

112TH CONGRESS
2D SESSION

S. 3351

To amend the American Recovery and Reinvestment Act with respect to the privacy of protected health information.

IN THE SENATE OF THE UNITED STATES

JUNE 27, 2012

Mr. FRANKEN introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To amend the American Recovery and Reinvestment Act with respect to the privacy of protected health information.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Protect Our Health
5 Privacy Act”.

6 **SEC. 2. REPORTING REQUIREMENTS.**

7 (a) NOTIFICATION IN THE CASE OF BREACH.—Para-
8 graph (2) of section 13402(i) of division A of the Amer-
9 ican Recovery and Reinvestment Act of 2009 (42 U.S.C.
10 17932(i)) is amended to read as follows:

1 “(2) INFORMATION.—The information de-
 2 scribed in this paragraph regarding breaches speci-
 3 fied in paragraph (1) shall include—

4 “(A) the number and nature of all such
 5 breaches, including a description of the types of
 6 unsecured protected health information that
 7 were involved in each breach;

8 “(B) the identity of the covered entity in-
 9 volved in each breach, or if the breach affected
 10 less than 500 individuals, the kind of covered
 11 entity involved (such as a health plan, health
 12 care clearinghouse, or a health care provider
 13 who transmits any health information in elec-
 14 tronic form in connection with a transaction
 15 covered by this subtitle); and

16 “(C) actions taken in response to such
 17 breaches.”.

18 (b) REPORT ON COMPLIANCE.—Section 13424 of di-
 19 vision A of the American Recovery and Reinvestment Act
 20 of 2009 (42 U.S.C. 17954) is amended—

21 (1) in subsection (a)(1)—

22 (A) by amending subparagraph (B) to read
 23 as follows:

24 “(B) information about such complaints
 25 resolved informally, including—

1 “(i) the number of such complaints
2 resolved informally;

3 “(ii) a summary of the types of com-
4 plaints so resolved, including identification
5 of the most common types complaints so
6 resolved, categorized by the privacy and se-
7 curity rule allegedly violated;

8 “(iii) for each such category, the aver-
9 age amount of time between receipt of a
10 complaint to resolution of such complaint;

11 “(iv) examples, with entity and pa-
12 tient names and other individually identifi-
13 able health information redacted, of com-
14 plaints resolved informally and the Sec-
15 retary’s rationale for resolving such com-
16 plaints informally; and

17 “(v) the number of covered entities
18 that received technical assistance from the
19 Secretary during such year in order to
20 achieve compliance with such provisions
21 and the types of such technical assistance
22 provided.”;

23 (B) in subparagraph (E), by inserting
24 “and a summary of the outcome of such sub-
25 poenas or inquiries” after “inquiries issued”;

1 (C) in subparagraph (F), by striking “fol-
2 lowing year; and” and inserting “following year
3 and enforcement priorities for the succeeding
4 year;”;

5 (D) in subparagraph (G), by striking the
6 period at the end and inserting a semicolon;
7 and

8 (E) by adding at the end the following:

9 “(H) the number of State attorney general
10 actions that were pursued under this subtitle
11 and notice of which was provided to the Sec-
12 retary pursuant to section 1176(d)(4) of the
13 Social Security Act; and

14 “(I) the number of health privacy or health
15 security or data breach complaints referred to
16 the Attorney General, including—

17 “(i) whether the Attorney General de-
18 clined enforcement; and

19 “(ii) the number of complaints re-
20 ferred to the Attorney General but re-
21 turned to the Secretary for enforcement
22 and a summary of enforcement actions
23 taken by the Secretary with respect to
24 such complaints, including informal resolu-
25 tions, civil monetary penalties, resolution

1 agreements or settlements, or voluntary
2 compliance actions.”; and

3 (2) by adding at the end the following:

4 “(g) ANNUAL STUDIES.—

5 “(1) IN GENERAL.—For the first year begin-
6 ning after the date of enactment of the Protect Our
7 Health Privacy Act, and every year thereafter, the
8 Attorney General shall submit to the Committee on
9 the Judiciary of the Senate and the Committee on
10 the Judiciary of the House of Representatives a re-
11 port concerning complaints of alleged violations de-
12 scribed in section 1177 of the Social Security Act,
13 including violations of the provisions of this subtitle
14 relating to privacy and security of health informa-
15 tion, that were referred to the Department of Jus-
16 tice by the Department of Health and Human Serv-
17 ices, the Federal Bureau of Investigation, or another
18 State or Federal agency during the year for which
19 the report is being prepared.

