

(A)(ii),” after “original research” and “, as long as the researcher enters into a data use agreement with the Institute for use of the data from the original research, as appropriate” after “publication”.

Subsec. (d)(2)(B)(iv). Pub. L. 111-148, §10602(1)(B), amended cl. (iv) generally. Prior to amendment, text read as follows: “Any research published under clause (ii)(IV) shall be within the bounds of and entirely consistent with the evidence and findings produced under the contract with the Institute under this subparagraph. If the Institute determines that those requirements are not met, the Institute shall not enter into another contract with the agency, instrumentality, or entity which managed or conducted such research for a period determined appropriate by the Institute (but not less than 5 years).”

Subsec. (d)(8)(A)(iv). Pub. L. 111-148, §10602(2), substituted “do not include” for “not be construed as mandates for”.

Subsec. (f)(1)(C)(ii). Pub. L. 111-148, §10602(3), amended cl. (ii) generally. Prior to amendment, cl. (ii) read as follows: “5 members representing physicians and providers, including at least 1 surgeon, nurse, State-licensed integrative health care practitioner, and representative of a hospital.”

§ 1320e-1. Limitations on certain uses of comparative clinical effectiveness research

(a) The Secretary may only use evidence and findings from research conducted under section 1320e of this title to make a determination regarding coverage under subchapter XVIII if such use is through an iterative and transparent process which includes public comment and considers the effect on subpopulations.

(b) Nothing in section 1320e of this title shall be construed as—

(1) superceding or modifying the coverage of items or services under subchapter XVIII that the Secretary determines are reasonable and necessary under section 1395y(l)(1) of this title; or

(2) authorizing the Secretary to deny coverage of items or services under such subchapter solely on the basis of comparative clinical effectiveness research.

(c)(1) The Secretary shall not use evidence or findings from comparative clinical effectiveness research conducted under section 1320e of this title in determining coverage, reimbursement, or incentive programs under subchapter XVIII in a manner that treats extending the life of an elderly, disabled, or terminally ill individual as of lower value than extending the life of an individual who is younger, nondisabled, or not terminally ill.

(2) Paragraph (1) shall not be construed as preventing the Secretary from using evidence or findings from such comparative clinical effectiveness research in determining coverage, reimbursement, or incentive programs under subchapter XVIII based upon a comparison of the difference in the effectiveness of alternative treatments in extending an individual's life due to the individual's age, disability, or terminal illness.

(d)(1) The Secretary shall not use evidence or findings from comparative clinical effectiveness research conducted under section 1320e of this title in determining coverage, reimbursement, or incentive programs under subchapter XVIII in a manner that precludes, or with the intent to discourage, an individual from choosing a

health care treatment based on how the individual values the tradeoff between extending the length of their life and the risk of disability.

(2)(A)¹ Paragraph (1) shall not be construed to—

(i) limit the application of differential co-payments under subchapter XVIII based on factors such as cost or type of service; or

(ii) prevent the Secretary from using evidence or findings from such comparative clinical effectiveness research in determining coverage, reimbursement, or incentive programs under such subchapter based upon a comparison of the difference in the effectiveness of alternative health care treatments in extending an individual's life due to that individual's age, disability, or terminal illness.

(3) Nothing in the provisions of, or amendments made by the Patient Protection and Affordable Care Act, shall be construed to limit comparative clinical effectiveness research or any other research, evaluation, or dissemination of information concerning the likelihood that a health care treatment will result in disability.

(e) The Patient-Centered Outcomes Research Institute established under section 1320e(b)(1) of this title shall not develop or employ a dollars-per-quality adjusted life year (or similar measure that discounts the value of a life because of an individual's disability) as a threshold to establish what type of health care is cost effective or recommended. The Secretary shall not utilize such an adjusted life year (or such a similar measure) as a threshold to determine coverage, reimbursement, or incentive programs under subchapter XVIII.

(Aug. 14, 1935, ch. 531, title XI, §1182, as added Pub. L. 111-148, title VI, §6301(c), Mar. 23, 2010, 124 Stat. 740.)

Editorial Notes

REFERENCES IN TEXT

The Patient Protection and Affordable Care Act, referred to in subsec. (d)(3), is Pub. L. 111-148, Mar. 23, 2010, 124 Stat. 119. For complete classification of this Act to the Code, see Short Title note set out under section 18001 of this title and Tables.

§ 1320e-2. Trust Fund transfers to Patient-Centered Outcomes Research Trust Fund

(a) In general

The Secretary shall provide for the transfer, from the Federal Hospital Insurance Trust Fund under section 1395i of this title and the Federal Supplementary Medical Insurance Trust Fund under section 1395t of this title, in proportion (as estimated by the Secretary) to the total expenditures during such fiscal year that are made under subchapter XVIII from the respective trust fund, to the Patient-Centered Outcomes Research Trust Fund (referred to in this section as the “PCORTF”) under section 9511 of the Internal Revenue Code of 1986, of the following:

(1) For fiscal year 2013, an amount equal to \$1 multiplied by the average number of individuals entitled to benefits under part A, or enrolled under part B, of subchapter XVIII during such fiscal year.

