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 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.

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