

“(ii) designated by the Secretary of Health and Human Services under section 162.910(a) of title 45, Code of Federal Regulations.

“(D) PROTECTION OF CONFIDENTIAL INFORMATION.—

“(i) IN GENERAL.—The Secretary of Health and Human Services shall ensure that any material provided under subparagraph (A) to the National Committee on Vital and Health Statistics or any organization described in subparagraph (C) is redacted so as to prevent the disclosure of any—

“(I) trade secrets;

“(II) commercial or financial information that is privileged or confidential; and

“(III) other information the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

“(ii) CONSTRUCTION.—Nothing in clause (i) shall be construed to affect the application of section 552 of title 5, United States Code (commonly known as the ‘Freedom of Information Act’), including the exceptions from disclosure provided under subsection (b) of such section.

“(6) ENFORCEMENT THROUGH EXCLUSION FROM PARTICIPATION IN MEDICARE.—

“(A) IN GENERAL.—In the case of a person described in paragraph (1) who fails to submit a plan in accordance with paragraph (2), and who is not in compliance with the applicable requirements of subparts I through R of part 162 of title 45, Code of Federal Regulations, on or after October 16, 2002, the person may be excluded at the discretion of the Secretary of Health and Human Services from participation (including under part C or as a contractor under sections 1816, 1842, and 1893) [42 U.S.C. 1395h, 1395u, 1395ddd] in title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.).

“(B) PROCEDURE.—The provisions of section 1128A of the Social Security Act (42 U.S.C. 1320a-7a) (other than the first and second sentences of subsection (a) and subsection (b)) shall apply to an exclusion under this paragraph in the same manner as such provisions apply with respect to an exclusion or proceeding under section 1128A(a) of such Act.

“(C) CONSTRUCTION.—The availability of an exclusion under this paragraph shall not be construed to affect the imposition of penalties under section 1176 of the Social Security Act (42 U.S.C. 1320d-5).

“(D) NONAPPLICABILITY TO COMPLYING PERSONS.—The exclusion under subparagraph (A) shall not apply to a person who—

“(i) submits a plan in accordance with paragraph (2); or

“(ii) who is in compliance with the applicable requirements of subparts I through R of part 162 of title 45, Code of Federal Regulations, on or before October 16, 2002.

“(b) SPECIAL RULES.—

“(1) RULES OF CONSTRUCTION.—Nothing in this section shall be construed—

“(A) as modifying the October 16, 2003, deadline for a small health plan to comply with the requirements of subparts I through R of part 162 of title 45, Code of Federal Regulations; or

“(B) as modifying—

“(i) the April 14, 2003, deadline for a health care provider, a health plan (other than a small health plan), or a health care clearinghouse to comply with the requirements of subpart E of part 164 of title 45, Code of Federal Regulations; or

“(ii) the April 14, 2004, deadline for a small health plan to comply with the requirements of such subpart.

“(2) APPLICABILITY OF PRIVACY STANDARDS BEFORE COMPLIANCE DEADLINE FOR INFORMATION TRANSACTION STANDARDS.—

“(A) IN GENERAL.—Notwithstanding any other provision of law, during the period that begins on April 14, 2003, and ends on October 16, 2003, a health care provider or, subject to subparagraph (B), a health care clearinghouse, that transmits any

health information in electronic form in connection with a transaction described in subparagraph (C) shall comply with the requirements of subpart E of part 164 of title 45, Code of Federal Regulations, without regard to whether the transmission meets the standards required by part 162 of such title.

“(B) APPLICATION TO HEALTH CARE CLEARINGHOUSES.—For purposes of this paragraph, during the period described in subparagraph (A), an entity that processes or facilitates the processing of information in connection with a transaction described in subparagraph (C) and that otherwise would be treated as a health care clearinghouse shall be treated as a health care clearinghouse without regard to whether the processing or facilitation produces (or is required to produce) standard data elements or a standard transaction as required by part 162 of title 45, Code of Federal Regulations.

“(C) TRANSACTIONS DESCRIBED.—The transactions described in this subparagraph are the following:

“(i) A health care claims or equivalent encounter information transaction.

“(ii) A health care payment and remittance advice transaction.