¹ So in original. No subpar. (B) has been enacted.

(2) For each of fiscal years 2014, 2015, 2016, 2017, 2018, and 2019, an amount equal to \$2 multiplied by the average number of individuals entitled to benefits under part A, or enrolled under part B, of subchapter XVIII during such fiscal year.

(b) Adjustments for increases in health care spending

In the case of any fiscal year beginning after September 30, 2014, the dollar amount in effect under subsection (a)(2) for such fiscal year shall be equal to the sum of such dollar amount for the previous fiscal year (determined after the application of this subsection), plus an amount equal to the product of—

(1) such dollar amount for the previous fiscal year, multiplied by

(2) the percentage increase in the projected per capita amount of National Health Expenditures, as most recently published by the Secretary before the beginning of the fiscal year.

(Aug. 14, 1935, ch. 531, title XI, §1183, as added Pub. L. 111-148, title VI, §6301(d), Mar. 23, 2010, 124 Stat. 741.)

Editorial Notes

REFERENCES IN TEXT

The Internal Revenue Code of 1986, referred to in subsec. (a), is classified generally to Title 26, Internal Revenue Code.

§ 1320e-3. Information exchange with payroll data providers

(a) In general

The Commissioner of Social Security may enter into an information exchange with a payroll data provider for purposes of—

(1) efficiently administering—

(A) monthly insurance benefits under subsections (d)(1)(B)(ii), (d)(6)(A)(ii), (d)(6)(B), (e)(1)(B)(ii), and (f)(1)(B)(ii) of section 402 of this title and subsection (a)(1) of section 423 of this title; and

(B) supplemental security income benefits under subchapter XVI; and

(2) preventing improper payments of such benefits without the need for verification by independent or collateral sources.

(b) Notification requirements

Before entering into an information exchange pursuant to subsection (a), the Commissioner shall publish in the Federal Register a notice describing the information exchange and the extent to which the information received through such exchange is—

(1) relevant and necessary to—

(A) accurately determine entitlement to, and the amount of, benefits described under subparagraph (A) of subsection (a)(1);

(B) accurately determine eligibility for, and the amount of, benefits described in subparagraph (B) of such subsection; and

(C) prevent improper payment of such benefits; and

(2) sufficiently accurate, up-to-date, and complete.

(c) Definitions

For purposes of this section:

(1) Payroll data provider

The term “payroll data provider” means payroll providers, wage verification companies, and other commercial or non-commercial entities that collect and maintain data regarding employment and wages, without regard to whether the entity provides such data for a fee or without cost.

(2) Information exchange

The term “information exchange” means the automated comparison of a system of records maintained by the Commissioner of Social Security with records maintained by a payroll data provider.

(Aug. 14, 1935, ch. 531, title XI, §1184, as added Pub. L. 114-74, title VIII, §824(a), Nov. 2, 2015, 129 Stat. 607.)

Statutory Notes and Related Subsidiaries

EFFECTIVE DATE

Section effective one year after Nov. 2, 2015, see section 824(e) of Pub. L. 114-74, set out as an Effective Date of 2015 Amendment note under section 425 of this title.

REGULATIONS

Pub. L. 114-74, title VIII, §824(d), Nov. 2, 2015, 129 Stat. 610, provided that: “Not later than 1 year after the date of the enactment of this Act [Nov. 2, 2015], the Commissioner of Social Security shall prescribe by regulation procedures for implementing the Commissioner’s access to and use of information held by payroll providers, including—

“(1) guidelines for establishing and maintaining information exchanges with payroll providers, pursuant to section 1184 of the Social Security Act [42 U.S.C. 1320e-3];

“(2) beneficiary authorizations;

“(3) reduced wage reporting responsibilities for individuals who authorize the Commissioner to access information held by payroll data providers through an information exchange; and

“(4) procedures for notifying individuals in writing when they become subject to such reduced wage reporting requirements and when such reduced wage reporting requirements no longer apply to them.”

PART E—PRICE NEGOTIATION PROGRAM TO LOWER PRICES FOR CERTAIN HIGH-PRICED SINGLE SOURCE DRUGS

§ 1320f. Establishment of program

(a) In general

The Secretary shall establish a Drug Price Negotiation Program (in this part referred to as the “program”). Under the program, with respect to each price applicability period, the Secretary shall—

(1) publish a list of selected drugs in accordance with section 1320f-1 of this title;

(2) enter into agreements with manufacturers of selected drugs with respect to such period, in accordance with section 1320f-2 of this title;

(3) negotiate and, if applicable, renegotiate maximum fair prices for such selected drugs, in accordance with section 1320f-3 of this title;¹

(4) carry out the publication and administrative duties and compliance monitoring in ac-

¹ So in original. Probably should be followed by “and”.