(D) Subsequent comments received during each of the public comment periods.

(E) In accordance with applicable laws and processes and as the Institute determines appropriate, proceedings of the Institute.

(4) Disclosure of conflicts of interest

(A) In general

A conflict of interest shall be disclosed in the following manner:

(i) By the Institute in appointing members to an expert advisory panel under subsection (d)(4), in selecting individuals to contribute to any peer-review process under subsection (d)(7), and for employment as executive staff of the Institute.

(ii) By the Comptroller General in appointing members of the methodology committee under subsection (d)(6);

(iii) By the Institute in the annual report under subsection (d)(10), except that, in the case of individuals contributing to any such peer review process, such description shall be in a manner such that those individuals cannot be identified with a particular research project.

(B) Manner of disclosure

Conflicts of interest shall be disclosed as described in subparagraph (A) as soon as practicable on the Internet web site of the Institute and of the Government Accountability Office. The information disclosed under the preceding sentence shall include the type, nature, and magnitude of the interests of the individual involved, except to the extent that the individual recuses himself or herself from participating in the consideration of or any other activity with respect to the study as to which the potential conflict exists.

(i) Rules

The Institute,[7] its Board or staff, shall be prohibited from accepting gifts, bequeaths,[8] or donations of services or property. In addition, the Institute shall be prohibited from establishing a corporation or generating revenues from activities other than as provided under this section.

(j) Rules of construction

(1)[9] Coverage

Nothing in this section shall be construed—

(A) to permit the Institute to mandate coverage, reimbursement, or other policies for any public or private payer; or

(B) as preventing the Secretary from covering the routine costs of clinical care received by an individual entitled to, or enrolled for, benefits under subchapter XVIII, XIX, or XXI in the case where such individual is participating in a clinical trial and such costs would otherwise be covered under such subchapter with respect to the beneficiary.

(Aug. 14, 1935, ch. 531, title XI, §1181, as added and amended Pub. L. 111–148, title VI, §6301(a), title X, §10602, Mar. 23, 2010, 124 Stat. 727, 1005.)

[8] So in original. Probably should be ''bequests''.

[9] So in original. No par. (2) has been enacted.

REFERENCES IN TEXT

The District of Columbia Nonprofit Corporation Act, referred to in subsec. (b)(2), is Pub. L. 87–569, Aug. 6, 1962, 76 Stat. 265, which is not classified to the Code.

The Internal Revenue Code of 1986, referred to in subsecs. (b)(3) and (g)(2)(A)(v), is classified generally to Title 26, Internal Revenue Code.

Section 399H of the Public Health Service Act, referred to in subsec. (d)(1)(A), probably means section 399HH of act July 1, 1944, which is classified to section 280j of this title.

AMENDMENTS

2010—Subsec. (d)(2)(B)(ii)(IV). Pub. L. 111–148, §10602(1)(A), inserted '', as described in subparagraph (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 effec-

tiveness 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 copayments 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.)

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.

(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.)

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—

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