“(iii) A coordination of benefits transaction.

“(iv) A health care claim status transaction.

“(v) An enrollment and disenrollment in a health plan transaction.

“(vi) An eligibility for a health plan transaction.

“(vii) A health plan premium payments transaction.

“(viii) A referral certification and authorization transaction.

“(c) DEFINITIONS.—In this section—

“(1) the terms ‘health care provider’, ‘health plan’, and ‘health care clearinghouse’ have the meaning given those terms in section 1171 of the Social Security Act (42 U.S.C. 1320d) and section 160.103 of title 45, Code of Federal Regulations;

“(2) the terms ‘small health plan’ and ‘transaction’ have the meaning given those terms in section 160.103 of title 45, Code of Federal Regulations; and

“(3) the terms ‘health care claims or equivalent encounter information transaction’, ‘health care payment and remittance advice transaction’, ‘coordination of benefits transaction’, ‘health care claim status transaction’, ‘enrollment and disenrollment in a health plan transaction’, ‘eligibility for a health plan transaction’, ‘health plan premium payments transaction’, and ‘referral certification and authorization transaction’ have the meanings given those terms in sections 162.1101, 162.1601, 162.1801, 162.1401, 162.1501, 162.1201, 162.1701, and 162.1301 of title 45, Code of Federal Regulations, respectively.”

§ 1320d-5. General penalty for failure to comply with requirements and standards

(a) General penalty

(1) In general

Except as provided in subsection (b), the Secretary shall impose on any person who violates a provision of this part—

(A) in the case of a violation of such provision in which it is established that the person did not know (and by exercising reasonable diligence would not have known) that such person violated such provision, a penalty for each such violation of an amount that is at least the amount described in paragraph (3)(A) but not to exceed the amount described in paragraph (3)(D);

(B) in the case of a violation of such provision in which it is established that the violation was due to reasonable cause and not to willful neglect, a penalty for each such vio-

lation of an amount that is at least the amount described in paragraph (3)(B) but not to exceed the amount described in paragraph (3)(D); and

(C) in the case of a violation of such provision in which it is established that the violation was due to willful neglect—

(i) if the violation is corrected as described in subsection (b)(3)(A),¹ a penalty in an amount that is at least the amount described in paragraph (3)(C) but not to exceed the amount described in paragraph (3)(D); and

(ii) if the violation is not corrected as described in such subsection, a penalty in an amount that is at least the amount described in paragraph (3)(D).

In determining the amount of a penalty under this section for a violation, the Secretary shall base such determination on the nature and extent of the violation and the nature and extent of the harm resulting from such violation.

(2) Procedures

The provisions of section 1320a-7a of this title (other than subsections (a) and (b) and the second sentence of subsection (f)) shall apply to the imposition of a civil money penalty under this subsection in the same manner as such provisions apply to the imposition of a penalty under such section 1320a-7a of this title.

(3) Tiers of penalties described

For purposes of paragraph (1), with respect to a violation by a person of a provision of this part—

(A) the amount described in this subparagraph is \$100 for each such violation, except that the total amount imposed on the person for all such violations of an identical requirement or prohibition during a calendar year may not exceed \$25,000;

(B) the amount described in this subparagraph is \$1,000 for each such violation, except that the total amount imposed on the person for all such violations of an identical requirement or prohibition during a calendar year may not exceed \$100,000;

(C) the amount described in this subparagraph is \$10,000 for each such violation, except that the total amount imposed on the person for all such violations of an identical requirement or prohibition during a calendar year may not exceed \$250,000; and

(D) the amount described in this subparagraph is \$50,000 for each such violation, except that the total amount imposed on the person for all such violations of an identical requirement or prohibition during a calendar year may not exceed \$1,500,000.

(b) Limitations

(1) Offenses otherwise punishable

No penalty may be imposed under subsection (a) and no damages obtained under subsection (d) with respect to an act if a penalty has been imposed under section 1320d-6 of this title with respect to such act.

¹ So in original. Probably should be "(b)(2)(A).".

