(E) for reporting to consumer reporting agencies; or

(F) for complying with—

(i) a civil or criminal subpoena; or

(ii) a Federal or State law regulating the entity.

(Aug. 14, 1935, ch. 531, title XI, §1179, as added Pub. L. 104–191, title II, §262(a), Aug. 21, 1996, 110 Stat. 2030.)

§ 1320d–9. Application of HIPAA regulations to genetic information

(a) In general

The Secretary shall revise the HIPAA privacy regulation (as defined in subsection (b)) so it is consistent with the following:

(1) Genetic information shall be treated as health information described in section 1320d(4)(B) of this title.

(2) The use or disclosure by a covered entity that is a group health plan, health insurance issuer that issues health insurance coverage, or issuer of a medicare supplemental policy of protected health information that is genetic information about an individual for underwriting purposes under the group health plan, health insurance coverage, or medicare supplemental policy shall not be a permitted use or disclosure.

(b) Definitions

For purposes of this section:

(1) Genetic information; genetic test; family member

The terms ''genetic information'', ''genetic test'', and ''family member'' have the meanings given such terms in section 300gg–91 of this title, as amended by the Genetic Information Nondiscrimination Act of 2007.[1]

(2) Group health plan; health insurance coverage; medicare supplemental policy

The terms ''group health plan'' and ''health insurance coverage'' have the meanings given such terms under section 300gg–91 of this title, and the term ''medicare supplemental policy'' has the meaning given such term in section 1395ss(g) of this title.

(3) HIPAA privacy regulation

The term ''HIPAA privacy regulation'' means the regulations promulgated by the Secretary under this part and section 264 of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2 note).

(4) Underwriting purposes

The term ''underwriting purposes'' means, with respect to a group health plan, health insurance coverage, or a medicare supplemental policy—

(A) rules for, or determination of, eligibility (including enrollment and continued eligibility) for, or determination of, benefits under the plan, coverage, or policy;

(B) the computation of premium or contribution amounts under the plan, coverage, or policy;

(C) the application of any pre-existing condition exclusion under the plan, coverage, or policy; and

(D) other activities related to the creation, renewal, or replacement of a contract of health insurance or health benefits.

(c) Procedure

The revisions under subsection (a) shall be made by notice in the Federal Register published not later than 60 days after May 21, 2008, and shall be effective upon publication, without opportunity for any prior public comment, but may be revised, consistent with this section, after opportunity for public comment.

(d) Enforcement

In addition to any other sanctions or remedies that may be available under law, a covered entity that is a group health plan, health insurance issuer, or issuer of a medicare supplemental policy and that violates the HIPAA privacy regulation (as revised under subsection (a) or otherwise) with respect to the use or disclosure of genetic information shall be subject to the penalties described in sections 1320d–5 and 1320d–6 of this title in the same manner and to the same extent that such penalties apply to violations of this part.

(Aug. 14, 1935, ch. 531, title XI, §1180, as added Pub. L. 110–233, title I, §105(a), May 21, 2008, 122 Stat. 903.)

REFERENCES IN TEXT

The Genetic Information Nondiscrimination Act of 2007, referred to in subsec. (b)(1), probably means the Genetic Information Nondiscrimination Act of 2008, Pub. L. 110–233, May 21, 2008, 122 Stat. 881. For complete classification of this Act to the Code, see Short Title note set out under section 2000ff of this title and Tables.

Section 264 of the Health Insurance Portability and Accountability Act of 1996, referred to in subsec. (b)(3), is section 264 of Pub. L. 104–191, which is set out as a note under section 1320d–2 of this title.

EFFECTIVE DATE

Pub. L. 110–233, title I, §105(b)(2), May 21, 2008, 122 Stat. 905, provided that: ''The amendment made by subsection (a) [enacting this section] shall take effect on the date that is 1 year after the date of the enactment of this Act [May 21, 2008].''

REGULATIONS

Pub. L. 110–233, title I, §105(b)(1), May 21, 2008, 122 Stat. 905, provided that: ''Not later than 12 months after the date of the enactment of this Act [May 21, 2008], the Secretary of Health and Human Services shall issue final regulations to carry out the revision required by section 1180(a) of the Social Security Act [42 U.S.C. 1320d–9(a)], as added by subsection (a). The Secretary has the sole authority to promulgate such regulations, but shall promulgate such regulations in consultation with the Secretaries of Labor and the Treasury.''