20 “(2) REQUIREMENTS.—Each report required
21 under paragraph (1) shall—

22 “(A) be made available to the public on the
23 websites of the Department of Justice and the
24 Department of Health and Human Services;
25 and

“(B) include, with respect to complaints received during the year for which the report is being prepared—

“(i) the total number of complaints received;

“(ii) the number of complaints received that were eligible for criminal enforcement; and

“(iii) of the complaints described in clause (ii), a summary of how each complaint was resolved that—

“(I) includes the rationale for declining enforcement, if applicable; and

“(II) does not identify the patients, individuals, or entities involved.”.

SEC. 3. ENCRYPTION FOR PORTABLE MEDIA.

(a) GUIDANCE REGARDING UNSECURED PROTECTED HEALTH INFORMATION.—

(1) IN GENERAL.—Section 13402(h)(2) of division A of the American Recovery and Reinvestment Act of 2009 (42 U.S.C. 17932(h)(2)) is amended by inserting “, including protected health information stored on portable media (as defined by the Secretary, which shall include thumb drives, laptop com-

1 puters, tablet computers, and other similar de-
2 vices),” after “protected health information”.

3 (2) APPLICABLE.—The amendment made by
4 paragraph (1) shall apply to updated guidance
5 issued under section 13402(h)(2) of division A of the
6 American Recovery and Reinvestment Act of 2009
7 (42 U.S.C. 17932(h)(2)) after the date of enactment
8 of this Act.

9 (b) PORTABLE MEDIA ENCRYPTION REQUIRE-
10 MENT.—

11 (1) IN GENERAL.—Section 13401 of division A
12 of the American Recovery and Reinvestment Act of
13 2009 (42 U.S.C. 17931) is amended by adding at
14 the end the following:

15 “(d) PORTABLE MEDIA ENCRYPTION REQUIRE-
16 MENT.—Not later than 1 year after the date of enactment
17 of the Protect Our Health Privacy Act, the Secretary shall
18 issue regulations to require covered entities and business
19 associates to render protected health information that is
20 stored on portable media (as defined by the Secretary,
21 which shall include thumb drives, laptop computers, tablet
22 computers, and other similar devices) unusable,
23 unreadable, or indecipherable to unauthorized individ-
24 uals.”.

1 (2) CONFORMING AMENDMENT.—Section
 2 13401(b) of such Act (42 U.S.C. 17931(b)) is
 3 amended by inserting “or (d)” after “subsection
 4 (a)”.

5 **SEC. 4. USE OF DATA IN BUSINESS ASSOCIATE CONTRACTS;**
 6 **APPLICATION OF MINIMUM NECESSARY**
 7 **STANDARD TO BUSINESS ASSOCIATES.**

8 (a) IN GENERAL.—Section 13404 of division A of the
 9 American Recovery and Reinvestment Act (42 U.S.C.
 10 17934) is amended by adding at the end the following:

11 “(d) USE OF DATA IN BUSINESS ASSOCIATE CON-
 12 TRACTS; APPLICATION OF MINIMUM NECESSARY STAND-
 13 ARD TO BUSINESS ASSOCIATES.—

14 “(1) LIMITATION ON SCOPE AND USE OF PRO-
 15 TECTED HEALTH INFORMATION.—As required by
 16 section 164.504(e) of title 45, Code of Regulations
 17 (as in effect on the date of enactment of this sub-
 18 section), any business associate agreement between a
 19 covered entity and a business associate shall limit
 20 the use of protected health information by such busi-
 21 ness associate—

22 “(A) to only such information as necessary
 23 for the performance of the service or function
 24 that the covered entity has contracted with the

1 business associate to perform on behalf of the
 2 covered entity; and

3 “(B) to only those uses that are necessary
 4 for the performance of the service or function
 5 described in subparagraph (A).

