Stat. 1653. Section 2(a) of Pub. L. 106-129 enacted new sections 912 to 914 of act July 1, 1944, which are classified to sections 299b-1 to 299b-3, respectively, of this title.

CODIFICATION

Subsec. (h) of this section, which required the Secretary to report biennially to Congress on the progress of the activities under this section during the preceding 2 fiscal years, including the impact of such activities on medical care (particularly medical care for individuals receiving benefits under subchapter XVIII of this chapter), terminated, effective May 15, 2000, pursuant to section 3003 of Pub. L. 104-66, as amended, set out as a note under section 1113 of Title 31, Money and Finance. See, also, item 10 on page 94 of House Document No. 103-7.

Another section 1142 of act Aug. 14, 1935, was renumbered section 1143 by Pub. L. 101-508, title V, § 5111(a)(1), Nov. 5, 1990, 104 Stat. 1388-272, and is classified to section 1320b-13 of this title.

AMENDMENTS

2003—Subsec. (b)(3). Pub. L. 108-173, § 900(e)(1)(C), substituted “Centers for Medicare & Medicaid Services” for “Health Care Financing Administration”.

1999—Subsec. (a)(1). Pub. L. 106-129 substituted “Director of the Agency for Healthcare Research and Quality” for “Administrator for Health Care Policy and Research” in introductory provisions.

**Statutory Notes and Related Subsidiaries**

AHCPR STUDY ON EFFECT OF CREDENTIALING OF TECHNOLOGISTS AND SONOGRAPHERS ON QUALITY OF ULTRASOUND

Pub. L. 106-113, div. B, § 1000(a)(6) [title II, § 229(b)], Nov. 29, 1999, 113 Stat. 1536, 1501A-357, required a study on the effect of credentialing of technologists and sonographers on the quality of ultrasounds and submission of a report to Congress no later than two years after Nov. 29, 1999.

REPORT ON LINKAGE OF PUBLIC AND PRIVATE RESEARCH RELATED DATA

Pub. L. 101-239, title VI, § 6103(b)(2), Dec. 19, 1989, 103 Stat. 2198, provided that, no later than 1 year after Dec. 19, 1989, the Secretary of Health and Human Services would report to Congress on the feasibility of linking research-related data described in subsec. (d) of this section with similar data collected or maintained by non-Federal entities and by Federal agencies other than the Department of Health and Human Services (including the Departments of Defense and Veterans Affairs and the Office of Personnel Management).

**§ 1320b-13. Social security account statements****(a) Provision upon request**

(1) Beginning not later than October 1, 1990, the Commissioner of Social Security shall provide upon the request of an eligible individual a social security account statement (hereinafter referred to as the “statement”).

(2) Each statement shall contain—

(A) the amount of wages paid to and self-employment income derived by the eligible individual as shown by the records of the Commissioner at the date of the request;

(B) an estimate of the aggregate of the employer, employee, and self-employment contributions of the eligible individual for old-age, survivors, and disability insurance as shown by the records of the Commissioner on the date of the request;

(C) a separate estimate of the aggregate of the employer, employee, and self-employment contributions of the eligible individual for hospital insurance as shown by the records of the Commissioner on the date of the request;

(D) an estimate of the potential monthly retirement, disability, survivor, and auxiliary benefits payable on the eligible individual’s account together with a description of the benefits payable under the medicare program of subchapter XVIII; and

(E) in the case of an eligible individual described in paragraph (3)(C)(ii), an explanation, in language calculated to be understood by the average eligible individual, of the operation of the provisions under sections 402(k)(5) and 415(a)(7) of this title and an explanation of the maximum potential effects of such provisions on the eligible individual’s monthly retirement, survivor, and auxiliary benefits.

(3) For purposes of this section, the term “eligible individual” means an individual—

(A) who has a social security account number,

(B) who has attained age 25 or over, and

(C)(i) who has wages or net earnings from self-employment, or (ii) with respect to whom the Commissioner has information that the pattern of wages or self-employment income indicate a likelihood of noncovered employment.

**(b) Notice to eligible individuals**

The Commissioner shall, to the maximum extent practicable, take such steps as are necessary to assure that eligible individuals are informed of the availability of the statement described in subsection (a).

**(c) Mandatory provision of statements**

(1) By not later than September 30, 1995, the Commissioner shall provide a statement to each eligible individual who has attained age 60 by October 1, 1994, and who is not receiving benefits under subchapter II and for whom a current mailing address can be determined through such methods as the Commissioner determines to be appropriate. In fiscal years 1995 through 1999 the Commissioner shall provide a statement to each eligible individual who attains age 60 in such fiscal years and who is not receiving benefits under subchapter II and for whom a current mailing

address can be determined through such methods as the Commissioner determines to be appropriate. The Commissioner shall provide with each statement to an eligible individual notice that such statement is updated annually and is available upon request.

(2) Beginning not later than October 1, 1999, the Commissioner shall provide a statement on an annual basis to each eligible individual who is not receiving benefits under subchapter II and for whom a mailing address can be determined through such methods as the Commissioner determines to be appropriate. With respect to statements provided to eligible individuals who have not attained age 50, such statements need not include estimates of monthly retirement benefits. However, if such statements provided to eligible individuals who have not attained age 50 do not include estimates of retirement benefit amounts, such statements shall include a description of the benefits (including auxiliary benefits) that are available upon retirement.

**(d) Disclosure to governmental employees of effect of noncovered employment**

(1) In the case of any individual commencing employment on or after January 1, 2005, in any agency or instrumentality of any State (or political subdivision thereof, as defined in section 418(b)(2) of this title) in a position in which service performed by the individual does not constitute “employment” as defined in section 410 of this title, the head of the agency or instrumentality shall ensure that, prior to the date of the commencement of the individual’s employment in the position, the individual is provided a written notice setting forth an explanation, in language calculated to be understood by the average individual, of the maximum effect on computations of primary insurance amounts (under section 415(a)(7) of this title) and the effect on benefit amounts (under section 402(k)(5) of this title) of monthly periodic payments or benefits payable based on earnings derived in such service. Such notice shall be in a form which shall be prescribed by the Commissioner of Social Security.

(2) The written notice provided to an individual pursuant to paragraph (1) shall include a form which, upon completion and signature by the individual, would constitute certification by the individual of receipt of the notice. The agency or instrumentality providing the notice to the individual shall require that the form be completed and signed by the individual and submitted to the agency or instrumentality and to the pension, annuity, retirement, or similar fund or system established by the governmental entity involved responsible for paying the monthly periodic payments or benefits, before commencement of service with the agency or instrumentality.

(Aug. 14, 1935, ch. 531, title XI, §1143, formerly §1142, as added Pub. L. 101-239, title X, §10308, Dec. 19, 1989, 103 Stat. 2485; renumbered §1143 and amended Pub. L. 101-508, title V, §5111(a), Nov. 5, 1990, 104 Stat. 1388-272; Pub. L. 105-78, title VI, §605, Nov. 13, 1997, 111 Stat. 1521; Pub. L. 108-203, title IV, §§419(a)-(c), 421, Mar. 2, 2004, 118 Stat. 533-535.)