(2) Failures due to reasonable cause

(A) In general

Except as provided in subparagraph (B) or subsection (a)(1)(C), no penalty may be imposed under subsection (a) and no damages obtained under subsection (d) if the failure to comply is corrected during the 30-day period beginning on the first date the person liable for the penalty or damages knew, or by exercising reasonable diligence would have known, that the failure to comply occurred.

(B) Extension of period

(i) No penalty

With respect to the imposition of a penalty by the Secretary under subsection (a), the period referred to in subparagraph (A) may be extended as determined appropriate by the Secretary based on the nature and extent of the failure to comply.

(ii) Assistance

If the Secretary determines that a person failed to comply because the person was unable to comply, the Secretary may provide technical assistance to the person during the period described in subparagraph (A). Such assistance shall be provided in any manner determined appropriate by the Secretary.

(3) Reduction

In the case of a failure to comply which is due to reasonable cause and not to willful neglect, any penalty under subsection (a) and any damages under subsection (d) that is² not entirely waived under paragraph (3)³ may be waived to the extent that the payment of such penalty⁴ would be excessive relative to the compliance failure involved.

(c) Noncompliance due to willful neglect

(1) In general

A violation of a provision of this part due to willful neglect is a violation for which the Secretary is required to impose a penalty under subsection (a)(1).

(2) Required investigation

For purposes of paragraph (1), the Secretary shall formally investigate any complaint of a violation of a provision of this part if a preliminary investigation of the facts of the complaint indicate such a possible violation due to willful neglect.

(d) Enforcement by State attorneys general

(1) Civil action

Except as provided in subsection (b), in any case in which the attorney general of a State has reason to believe that an interest of one or more of the residents of that State has been or is threatened or adversely affected by any person who violates a provision of this part, the attorney general of the State, as *parens patriae*, may bring a civil action on behalf of

² So in original. Probably should be "are".

³ So in original. Probably should be "(2)".

⁴ So in original. The words "or damages" probably should appear after "penalty".

such residents of the State in a district court of the United States of appropriate jurisdiction—

(A) to enjoin further such violation by the defendant; or

(B) to obtain damages on behalf of such residents of the State, in an amount equal to the amount determined under paragraph (2).

(2) Statutory damages

(A) In general

For purposes of paragraph (1)(B), the amount determined under this paragraph is the amount calculated by multiplying the number of violations by up to \$100. For purposes of the preceding sentence, in the case of a continuing violation, the number of violations shall be determined consistent with the HIPAA privacy regulations (as defined in section 1320d-9(b)(3) of this title) for violations of subsection (a).

(B) Limitation

The total amount of damages imposed on the person for all violations of an identical requirement or prohibition during a calendar year may not exceed \$25,000.

(C) Reduction of damages

In assessing damages under subparagraph (A), the court may consider the factors the Secretary may consider in determining the amount of a civil money penalty under subsection (a) under the HIPAA privacy regulations.

(3) Attorney fees

In the case of any successful action under paragraph (1), the court, in its discretion, may award the costs of the action and reasonable attorney fees to the State.

(4) Notice to Secretary

The State shall serve prior written notice of any action under paragraph (1) upon the Secretary and provide the Secretary with a copy of its complaint, except in any case in which such prior notice is not feasible, in which case the State shall serve such notice immediately upon instituting such action. The Secretary shall have the right—

(A) to intervene in the action;

(B) upon so intervening, to be heard on all matters arising therein; and

(C) to file petitions for appeal.

(5) Construction

For purposes of bringing any civil action under paragraph (1), nothing in this section shall be construed to prevent an attorney general of a State from exercising the powers conferred on the attorney general by the laws of that State.

(6) Venue; service of process

(A) Venue

Any action brought under paragraph (1) may be brought in the district court of the United States that meets applicable requirements relating to venue under section 1391 of title 28.

(B) Service of process

In an action brought under paragraph (1), process may be served in any district in which the defendant—

(i) is an inhabitant; or

(ii) maintains a physical place of business.

(7) Limitation on State action while Federal action is pending

If the Secretary has instituted an action against a person under subsection (a) with respect to a specific violation of this part, no State attorney general may bring an action under this subsection against the person with respect to such violation during the pendency of that action.