PART D—COMPARATIVE CLINICAL EFFECTIVENESS RESEARCH

§ 1320e. Comparative clinical effectiveness research

(a) Definitions

In this section:

(1) Board

The term ''Board'' means the Board of Governors established under subsection (f).

[1] See References in Text note below.

(2) Comparative clinical effectiveness research; research

(A) In general

The terms ''comparative clinical effectiveness research'' and ''research'' mean research evaluating and comparing health outcomes and the clinical effectiveness, risks, and benefits of 2 or more medical treatments, services, and items described in subparagraph (B).

(B) Medical treatments, services, and items described

The medical treatments, services, and items described in this subparagraph are health care interventions, protocols for treatment, care management, and delivery, procedures, medical devices, diagnostic tools, pharmaceuticals (including drugs and biologicals), integrative health practices, and any other strategies or items being used in the treatment, management, and diagnosis of, or prevention of illness or injury in, individuals.

(3) Conflict of interest

The term ''conflict of interest'' means an association, including a financial or personal association, that have[1] the potential to bias or have[1] the appearance of biasing an individual's decisions in matters related to the Institute or the conduct of activities under this section.

(4) Real conflict of interest

The term ''real conflict of interest'' means any instance where a member of the Board, the methodology committee established under subsection (d)(6), or an advisory panel appointed under subsection (d)(4), or a close relative of such member, has received or could receive either of the following:

(A) A direct financial benefit of any amount deriving from the result or findings of a study conducted under this section.

(B) A financial benefit from individuals or companies that own or manufacture medical treatments, services, or items to be studied under this section that in the aggregate exceeds $10,000 per year. For purposes of the preceding sentence, a financial benefit includes honoraria, fees, stock, or other financial benefit and the current value of the member or close relative's already existing stock holdings, in addition to any direct financial benefit deriving from the results or findings of a study conducted under this section.

(b) Patient-Centered Outcomes Research Institute

(1) Establishment

There is authorized to be established a nonprofit corporation, to be known as the ''Patient-Centered Outcomes Research Institute'' (referred to in this section as the ''Institute'') which is neither an agency nor establishment of the United States Government.

(2) Application of provisions

The Institute shall be subject to the provisions of this section, and, to the extent consistent with this section, to the District of Columbia Nonprofit Corporation Act.

(3) Funding of comparative clinical effectiveness research

For fiscal year 2010 and each subsequent fiscal year, amounts in 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 shall be available, without further appropriation, to the Institute to carry out this section.

(c) Purpose

The purpose of the Institute is to assist patients, clinicians, purchasers, and policy-makers in making informed health decisions by advancing the quality and relevance of evidence concerning the manner in which diseases, disorders, and other health conditions can effectively and appropriately be prevented, diagnosed, treated, monitored, and managed through research and evidence synthesis that considers variations in patient subpopulations, and the dissemination of research findings with respect to the relative health outcomes, clinical effectiveness, and appropriateness of the medical treatments, services, and items described in subsection (a)(2)(B).

(d) Duties

(1) Identifying research priorities and establishing research project agenda

(A) Identifying research priorities

The Institute shall identify national priorities for research, taking into account factors of disease incidence, prevalence, and burden in the United States (with emphasis on chronic conditions), gaps in evidence in terms of clinical outcomes, practice variations and health disparities in terms of delivery and outcomes of care, the potential for new evidence to improve patient health, well-being, and the quality of care, the effect on national expenditures associated with a health care treatment, strategy, or health conditions, as well as patient needs, outcomes, and preferences, the relevance to patients and clinicians in making informed health decisions, and priorities in the National Strategy for quality care established under section 399H[2] of the Public Health Service Act that are consistent with this section.

(B) Establishing research project agenda

The Institute shall establish and update a research project agenda for research to address the priorities identified under subparagraph (A), taking into consideration the types of research that might address each priority and the relative value (determined based on the cost of conducting research compared to the potential usefulness of the information produced by research) associated with the different types of research, and such other factors as the Institute determines appropriate.

(2) Carrying out research project agenda

(A) Research

The Institute shall carry out the research project agenda established under paragraph

[1] So in original. Probably should be ''has''.

[2] See References in Text note below.

(1)(B) in accordance with the methodological standards adopted under paragraph (9) using methods, including the following:

(i) Systematic reviews and assessments of existing and future research and evidence including original research conducted subsequent to March 23, 2010.

