

in each regional office of the Department of Health and Human Services to offer guidance and education to covered entities, business associates, and individuals on their rights and responsibilities related to Federal privacy and security requirements for protected health information.

**(b) Education initiative on uses of health information**

Not later than 12 months after February 17, 2009, the Office for Civil Rights within the Department of Health and Human Services shall develop and maintain a multi-faceted national education initiative to enhance public transparency regarding the uses of protected health information, including programs to educate individuals 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 provi-

sion 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.<sup>1</sup> In issuing

<sup>1</sup> So in original. Probably should be “Regulations.”

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.

**(3) Application of exceptions**

The exceptions described in section 164.502(b)(2) of title 45, Code of Federal Regulations, shall apply to the requirement under paragraph (1) as of the effective date described in section 13423<sup>2</sup> in the same manner that such exceptions apply to section 164.502(b)(1) of such title before such date.

**(4) Rule of construction**

Nothing in this subsection shall be construed as affecting the use, disclosure, or request of protected health information that has been de-identified.

**(c) Accounting of certain protected health information disclosures required if covered entity uses electronic health record**

**(1) In general**

In applying section 164.528 of title 45, Code of Federal Regulations, in the case that a covered entity uses or maintains an electronic health record with respect to protected health information—

(A) the exception under paragraph (a)(1)(i) of such section shall not apply to disclosures through an electronic health record made by such entity of such information; and

(B) an individual shall have a right to receive an accounting of disclosures described in such paragraph of such information made by such covered entity during only the three years prior to the date on which the accounting is requested.

**(2) Regulations**

The Secretary shall promulgate regulations on what information shall be collected about each disclosure referred to in paragraph (1), not later than 6 months after the date on which the Secretary adopts standards on accounting for disclosure described in the section 300jj-12(b)(2)(B)(iv) of this title, as added by section 13101.<sup>2</sup> Such regulations shall only require such information to be collected through an electronic health record in a manner that takes into account the interests of the individuals in learning the circumstances under which their protected health information is being disclosed and takes into account the administrative burden of accounting for such disclosures.

**(3) Process**

In response to an<sup>3</sup> request from an individual for an accounting, a covered entity shall elect to provide either an—

(A) accounting, as specified under paragraph (1), for disclosures of protected health information that are made by such covered entity and by a business associate acting on behalf of the covered entity; or

(B) accounting, as specified under paragraph (1), for disclosures that are made by such covered entity and provide a list of all business associates acting on behalf of the covered entity, including contact information for such associates (such as mailing address, phone, and email address).

A business associate included on a list under subparagraph (B) shall provide an accounting of disclosures (as required under paragraph (1) for a covered entity) made by the business associate upon a request made by an individual directly to the business associate for such an accounting.

**(4) Effective date**

**(A) Current users of electronic records**

In the case of a covered entity insofar as it acquired an electronic health record as of January 1, 2009, paragraph (1) shall apply to disclosures, with respect to protected health information, made by the covered entity from such a record on and after January 1, 2014.

**(B) Others**

In the case of a covered entity insofar as it acquires an electronic health record after January 1, 2009, paragraph (1) shall apply to disclosures, with respect to protected health information, made by the covered entity from such record on and after the later of the following:

(i) January 1, 2011; or

(ii) the date that it acquires an electronic health record.

**(C) Later date**

The Secretary may set an effective date that is later than<sup>4</sup> the date specified under subparagraph (A) or (B) if the Secretary determines that such later date is necessary, but in no case may the date specified under—

(i) subparagraph (A) be later than 2016; or

(ii) subparagraph (B) be later than 2013.

**(d) Prohibition on sale of electronic health records or protected health information**

**(1) In general**

Except as provided in paragraph (2), a covered entity or business associate shall not directly or indirectly receive remuneration in exchange for any protected health information of an individual unless the covered entity obtained from the individual, in accordance with section 164.508 of title 45, Code of Federal Regulations, a valid authorization that includes,

<sup>3</sup>So in original. Probably should be “a”.

<sup>4</sup>So in original. Probably should be “than”.

<sup>2</sup>See References in Text note below.

in accordance with such section, a specification of whether the protected health information can be further exchanged for remuneration by the entity receiving protected health information of that individual.