(8) Application of CMP statute of limitation

A civil action may not be instituted with respect to a violation of this part unless an action to impose a civil money penalty may be instituted under subsection (a) with respect to such violation consistent with the second sentence of section 1320a-7a(c)(1) of this title.

(e) Allowing continued use of corrective action

Nothing in this section shall be construed as preventing the Office for Civil Rights of the Department of Health and Human Services from continuing, in its discretion, to use corrective action without a penalty in cases where the person did not know (and by exercising reasonable diligence would not have known) of the violation involved.

(Aug. 14, 1935, ch. 531, title XI, §1176, as added Pub. L. 104-191, title II, §262(a), Aug. 21, 1996, 110 Stat. 2028; amended Pub. L. 111-5, div. A, title XIII, §13410(a)(1), (d)(1)-(3), (e)(1), (2), (f), Feb. 17, 2009, 123 Stat. 271-276.)

AMENDMENTS

2009—Subsec. (a)(1). Pub. L. 111-5, §13410(d)(1), substituted “who violates a provision of this part—” for “who violates a provision of this part a penalty of not more than \$100 for each such violation, except that the total amount imposed on the person for all violations of an identical requirement or prohibition during a calendar year may not exceed \$25,000.”, added subpars. (A) to (C), and inserted concluding provisions.

Subsec. (a)(3). Pub. L. 111-5, §13410(d)(2), added par. (3).

Subsec. (b)(1). Pub. L. 111-5, §13410(e)(2)(A), substituted “No penalty may be imposed under subsection (a) and no damages obtained under subsection (d)” for “A penalty may not be imposed under subsection (a)”.

Pub. L. 111-5, §13410(a)(1)(A), substituted “a penalty has been imposed under section 1320d-6 of this title with respect to such act” for “the act constitutes an offense punishable under section 1320d-6 of this title”.

Subsec. (b)(2). Pub. L. 111-5, §13410(d)(3)(A), redesignated par. (3) as (2) and struck out former par. (2). Prior to amendment, text of par. (2) read as follows: “A penalty may not be imposed under subsection (a) of this section with respect to a provision of this part if it is established to the satisfaction of the Secretary that the person liable for the penalty did not know, and by exercising reasonable diligence would not have known, that such person violated the provision.”

Subsec. (b)(2)(A). Pub. L. 111-5, §13410(e)(2)(B)(ii), which directed amendment of cl. (ii) of subpar. (A) by inserting “or damages” after “the penalty”, was executed by making the insertion in subpar. (A) to reflect the probable intent of Congress and the intervening amendment by Pub. L. 111-5, §13410(d)(3)(B)(i), which struck out the cl. (ii) designation. See below.

Pub. L. 111-5, §13410(e)(2)(B)(i), substituted “no penalty may be imposed under subsection (a) and no damages obtained under subsection (d)” for “a penalty may not be imposed under subsection (a)”.

Pub. L. 111-5, § 13410(d)(3)(B)(i), substituted “in subparagraph (B) or subsection (a)(1)(C), a penalty may not be imposed under subsection (a) if the failure to comply is corrected” for “in subparagraph (B), a penalty may not be imposed under subsection (a) of this section if—

“(i) the failure to comply was due to reasonable cause and not to willful neglect; and

“(ii) the failure to comply is corrected”.

Subsec. (b)(2)(B), Pub. L. 111-5, § 13410(d)(3)(B)(ii), substituted “(A)” for “(A)(ii)” in two places.

Subsec. (b)(2)(B)(i), Pub. L. 111-5, § 13410(e)(2)(C), substituted “With respect to the imposition of a penalty by the Secretary under subsection (a), the period” for “The period”.

Subsec. (b)(3), Pub. L. 111-5, § 13410(e)(2)(D), inserted “and any damages under subsection (d)” after “any penalty under subsection (a)”.

Pub. L. 111-5, § 13410(d)(3)(A), redesignated par. (4) as (3). Former par. (3) redesignated (2).

Subsec. (b)(4), Pub. L. 111-5, § 13410(d)(3)(A), redesignated par. (4) as (3).

Subsec. (c), Pub. L. 111-5, § 13410(a)(1)(B), added subsec. (c).

