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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

45 CFR Parts 160 and 164

RIN 0945-AA03

Technical Corrections to the HIPAA Privacy, Security, and Enforcement Rules

AGENCY: Office for Civil Rights, Department of Health and Human Services.

ACTION: Final rule.

SUMMARY: These technical corrections address certain inadvertent errors and omissions in the HIPAA Privacy, Security, and Enforcement Rules that are located at 45 CFR Parts 160 and 164.

DATES: This final rule is effective on [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Andra Wicks 202-205-2292.

SUPPLEMENTARY INFORMATION:

I. Executive Summary and Background

On January 25, 2013, the Department of Health and Human Services (HHS or “the Department”) published a final rule to implement changes to the HIPAA Privacy, Security, Enforcement, and Breach Notification Rules (“the HIPAA Rules”) pursuant to statutory amendments under the

Health Information Technology for Economic and Clinical Health Act (“the HITECH Act”), pursuant to section 105 of Title I of the Genetic Information Nondiscrimination Act of 2008, to address public comment received on the interim final Breach Notification Rule, and to make certain other modifications to the HIPAA Rules to improve their workability and effectiveness and to increase flexibility for and decrease burden on the regulated entities. See 78 FR 5566. Since then, HHS has discovered a number of minor inadvertent errors and omissions in citations, and one typographical error, in several provisions of the HIPAA Rules. As explained below, with one exception, the errors and omissions are related to the modifications made in the final rule published on January 25, 2013. This final rule contains technical corrections to the HIPAA Rules to revise these errors and omissions, which are discussed below.

II. Discussion of Technical Corrections to 45 CFR Part 160

- a. Section 160.508(c)(5) should be corrected to refer to § 160.410(b)(2)(ii)(B) and 42 U.S.C. 1320d-5(b)(2)(B) instead of § 160.410(b)(3)(ii)(B) and 42 U.S.C. 1320d-5(b)(3)(B), respectively, as § 160.410(b)(3)(ii)(B) and 42 U.S.C. 1320d-5(b)(3)(B) were previously amended and became § 160.410(b)(2)(ii)(B) and 42 U.S.C. 1320d-5(b)(2)(B) as a result. Also, § 160.508(c)(5) should include a reference to § 160.410(c)(2)(ii) after the reference to § 160.410(b)(2)(ii)(B), so that there is a corresponding regulatory reference for the grant of an extension of time pursuant to the Secretary’s discretion for violations occurring on or after February 18, 2009, as there is for violations occurring prior to February 18, 2009.

- b. Section 160.548(e) references an affirmative defense by which the Secretary may not impose a civil money penalty on a covered entity if the violation falls under the HIPAA criminal provisions at 42 U.S.C. 1320d-6 and cites § 160.410(b)(1) as the regulatory reference for this affirmative defense. However, § 160.410(b)(1) was changed to be § 160.410(a)(1) and (2). Thus, § 160.548(e) should be corrected to refer to § 160.410(a)(1) or (2) instead of § 160.410(b)(1).

III. Discussion of Technical Corrections to 45 CFR Part 164

- a. The definition of health care component found at § 164.103 references § 164.105(a)(2)(iii)(C), but that reference should be corrected to be § 164.105(a)(2)(iii)(D), as § 164.105(a)(2)(iii)(D) now contains the hybrid entity designation requirements referenced by the definition of health care component.
- b. The definition of hybrid entity found at § 164.103 references § 164.105(a)(2)(iii)(C), but that reference should be corrected to be § 164.105(a)(2)(iii)(D), as § 164.105(a)(2)(iii)(D) now contains the hybrid entity designation requirements referenced by the definition of hybrid entity.
- c. Section 164.314(a)(1), in discussing business associate contracts or other arrangements, refers to the requirements for such contracts or other arrangements found at § 164.308(b)(4). However, as such requirements were renumbered and are now found at § 164.308(b)(3), § 164.314(a)(1) should be revised to refer to § 164.308(b)(3).

- d. Section 164.512(k)(4)(i) refers to Executive Order (“E.O.”)12698. However E.O. 12698 discusses pay rate adjustments and is not applicable to the subject of § 164.512(k)(4)(i). The preamble to the 2000 HIPAA Privacy Final Rule refers to E.O. 12968, which discusses classified information and is applicable to the subject of § 164.512(k)(4)(i). See 65 FR 82707. Given that § 164.512(k)(4)(i) relates to uses and disclosures of protected health information to the Department of State to determine medical suitability for the purpose of a required security clearance, as discussed in the preamble to the 2000 Privacy Final Rule, § 164.512(k)(4)(i) should properly refer to E.O. 12968.
- e. Section 164.514(f)(2)(iv), in discussing the implementation specifications for covered entities that make fundraising communications, refers to the requirements to allow an individual to opt out of receiving fundraising communications, and erroneously refers to § 164.514(f)(1)(ii)(B), which does not exist. The proper reference for the opt out requirements is at § 164.514(f)(2)(ii). Accordingly, § 164.514(f)(2)(iv) should be revised to refer to § 164.514(f)(2)(ii).
- f. Section 164.524(c)(4)(iv) describes the summary or explanation allowed by § 164.524(c)(2)(iii), while incorrectly referring to § 164.524(c)(2)(ii), which discusses the form of access requested by an individual. As such, § 164.524(c)(4)(iv) should be revised to refer to § 164.524(c)(2)(iii).