(ii) Primary research, such as randomized clinical trials, molecularly informed trials, and observational studies.

(iii) Any other methodologies recommended by the methodology committee established under paragraph (6) that are adopted by the Board under paragraph (9).

(B) Contracts for the management of funding and conduct of research

(i) Contracts

(I) In general

In accordance with the research project agenda established under paragraph (1)(B), the Institute shall enter into contracts for the management of funding and conduct of research in accordance with the following:

(aa) Appropriate agencies and instrumentalities of the Federal Government.

(bb) Appropriate academic research, private sector research, or study-conducting entities.

(II) Preference

In entering into contracts under subclause (I), the Institute shall give preference to the Agency for Healthcare Research and Quality and the National Institutes of Health, but only if the research to be conducted or managed under such contract is authorized by the governing statutes of such Agency or Institutes.

(ii) Conditions for contracts

A contract entered into under this subparagraph shall require that the agency, instrumentality, or other entity—

(I) abide by the transparency and conflicts of interest requirements under subsection (h) that apply to the Institute with respect to the research managed or conducted under such contract;

(II) comply with the methodological standards adopted under paragraph (9) with respect to such research;

(III) consult with the expert advisory panels for clinical trials and rare disease appointed under clauses (ii) and (iii), respectively, of paragraph (4)(A);

(IV) subject to clause (iv), permit a researcher who conducts original research, as described in subparagraph (A)(ii), under the contract for the agency, instrumentality, or other entity to have such research published in a peer-reviewed journal or other publication, 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;

(V) have appropriate processes in place to manage data privacy and meet ethical standards for the research;

(VI) comply with the requirements of the Institute for making the information available to the public under paragraph (8); and

(VII) comply with other terms and conditions determined necessary by the Institute to carry out the research agenda adopted under paragraph (2).

(iii) Coverage of copayments or coinsurance

A contract entered into under this subparagraph may allow for the coverage of copayments or coinsurance, or allow for other appropriate measures, to the extent that such coverage or other measures are necessary to preserve the validity of a research project, such as in the case where the research project must be blinded.

(iv) Subsequent use of the data

The Institute shall not allow the subsequent use of data from original research in work-for-hire contracts with individuals, entities, or instrumentalities that have a financial interest in the results, unless approved under a data use agreement with the Institute.

(C) Review and update of evidence

The Institute shall review and update evidence on a periodic basis as appropriate.

(D) Taking into account potential differences

Research shall be designed, as appropriate, to take into account the potential for differences in the effectiveness of health care treatments, services, and items as used with various subpopulations, such as racial and ethnic minorities, women, age, and groups of individuals with different comorbidities, genetic and molecular sub-types, or quality of life preferences and include members of such subpopulations as subjects in the research as feasible and appropriate.

(E) Differences in treatment modalities

Research shall be designed, as appropriate, to take into account different characteristics of treatment modalities that may affect research outcomes, such as the phase of the treatment modality in the innovation cycle and the impact of the skill of the operator of the treatment modality.

(3) Data collection

(A) In general

The Secretary shall, with appropriate safeguards for privacy, make available to the Institute such data collected by the Centers for Medicare & Medicaid Services under the programs under subchapters XVIII, XIX, and XXI, as well as provide access to the data networks developed under section 937(f) of the Public Health Service Act [42 U.S.C. 299b–37(f)], as the Institute and its contractors may require to carry out this section. The Institute may also request and obtain data from Federal, State, or private entities, including data from clinical databases and registries.

(B) Use of data

The Institute shall only use data provided to the Institute under subparagraph (A) in

accordance with laws and regulations governing the release and use of such data, including applicable confidentiality and privacy standards.

(4) Appointing expert advisory panels

(A) Appointment

(i) In general

The Institute may appoint permanent or ad hoc expert advisory panels as determined appropriate to assist in identifying research priorities and establishing the research project agenda under paragraph (1) and for other purposes.

(ii) Expert advisory panels for clinical trials

The Institute shall appoint expert advisory panels in carrying out randomized clinical trials under the research project agenda under paragraph (2)(A)(ii). Such expert advisory panels shall advise the Institute and the agency, instrumentality, or entity conducting the research on the research question involved and the research design or protocol, including important patient subgroups and other parameters of the research. Such panels shall be available as a resource for technical questions that may arise during the conduct of such research.

