



3002(b)(2)(B)(iv) of the Public Health Service Act, as added by section 13101. 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 a 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 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, 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 the date of enactment of this title, 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).

SEC. 13406. 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—