- g. In section 164.532(f), the “[” should be removed before “January 25, 2013” to correct a typographical error.

IV. Inapplicability of Notice and Delayed Effective Date

Under the Administrative Procedure Act, an agency may waive the normal notice and comment procedures if it finds, for good cause, that they are impracticable, unnecessary, or contrary to the public interest. The Department has determined that the corrections in this final rule are minor, routine determinations in which the public would not be particularly interested, or about which the public has already been put on notice, given the context of the errors or omissions to be corrected. Therefore, the Department finds that good cause exists for waiving the notice and public comment procedures as unnecessary under 5 U.S.C. 553(b)(B). For the same reasons, pursuant to 5 U.S.C. 553(d)(3), a delayed effective date is not required.

V. Regulatory Flexibility Act

Because this document is not subject to the notice and public procedure requirements of 5 U.S.C. 553, it is not subject to the provisions of the Regulatory Flexibility Act (5 U.S.C. 601 et seq.).

VI. Executive Order 12866

These technical corrections do not meet the criteria for a “significant regulatory action” as specified in Executive Order 12866, as supplemented by Executive Order 13563.

List of Subjects

45 CFR Part 160

Administrative practice and procedure, Computer technology, Electronic information system, Electronic transactions, Employer benefit plan, Health, Health care, Health facilities, Health insurance, Health records, Hospitals, Investigations, Medicaid, Medical research, Medicare, Penalties, Privacy, Reporting and recordkeeping requirements, Security.

45 CFR Part 164

Administrative practice and procedure, Computer technology, Electronic information system, Electronic transactions, Employer benefit plan, Health, Health care, Health facilities, Health insurance, Health records, Hospitals, Medicaid, Medical research, Medicare, Privacy, Reporting and recordkeeping requirements, Security.

For the reasons set forth in the preamble, the Department amends 45 CFR Subtitle A, Subchapter C, parts 160 and 164, as set forth below:

PART 160—GENERAL ADMINISTRATIVE REQUIREMENTS

1. The authority citation for part 160 continues to read as follows:

AUTHORITY: 42 U.S.C. 1302(a); 42 U.S.C. 1320d-1320d-9; sec. 264, Pub. L. 104-191, 110 Stat. 2033-2034 (42 U.S.C. 1320d-2 (note)); 5 U.S.C. 552; secs. 13400-13424, Pub. L. 111-5, 123 Stat. 258-279; and sec. 1104 of Pub. L. 111-148, 124 Stat. 146-154.

§ 160.508 [Amended]

2. Amend § 160.508(c)(5) by correcting “§ 160.410(b)(3)(ii)(B)” to read “§ 160.410(b)(2)(ii)(B) or (c)(2)(ii)” and by correcting “42 U.S.C. 1320d-5(b)(3)(B)” to read “42 U.S.C. 1320d-5(b)(2)(B)”.

§ 160.548 [Amended]

3. Amend § 160.548(e) by correcting “§ 160.410(b)(1)” to read “§ 160.410(a)(1) or (2)”.

PART 164—SECURITY AND PRIVACY

4. The authority citation for part 164 continues to read as follows:

AUTHORITY: 42 U.S.C. 1302(a); 42 U.S.C. 1320d-1320d-9; sec. 264, Pub. L. 104-191, 110 Stat. 2033-2034 (42 U.S.C. 1320d-2(note)); and secs. 13400-13424, Pub. L. 111-5, 123 Stat. 258-279.

§ 164.103 [Amended]

5. Amend § 164.103 as follows:

a. In the definition of health care component, by correcting “§ 164.105(a)(2)(iii)(C)” to read “§ 164.105(a)(2)(iii)(D)”.

b. In the definition of hybrid entity, by correcting “§ 164.105(a)(2)(iii)(C)” to read “§ 164.105(a)(2)(iii)(D)”.

§ 164.314 [Amended]

6. Amend § 164.314(a)(1) by correcting “§ 164.308(b)(4)” to read “§ 164.308(b)(3)”.

§ 164.512 [Amended]

7. Amend § 164.512(k)(4)(i) by correcting “12698” to read “12968”.

§ 164.514 [Amended]

8. Amend § 164.514(f)(2)(iv) by correcting “paragraph (f)(1)(ii)(B)” to read “paragraph (f)(2)(ii)”.

§ 164.524 [Amended]

9. Amend § 164.524(c)(4)(iv) by correcting “paragraph (c)(2)(ii)” to read “paragraph(c)(2)(iii)”.

§ 164.532 [Amended]

10. Amend the introductory text of § 164.532(f) by correcting “[January 25, 2013” to read “January 25, 2013”.

Dated: May 31, 2013.

Jennifer M. Cannistra

Executive Secretary to the Department.

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