(iii) Expert advisory panel for rare disease

In the case of a research study for rare disease, the Institute shall appoint an expert advisory panel for purposes of assisting in the design of the research study and determining the relative value and feasibility of conducting the research study.

(B) Composition

An expert advisory panel appointed under subparagraph (A) shall include representatives of practicing and research clinicians, patients, and experts in scientific and health services research, health services delivery, and evidence-based medicine who have experience in the relevant topic, and as appropriate, experts in integrative health and primary prevention strategies. The Institute may include a technical expert of each manufacturer or each medical technology that is included under the relevant topic, project, or category for which the panel is established.

(5) Supporting patient and consumer representatives

The Institute shall provide support and resources to help patient and consumer representatives effectively participate on the Board and expert advisory panels appointed by the Institute under paragraph (4).

(6) Establishing methodology committee

(A) In general

The Institute shall establish a standing methodology committee to carry out the functions described in subparagraph (C).

(B) Appointment and composition

The methodology committee established under subparagraph (A) shall be composed of not more than 15 members appointed by the Comptroller General of the United States. Members appointed to the methodology committee shall be experts in their scientific field, such as health services research, clinical research, comparative clinical effectiveness research, biostatistics, genomics, and research methodologies. Stakeholders with such expertise may be appointed to the methodology committee. In addition to the members appointed under the first sentence, the Directors of the National Institutes of Health and the Agency for Healthcare Research and Quality (or their designees) shall each be included as members of the methodology committee.

(C) Functions

Subject to subparagraph (D), the methodology committee shall work to develop and improve the science and methods of comparative clinical effectiveness research by, not later than 18 months after the establishment of the Institute, directly or through subcontract, developing and periodically updating the following:

(i) Methodological standards for research. Such methodological standards shall provide specific criteria for internal validity, generalizability, feasibility, and timeliness of research and for health outcomes measures, risk adjustment, and other relevant aspects of research and assessment with respect to the design of research. Any methodological standards developed and updated under this subclause[3] shall be scientifically based and include methods by which new information, data, or advances in technology are considered and incorporated into ongoing research projects by the Institute, as appropriate. The process for developing and updating such standards shall include input from relevant experts, stakeholders, and decisionmakers, and shall provide opportunities for public comment. Such standards shall also include methods by which patient subpopulations can be accounted for and evaluated in different types of research. As appropriate, such standards shall build on existing work on methodological standards for defined categories of health interventions and for each of the major categories of comparative clinical effectiveness research methods (determined as of March 23, 2010).

(ii) A translation table that is designed to provide guidance and act as a reference for the Board to determine research methods that are most likely to address each specific research question.

(D) Consultation and conduct of examinations

The methodology committee may consult and contract with the Institute of Medicine of the National Academies and academic, nonprofit, or other private and governmental entities with relevant expertise to carry out activities described in subpara-

[3] So in original. Probably should be ''clause''.

graph (C) and may consult with relevant stakeholders to carry out such activities.

(E) Reports

The methodology committee shall submit reports to the Board on the committee's performance of the functions described in subparagraph (C). Reports shall contain recommendations for the Institute to adopt methodological standards developed and updated by the methodology committee as well as other actions deemed necessary to comply with such methodological standards.

(7) Providing for a peer-review process for primary research

(A) In general

The Institute shall ensure that there is a process for peer review of primary research described in subparagraph (A)(ii) of paragraph (2) that is conducted under such paragraph. Under such process—

(i) evidence from such primary research shall be reviewed to assess scientific integrity and adherence to methodological standards adopted under paragraph (9); and

(ii) a list of the names of individuals contributing to any peer-review process during the preceding year or years shall be made public and included in annual reports in accordance with paragraph (10)(D).

(B) Composition

Such peer-review process shall be designed in a manner so as to avoid bias and conflicts of interest on the part of the reviewers and shall be composed of experts in the scientific field relevant to the research under review.

(C) Use of existing processes

(i) Processes of another entity

In the case where the Institute enters into a contract or other agreement with another entity for the conduct or management of research under this section, the Institute may utilize the peer-review process of such entity if such process meets the requirements under subparagraphs (A) and (B).

(ii) Processes of appropriate medical journals

The Institute may utilize the peer-review process of appropriate medical journals if such process meets the requirements under subparagraphs (A) and (B).

