

mation that is not protected through the use of a technology or methodology specified by the Secretary in the guidance issued under section 17932(h)(2) of this title.

(B) Exception in case timely guidance not issued

In the case that the Secretary does not issue guidance under section 17932(h)(2) of this title by the date specified in such section, for purposes of this section, the term “unsecured PHR identifiable health information” shall mean PHR identifiable health information that is not secured by a technology standard that renders protected health information unusable, unreadable, or indecipherable to unauthorized individuals and that is developed or endorsed by a standards developing organization that is accredited by the American National Standards Institute.

(g) Regulations; effective date; sunset

(1) Regulations; effective date

To carry out this section, the Federal Trade Commission shall promulgate interim final regulations by not later than the date that is 180 days after February 17, 2009. The provisions of this section shall apply to breaches of security that are discovered on or after the date that is 30 days after the date of publication of such interim final regulations.

(2) Sunset

If Congress enacts new legislation establishing requirements for notification in the case of a breach of security, that apply to entities that are not covered entities or business associates, the provisions of this section shall not apply to breaches of security discovered on or after the effective date of regulations implementing such legislation.

(Pub. L. 111–5, div. A, title XIII, §13407, Feb. 17, 2009, 123 Stat. 269.)

Statutory Notes and Related Subsidiaries

EFFECTIVE DATE

Section effective 12 months after Feb. 17, 2009, except as otherwise specifically provided, see section 13423 of Pub. L. 111–5, set out as a note under section 17931 of this title.

§ 17938. Business associate contracts required for certain entities

Each organization, with respect to a covered entity, that provides data transmission of protected health information to such entity (or its business associate) and that requires access on a routine basis to such protected health information, such as a Health Information Exchange Organization, Regional Health Information Organization, E-prescribing Gateway, or each vendor that contracts with a covered entity to allow that covered entity to offer a personal health record to patients as part of its electronic health record, is required to enter into a written contract (or other written arrangement) described in section 164.502(e)(2) of title 45, Code of Federal Regulations and a written contract (or other arrangement) described in section

164.308(b) of such title, with such entity and shall be treated as a business associate of the covered entity for purposes of the provisions of this subchapter and subparts C and E of part 164 of title 45, Code of Federal Regulations, as such provisions are in effect as of February 17, 2009.

(Pub. L. 111–5, div. A, title XIII, §13408, Feb. 17, 2009, 123 Stat. 271.)

Editorial Notes

REFERENCES IN TEXT

This subchapter, referred to in text, 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.

Statutory Notes and Related Subsidiaries

EFFECTIVE DATE

Section effective 12 months after Feb. 17, 2009, except as otherwise specifically provided, see section 13423 of Pub. L. 111–5, set out as a note under section 17931 of this title.

§ 17939. Improved enforcement

(a) In general

(1) Omitted

(2) Enforcement under Social Security Act

Any violation by a covered entity under thus¹ subchapter is subject to enforcement and penalties under section² 1176 and 1177 of the Social Security Act [42 U.S.C. 1320d–5, 1320d–6].

(b) Effective date; regulations

(1) The amendments made by subsection (a) shall apply to penalties imposed on or after the date that is 24 months after February 17, 2009.

(2) Not later than 18 months after February 17, 2009, the Secretary of Health and Human Services shall promulgate regulations to implement such amendments.

(c) Distribution of certain civil monetary penalties collected

(1) In general

Subject to the regulation promulgated pursuant to paragraph (3), any civil monetary penalty or monetary settlement collected with respect to an offense punishable under this subchapter or section 1176 of the Social Security Act (42 U.S.C. 1320d–5) insofar as such section relates to privacy or security shall be transferred to the Office for Civil Rights of the Department of Health and Human Services to be used for purposes of enforcing the provisions of this subchapter and subparts C and E of part 164 of title 45, Code of Federal Regulations, as such provisions are in effect as of February 17, 2009.

(2) GAO report

Not later than 18 months after February 17, 2009, the Comptroller General shall submit to the Secretary a report including recommenda-

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

² So in original. Probably should be “sections”.

tions for a methodology under which an individual who is harmed by an act that constitutes an offense referred to in paragraph (1) may receive a percentage of any civil monetary penalty or monetary settlement collected with respect to such offense.

