

dividuals about the potential uses of their protected health information, the effects of such uses, and the rights of individuals with respect to such uses. Such programs shall be conducted in a variety of languages and present information in a clear and understandable manner.

(Pub. L. 111-5, div. A, title XIII, §13403, Feb. 17, 2009, 123 Stat. 263.)

§ 17934. Application of privacy provisions and penalties to business associates of covered entities

(a) Application of contract requirements

In the case of a business associate of a covered entity that obtains or creates protected health information pursuant to a written contract (or other written arrangement) described in section 164.502(e)(2) of title 45, Code of Federal Regulations, with such covered entity, the business associate may use and disclose such protected health information only if such use or disclosure, respectively, is in compliance with each applicable requirement of section 164.504(e) of such title. The additional requirements of this subchapter that relate to privacy and that are made applicable with respect to covered entities shall also be applicable to such a business associate and shall be incorporated into the business associate agreement between the business associate and the covered entity.

(b) Application of knowledge elements associated with contracts

Section 164.504(e)(1)(ii) of title 45, Code of Federal Regulations, shall apply to a business associate described in subsection (a), with respect to compliance with such subsection, in the same manner that such section applies to a covered entity, with respect to compliance with the standards in sections 164.502(e) and 164.504(e) of such title, except that in applying such section 164.504(e)(1)(ii) each reference to the business associate, with respect to a contract, shall be treated as a reference to the covered entity involved in such contract.

(c) Application of civil and criminal penalties

In the case of a business associate that violates any provision of subsection (a) or (b), the provisions of sections 1176 and 1177 of the Social Security Act (42 U.S.C. 1320d-5, 1320d-6) shall apply to the business associate with respect to such violation in the same manner as such provisions apply to a person who violates a provision of part C of title XI of such Act [42 U.S.C. 1320d et seq.].

(Pub. L. 111-5, div. A, title XIII, §13404, Feb. 17, 2009, 123 Stat. 264.)

REFERENCES IN TEXT

This subchapter, referred to in subsec. (a), was in the original “this subtitle”, meaning subtitle D (§13400 et seq.) of title XIII of div. A of Pub. L. 111-5, Feb. 17, 2009, 123 Stat. 258, which is classified principally to this subchapter. For complete classification of subtitle D to the Code, see Tables.

The Social Security Act, referred to in subsec. (c), is act Aug. 14, 1935, ch. 531, 49 Stat. 620. Part C of title XI of the Act is classified generally to part C (§1320d et seq.) of subchapter XI of chapter 7 of this title. For complete classification of this Act to the Code, see section 1305 of this title and Tables.

§ 17935. Restrictions on certain disclosures and sales of health information; accounting of certain protected health information disclosures; access to certain information in electronic format

(a) Requested restrictions on certain disclosures of health information

In the case that an individual requests under paragraph (a)(1)(i)(A) of section 164.522 of title 45, Code of Federal Regulations, that a covered entity restrict the disclosure of the protected health information of the individual, notwithstanding paragraph (a)(1)(ii) of such section, the covered entity must comply with the requested restriction if—

(1) except as otherwise required by law, the disclosure is to a health plan for purposes of carrying out payment or health care operations (and is not for purposes of carrying out treatment); and

(2) the protected health information pertains solely to a health care item or service for which the health care provider involved has been paid out of pocket in full.

(b) Disclosures required to be limited to the limited data set or the minimum necessary

(1) In general

(A) In general

Subject to subparagraph (B), a covered entity shall be treated as being in compliance with section 164.502(b)(1) of title 45, Code of Federal Regulations, with respect to the use, disclosure, or request of protected health information described in such section, only if the covered entity limits such protected health information, to the extent practicable, to the limited data set (as defined in section 164.514(e)(2) of such title) or, if needed by such entity, to the minimum necessary to accomplish the intended purpose of such use, disclosure, or request, respectively.

(B) Guidance

Not later than 18 months after February 17, 2009, the Secretary shall issue guidance on what constitutes “minimum necessary” for purposes of subpart E of part 164 of title 45, Code of Federal Regulation.¹ In issuing such guidance the Secretary shall take into consideration the guidance under section 17953(c) of this title and the information necessary to improve patient outcomes and to detect, prevent, and manage chronic disease.

(C) Sunset

Subparagraph (A) shall not apply on and after the effective date on which the Secretary issues the guidance under subparagraph (B).

(2) Determination of minimum necessary

For purposes of paragraph (1), in the case of the disclosure of protected health information, the covered entity or business associate disclosing such information shall determine what constitutes the minimum necessary to accomplish the intended purpose of such disclosure.

¹ So in original. Probably should be “Regulations.”