(8) Release of research findings

(A) In general

The Institute shall, not later than 90 days after the conduct or receipt of research findings under this part, make such research findings available to clinicians, patients, and the general public. The Institute shall ensure that the research findings—

(i) convey the findings of research in a manner that is comprehensible and useful to patients and providers in making health care decisions;

(ii) fully convey findings and discuss considerations specific to certain subpopulations, risk factors, and comorbidities, as appropriate;

(iii) include limitations of the research and what further research may be needed as appropriate;

(iv) do not include practice guidelines, coverage recommendations, payment, or policy recommendations; and

(v) not include any data which would violate the privacy of research participants or any confidentiality agreements made with respect to the use of data under this section.

(B) Definition of research findings

In this paragraph, the term ''research findings'' means the results of a study or assessment.

(9) Adoption

Subject to subsection (h)(1), the Institute shall adopt the national priorities identified under paragraph (1)(A), the research project agenda established under paragraph (1)(B), the methodological standards developed and updated by the methodology committee under paragraph (6)(C)(i), and any peer-review process provided under paragraph (7) by majority vote. In the case where the Institute does not adopt such processes in accordance with the preceding sentence, the processes shall be referred to the appropriate staff or entity within the Institute (or, in the case of the methodological standards, the methodology committee) for further review.

(10) Annual reports

The Institute shall submit an annual report to Congress and the President, and shall make the annual report available to the public. Such report shall contain—

(A) a description of the activities conducted under this section, research priorities identified under paragraph (1)(A) and methodological standards developed and updated by the methodology committee under paragraph (6)(C)(i) that are adopted under paragraph (9) during the preceding year;

(B) the research project agenda and budget of the Institute for the following year;

(C) any administrative activities conducted by the Institute during the preceding year;

(D) the names of individuals contributing to any peer-review process under paragraph (7), without identifying them with a particular research project; and

(E) any other relevant information (including information on the membership of the Board, expert advisory panels, methodology committee, and the executive staff of the Institute, any conflicts of interest with respect to these individuals, and any bylaws adopted by the Board during the preceding year).

(e) Administration

(1) In general

Subject to paragraph (2), the Board shall carry out the duties of the Institute.

(2) Nondelegable duties

The activities described in subsections (d)(1) and (d)(9) are nondelegable.

(f) Board of Governors

(1) In general

The Institute shall have a Board of Governors, which shall consist of the following members:

(A) The Director of Agency[4] for Healthcare Research and Quality (or the Director's designee).

(B) The Director of the National Institutes of Health (or the Director's designee).

(C) Seventeen[5] members appointed, not later than 6 months after March 23, 2010, by the Comptroller General of the United States as follows:

(i) 3 members representing patients and health care consumers.

(ii) 7 members representing physicians and providers, including 4 members representing physicians (at least 1 of whom is a surgeon), 1 nurse, 1 State-licensed integrative health care practitioner, and 1 representative of a hospital.

(iii) 3 members representing private payers, of whom at least 1 member shall represent health insurance issuers and at least 1 member shall represent employers who self-insure employee benefits.

(iv) 3 members representing pharmaceutical, device, and diagnostic manufacturers or developers.

(v) 1 member representing quality improvement or independent health service researchers.

(vi) 2 members representing the Federal Government or the States, including at least 1 member representing a Federal health program or agency.

(2) Qualifications

The Board shall represent a broad range of perspectives and collectively have scientific expertise in clinical health sciences research, including epidemiology, decisions sciences, health economics, and statistics. In appointing the Board, the Comptroller General of the United States shall consider and disclose any conflicts of interest in accordance with subsection (h)(4)(B). Members of the Board shall be recused from relevant Institute activities in the case where the member (or an immediate family member of such member) has a real conflict of interest directly related to the research project or the matter that could affect or be affected by such participation.

(3) Terms; vacancies

A member of the Board shall be appointed for a term of 6 years, except with respect to the members first appointed, whose terms of appointment shall be staggered evenly over 2-year increments. No individual shall be appointed to the Board for more than 2 terms. Vacancies shall be filled in the same manner as the original appointment was made.

(4) Chairperson and Vice-Chairperson

The Comptroller General of the United States shall designate a Chairperson and Vice Chairperson of the Board from among the members of the Board. Such members shall serve as Chairperson or Vice Chairperson for a period of 3 years.