**(2) Exceptions**

Paragraph (1) shall not apply in the following cases:

(A) The purpose of the exchange is for public health activities (as described in section 164.512(b) of title 45, Code of Federal Regulations).

(B) The purpose of the exchange is for research (as described in sections 164.501 and 164.512(i) of title 45, Code of Federal Regulations) and the price charged reflects the costs of preparation and transmittal of the data for such purpose.

(C) The purpose of the exchange is for the treatment of the individual, subject to any regulation that the Secretary may promulgate to prevent protected health information from inappropriate access, use, or disclosure.

(D) The purpose of the exchange is the health care operation specifically described in subparagraph (iv) of paragraph (6) of the definition of healthcare operations in section 164.501 of title 45, Code of Federal Regulations.

(E) The purpose of the exchange is for remuneration that is provided by a covered entity to a business associate for activities involving the exchange of protected health information that the business associate undertakes on behalf of and at the specific request of the covered entity pursuant to a business associate agreement.

(F) The purpose of the exchange is to provide an individual with a copy of the individual's protected health information pursuant to section 164.524 of title 45, Code of Federal Regulations.

(G) The purpose of the exchange is otherwise determined by the Secretary in regulations to be similarly necessary and appropriate as the exceptions provided in subparagraphs (A) through (F).

**(3) Regulations**

Not later than 18 months after February 17, 2009, the Secretary shall promulgate regulations to carry out this subsection. In promulgating such regulations, the Secretary—

(A) shall evaluate the impact of restricting the exception described in paragraph (2)(A) to require that the price charged for the purposes described in such paragraph reflects the costs of the preparation and transmittal of the data for such purpose, on research or public health activities, including those conducted by or for the use of the Food and Drug Administration; and

(B) may further restrict the exception described in paragraph (2)(A) to require that the price charged for the purposes described in such paragraph reflects the costs of the preparation and transmittal of the data for such purpose, if the Secretary finds that such further restriction will not impede such research or public health activities.

**(4) Effective date**

Paragraph (1) shall apply to exchanges occurring on or after the date that is 6 months after the date of the promulgation of final regulations implementing this subsection.

**(e) Access to certain information in electronic format**

In applying section 164.524 of title 45, Code of Federal Regulations, in the case that a covered entity uses or maintains an electronic health record with respect to protected health information of an individual—

(1) the individual shall have a right to obtain from such covered entity a copy of such information in an electronic format and, if the individual chooses, to direct the covered entity to transmit such copy directly to an entity or person designated by the individual, provided that any such choice is clear, conspicuous, and specific; and

(2) notwithstanding paragraph (c)(4) of such section, any fee that the covered entity may impose for providing such individual with a copy of such information (or a summary or explanation of such information) if such copy (or summary or explanation) is in an electronic form shall not be greater than the entity's labor costs in responding to the request for the copy (or summary or explanation).

(Pub. L. 111-5, div. A, title XIII, §13405, Feb. 17, 2009, 123 Stat. 264.)

REFERENCES IN TEXT

Section 13423, referred to in subsec. (b)(3), means section 13423 of div. A of Pub. L. 111-5, which is set out as an Effective Date note under section 17931 of this title.

Section 13101, referred to in subsec. (c)(2), means section 13101 of div. A of Pub. L. 111-5.

**§ 17936. Conditions on certain contacts as part of health care operations**

**(a) Marketing**

**(1) In general**

A communication by a covered entity or business associate that is about a product or service and that encourages recipients of the communication to purchase or use the product or service shall not be considered a health care operation for purposes of subpart E of part 164 of title 45, Code of Federal Regulations, unless the communication is made as described in subparagraph (i), (ii), or (iii) of paragraph (1) of the definition of marketing in section 164.501 of such title.

**(2) Payment for certain communications**

A communication by a covered entity or business associate that is described in subparagraph (i), (ii), or (iii) of paragraph (1) of the definition of marketing in section 164.501 of title 45, Code of Federal Regulations, shall not be considered a health care operation for purposes of subpart E of part 164 of title 45, Code of Federal Regulations if the covered entity receives or has received direct or indirect payment in exchange for making such communication, except where—

(A)(i) such communication describes only a drug or biologic that is currently being