

tity 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 prescribed for the recipient of the communication; and

(ii) any payment received by such covered entity in exchange for making a communication described in clause (i) is reasonable in amount;

(B) each of the following conditions apply—

(i) the communication is made by the covered entity; and

(ii) the covered entity making such communication obtains from the recipient of the communication, in accordance with section 164.508 of title 45, Code of Federal Regulations, a valid authorization (as described in paragraph (b) of such section) with respect to such communication; or

(C) each of the following conditions apply—

(i) the communication is made by a business associate on behalf of the covered entity; and

(ii) the communication is consistent with the written contract (or other written arrangement described in section 164.502(e)(2) of such title) between such business associate and covered entity.

(3) Reasonable in amount defined

For purposes of paragraph (2), the term “reasonable in amount” shall have the meaning given such term by the Secretary by regulation.

(4) Direct or indirect payment

For purposes of paragraph (2), the term “direct or indirect payment” shall not include any payment for treatment (as defined in section 164.501 of title 45, Code of Federal Regulations) of an individual.

(b) Opportunity to opt out of fundraising

The Secretary shall by rule provide that any written fundraising communication that is a healthcare operation as defined under section 164.501 of title 45, Code of Federal Regulations, shall, in a clear and conspicuous manner, provide an opportunity for the recipient of the communications to elect not to receive any further such communication. When an individual elects not to receive any further such communication, such election shall be treated as a revocation of authorization under section 164.508 of title 45, Code of Federal Regulations.

(c) Effective date

This section shall apply to written communications occurring on or after the effective date specified under section 13423.¹

(Pub. L. 111-5, div. A, title XIII, §13406, Feb. 17, 2009, 123 Stat. 268.)

REFERENCES IN TEXT

Section 13423, referred to in subsec. (c), 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.

§ 17937. Temporary breach notification requirement for vendors of personal health records and other non-HIPAA covered entities

(a) In general

In accordance with subsection (c), each vendor of personal health records, following the discovery of a breach of security of unsecured PHR identifiable health information that is in a personal health record maintained or offered by such vendor, and each entity described in clause (ii), (iii), or (iv) of section 17953(b)(1)(A) of this title, following the discovery of a breach of security of such information that is obtained through a product or service provided by such entity, shall—

(1) notify each individual who is a citizen or resident of the United States whose unsecured PHR identifiable health information was acquired by an unauthorized person as a result of such a breach of security; and

(2) notify the Federal Trade Commission.

¹ See References in Text note below.