(3) Establishment of methodology to distribute percentage of CMPS collected to harmed individuals

Not later than 3 years after February 17, 2009, the Secretary shall establish by regulation and based on the recommendations submitted under paragraph (2), a methodology under which an individual who is harmed by an act that constitutes an offense referred to in paragraph (1) may receive a percentage of any civil monetary penalty or monetary settlement collected with respect to such offense.

(4) Application of methodology

The methodology under paragraph (3) shall be applied with respect to civil monetary penalties or monetary settlements imposed on or after the effective date of the regulation.

(d) Tiered increase in amount of civil monetary penalties

(1) to (3) Omitted

(4) Effective date

The amendments made by this subsection shall apply to violations occurring after February 17, 2009.

(e) Enforcement through State attorneys general

(1), (2) Omitted

(3) Effective date

The amendments made by this subsection shall apply to violations occurring after February 17, 2009.

(Pub. L. 111-5, div. A, title XIII, §13410, Feb. 17, 2009, 123 Stat. 271.)

Editorial Notes

REFERENCES IN TEXT

This subchapter, referred to in subsecs. (a)(2) and (c)(1), 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.

For reference to “the amendments made by subsection (a)” in subsec. (b)(1) and “the amendments made by this subsection” in subsecs. (d)(4) and (e)(3), see Codification note below.

CODIFICATION

Section is comprised of section 13410 of Pub. L. 111-5. Subsecs. (a)(1), (d)(1)–(3), (e)(1), (2), and (f) of section 13410 of Pub. L. 111-5 amended section 1320d-5 of this title.

Statutory Notes and Related Subsidiaries

EFFECTIVE DATE

Section effective 12 months after Feb. 17, 2009, except as otherwise specifically provided, see section 13423 of Pub. L. 111-5, set out as a note under section 17931 of this title.

§ 17940. Audits

The Secretary shall provide for periodic audits to ensure that covered entities and business as-

sociates that are subject to the requirements of this subchapter and subparts C and E of part 164 of title 45, Code of Federal Regulations, as such provisions are in effect as of February 17, 2009, comply with such requirements.

(Pub. L. 111-5, div. A, title XIII, §13411, Feb. 17, 2009, 123 Stat. 276.)

Editorial Notes

REFERENCES IN TEXT

This subchapter, referred to in text, 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.

Statutory Notes and Related Subsidiaries

EFFECTIVE DATE

Section effective 12 months after Feb. 17, 2009, except as otherwise specifically provided, see section 13423 of Pub. L. 111-5, set out as a note under section 17931 of this title.

§ 17941. Recognition of security practices

(a) In general

Consistent with the authority of the Secretary under sections 1320d-5 and 1320d-6 of this title, when making determinations relating to fines under such section 1320d-5 (as amended by section 13410 of Pub. L. 111-5) or such section 1320d-6, decreasing the length and extent of an audit under section 17940 of this title, or remedies otherwise agreed to by the Secretary, the Secretary shall consider whether the covered entity or business associate has adequately demonstrated that it had, for not less than the previous 12 months, recognized security practices in place that may—

(1) mitigate fines under section 1320d-5 of this title (as amended by section 13410 of Pub. L. 111-5);

(2) result in the early, favorable termination of an audit under section 17940 of this title; and

(3) mitigate the remedies that would otherwise be agreed to in any agreement with respect to resolving potential violations of the HIPAA Security rule (part 160 of title 45 Code of Federal Regulations and subparts A and C of part 164 of such title) between the covered entity or business associate and the Department of Health and Human Services.

(b) Definition and miscellaneous provisions

(1) Recognized security practices

The term “recognized security practices” means the standards, guidelines, best practices, methodologies, procedures, and processes developed under section 272(c)(15) of title 15, the approaches promulgated under section 1533(d) of title 6, and other programs and processes that address cybersecurity and that are developed, recognized, or promulgated through regulations under other statutory authorities. Such practices shall be determined by the covered entity or business associate, consistent with the HIPAA Security rule (part 160 of title 45 Code of Federal Regulations and subparts A and C of part 164 of such title).