Subsec. (d), Pub. L. 111-5, § 13410(e)(1), added subsec. (d).

Subsec. (e), Pub. L. 111-5, § 13410(f), added subsec. (e).

EFFECTIVE DATE OF 2009 AMENDMENT

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

Amendment by section 13410(a)(1) of Pub. L. 111-5 applicable to penalties imposed on or after the date that is 24 months after Feb. 17, 2009, see section 17939(b)(1) of this title.

Amendment by section 13410(d)(1)–(3) of Pub. L. 111-5 applicable to violations occurring after Feb. 17, 2009, see section 17939(d)(4) of this title.

Amendment by section 13410(e)(1), (2) of Pub. L. 111-5 applicable to violations occurring after Feb. 17, 2009, see section 17939(e)(3) of this title.

§ 1320d-6. Wrongful disclosure of individually identifiable health information

(a) Offense

A person who knowingly and in violation of this part—

(1) uses or causes to be used a unique health identifier;

(2) obtains individually identifiable health information relating to an individual; or

(3) discloses individually identifiable health information to another person,

shall be punished as provided in subsection (b). For purposes of the previous sentence, a person (including an employee or other individual) shall be considered to have obtained or disclosed individually identifiable health information in violation of this part if the information is maintained by a covered entity (as defined in the HIPAA privacy regulation described in section 1320d-9(b)(3) of this title) and the individual obtained or disclosed such information without authorization.

(b) Penalties

A person described in subsection (a) shall—

(1) be fined not more than \$50,000, imprisoned not more than 1 year, or both;

(2) if the offense is committed under false pretenses, be fined not more than \$100,000, imprisoned not more than 5 years, or both; and

(3) if the offense is committed with intent to sell, transfer, or use individually identifiable

health information for commercial advantage, personal gain, or malicious harm, be fined not more than \$250,000, imprisoned not more than 10 years, or both.

(Aug. 14, 1935, ch. 531, title XI, § 1177, as added Pub. L. 104-191, title II, § 262(a), Aug. 21, 1996, 110 Stat. 2029; amended Pub. L. 111-5, div. A, title XIII, § 13409, Feb. 17, 2009, 123 Stat. 271.)

AMENDMENTS

2009—Subsec. (a), Pub. L. 111-5 inserted at end “For purposes of the previous sentence, a person (including an employee or other individual) shall be considered to have obtained or disclosed individually identifiable health information in violation of this part if the information is maintained by a covered entity (as defined in the HIPAA privacy regulation described in section 1320d-9(b)(3) of this title) and the individual obtained or disclosed such information without authorization.”

EFFECTIVE DATE OF 2009 AMENDMENT

Amendment by Pub. L. 111-5 effective 12 months after Feb. 17, 2009, see section 13423 of Pub. L. 111-5, set out as an Effective Date note under section 17931 of this title.

§ 1320d-7. Effect on State law

(a) General effect

(1) General rule

Except as provided in paragraph (2), a provision or requirement under this part, or a standard or implementation specification adopted or established under sections 1320d-1 through 1320d-3 of this title, shall supersede any contrary provision of State law, including a provision of State law that requires medical or health plan records (including billing information) to be maintained or transmitted in written rather than electronic form.

(2) Exceptions

A provision or requirement under this part, or a standard or implementation specification adopted or established under sections 1320d-1 through 1320d-3 of this title, shall not supersede a contrary provision of State law, if the provision of State law—

(A) is a provision the Secretary determines—

(i) is necessary—

(I) to prevent fraud and abuse;

(II) to ensure appropriate State regulation of insurance and health plans;

(III) for State reporting on health care delivery or costs; or

(IV) for other purposes; or

(ii) addresses controlled substances; or

(B) subject to section 264(c)(2) of the Health Insurance Portability and Accountability Act of 1996, relates to the privacy of individually identifiable health information.

(b) Public health

Nothing in this part shall be construed to invalidate or limit the authority, power, or procedures established under any law providing for the reporting of disease or injury, child abuse, birth, or death, public health surveillance, or public health investigation or intervention.

(c) State regulatory reporting

Nothing in this part shall limit the ability of a State to require a health plan to report, or to