(5) Compensation

Each member of the Board who is not an officer or employee of the Federal Government shall be entitled to compensation (equivalent to the rate provided for level IV of the Executive Schedule under section 5315 of title 5) and expenses incurred while performing the duties of the Board. An officer or employee of the Federal government who is a member of the Board shall be exempt from compensation.

(6) Director and staff; experts and consultants

The Board may employ and fix the compensation of an Executive Director and such other personnel as may be necessary to carry out the duties of the Institute and may seek such assistance and support of, or contract with, experts and consultants that may be necessary for the performance of the duties of the Institute.

(7) Meetings and hearings

The Board shall meet and hold hearings at the call of the Chairperson or a majority of its members. Meetings not solely concerning matters of personnel shall be advertised at least 7 days in advance and open to the public. A majority of the Board members shall constitute a quorum, but a lesser number of members may meet and hold hearings.

(g) Financial and governmental oversight

(1) Contract for audit

The Institute shall provide for the conduct of financial audits of the Institute on an annual basis by a private entity with expertise in conducting financial audits.

(2) Review and annual reports

(A) Review

The Comptroller General of the United States shall review the following:

(i) Not less frequently than on an annual basis, the financial audits conducted under paragraph (1).

(ii) Not less frequently than every 5 years, the processes established by the Institute, including the research priorities and the conduct of research projects, in order to determine whether information produced by such research projects is objective and credible, is produced in a manner consistent with the requirements under this section, and is developed through a transparent process.

(iii) Not less frequently than every 5 years, the dissemination and training activities and data networks established under section 937 of the Public Health Service Act [42 U.S.C. 299b–37], including the methods and products used to disseminate research, the types of training conducted and supported, and the types and functions of the data networks established, in order to determine whether the activities and data are produced in a manner consistent with the requirements under such section.

[4] So in original. Probably should be preceded by ''the''.

[5] So in original. Probably should be ''Nineteen''.

(iv) Not less frequently than every 5 years, the overall effectiveness of activities conducted under this section and the dissemination, training, and capacity building activities conducted under section 937 of the Public Health Service Act. Such review shall include an analysis of the extent to which research findings are used by health care decision-makers, the effect of the dissemination of such findings on reducing practice variation and disparities in health care, and the effect of the research conducted and disseminated on innovation and the health care economy of the United States.

(v) Not later than 8 years after March 23, 2010, the adequacy and use of the funding for the Institute and the activities conducted under section 937 of the Public Health Service Act, including a determination as to whether, based on the utilization of research findings by public and private payers, funding sources for the Patient-Centered Outcomes Research Trust Fund under section 9511 of the Internal Revenue Code of 1986 are appropriate and whether such sources of funding should be continued or adjusted.

(B) Annual reports

Not later than April 1 of each year, the Comptroller General of the United States shall submit to Congress a report containing the results of the review conducted under subparagraph (A) with respect to the preceding year (or years, if applicable), together with recommendations for such legislation and administrative action as the Comptroller General determines appropriate.

(h) Ensuring transparency, credibility, and access

The Institute shall establish procedures to ensure that the following requirements for ensuring transparency, credibility, and access are met:

(1) Public comment periods

The Institute shall provide for a public comment period of not less than 45 days and not more than 60 days prior to the adoption under subsection (d)(9) of the national priorities identified under subsection (d)(1)(A), the research project agenda established under subsection (d)(1)(B), the methodological standards developed and updated by the methodology committee under subsection (d)(6)(C)(i), and the peer-review process provided under paragraph (7), and after the release of draft findings with respect to systematic reviews of existing research and evidence.

(2) Additional forums

The Institute shall support forums to increase public awareness and obtain and incorporate public input and feedback through media (such as an Internet website) on research priorities, research findings, and other duties, activities, or processes the Institute determines appropriate.

(3) Public availability

The Institute shall make available to the public and disclose through the official public Internet website of the Institute the following:

(A) Information contained in research findings as specified in subsection (d)(9).

(B) The process and methods for the conduct of research, including the identity of the entity and the investigators conducing[6] such research and any conflicts of interests of such parties, any direct or indirect links the entity has to industry, and research protocols, including measures taken, methods of research and analysis, research results, and such other information the Institute determines appropriate)[7] concurrent with the release of research findings.

(C) Notice of public comment periods under paragraph (1), including deadlines for public comments.

(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

[6] So in original. Probably should be ''conducting''.

[7] So in original.

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

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.)

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 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 es-

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

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