provide access to, information for management audits, financial audits, program monitoring and evaluation, facility licensure or certification, or individual licensure or certification.

(Aug. 14, 1935, ch. 531, title XI, §1178, as added Pub. L. 104–191, title II, §262(a), Aug. 21, 1996, 110 Stat. 2029.)

REFERENCES IN TEXT

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

§ 1320d–8. Processing payment transactions by financial institutions

To the extent that an entity is engaged in activities of a financial institution (as defined in section 3401 of title 12), or is engaged in authorizing, processing, clearing, settling, billing, transferring, reconciling, or collecting payments, for a financial institution, this part, and any standard adopted under this part, shall not apply to the entity with respect to such activities, including the following:

(1) The use or disclosure of information by the entity for authorizing, processing, clearing, settling, billing, transferring, reconciling or collecting, a payment for, or related to, health plan premiums or health care, where such payment is made by any means, including a credit, debit, or other payment card, an account, check, or electronic funds transfer.

(2) The request for, or the use or disclosure of, information by the entity with respect to a payment described in paragraph (1)—

(A) for transferring receivables;

(B) for auditing;

(C) in connection with—

(i) a customer dispute; or

(ii) an inquiry from, or to, a customer;

(D) in a communication to a customer of the entity regarding the customer's transactions, payment card, account, check, or electronic funds transfer;

(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

[1] See References in Text note below.

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).

(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,

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