6 “(2) APPLICATION OF MINIMUM NECESSARY
 7 STANDARD TO BUSINESS ASSOCIATES.—Section
 8 164.502(b) of title 45, Code of Federal Regulations
 9 shall apply to a business associate of a covered enti-
 10 ty in the same manner that such section applies to
 11 the covered entity. The additional requirements of
 12 this title that relate to the minimum necessary
 13 standard with respect to the use, disclosure, and re-
 14 quest of protected health information that are made
 15 applicable with respect to covered entities shall also
 16 be applicable to such a business associate and shall
 17 be incorporated into the business associate agree-
 18 ment between the business associate and the covered
 19 entity.”.

20 (b) CONFORMING AMENDMENT.—Subsection (c) of
 21 such section 13404 (42 U.S.C. 17934) is amended by
 22 striking “(a) or (b)” and inserting “(a), (b), or (d)(2)”.

23 (c) CLARIFICATION.—Nothing in subsection (d)(2) of
 24 section 13404 of division A of the American Recovery and
 25 Reinvestment Act (42 U.S.C. 17934) (as amended by sub-

1 section (a)) affects the application of the minimum nec-
 2 essary standard to business associates pursuant to section
 3 164.504(e) of title 45, Code of Federal Regulations (relat-
 4 ing to contracts and other arrangements between business
 5 associates and covered entities) as in effect on the date
 6 of enactment of this Act.

7 **SEC. 5. HEALTH INFORMATION TECHNOLOGY IMPROVE-**
 8 **MENT INITIATIVE.**

9 Title XXX of the Public Health Service Act (42
 10 U.S.C. 300jj et seq.) is amended by adding at the end
 11 the following:

12 **“SEC. 3022. HEALTH INFORMATION TECHNOLOGY IM-**
 13 **PROVEMENT INITIATIVE.**

14 “(a) IN GENERAL.—Not later than 18 months after
 15 the date of enactment of the Protect Our Health Privacy
 16 Act, the Secretary shall issue regulations to improve the
 17 safety, interoperability, and utility of health information
 18 technology systems.

19 “(b) CONTENT.—The regulations issued under sub-
 20 section (a) shall include—

- 21 “(1) a system to track the effect of health in-
 22 formation technology on the health of patients; and
 23 “(2) minimum quality and risk management re-
 24 quirements for health information technology ven-
 25 dors.

1 “(c) HEALTH INFORMATION TECHNOLOGY ADVERSE
2 HEALTH EVENT REPORTING.—

3 “(1) IN GENERAL.—The Secretary shall des-
4 ignate an agency within the Department of Health
5 and Human Services to promulgate regulations re-
6 lating to a health information technology adverse
7 health event reporting program and database. The
8 Department shall consider definitions and standards
9 developed by the National Quality Forum before
10 promulgating such regulations.

11 “(2) CONTENT.—The regulations promulgated
12 under paragraph (1) shall include mandatory sub-
13 mission of adverse health event reports by health in-
14 formation technology vendors and voluntary submis-
15 sion of adverse health event reports by users of
16 health information, including patients and their fam-
17 ily caregivers.

18 “(3) USE OF REPORTS.—The agency designated
19 under paragraph (1) shall analyze adverse health
20 event reports and report findings and recommenda-
21 tions to the applicable industry and policymakers.

22 “(4) PROTECTION OF REPORTS.—The agency
23 designated under paragraph (1) shall remove identi-
24 fying information if adverse health event reports are
25 made public. An adverse health event report may not

1 be admitted or used in any action in a Federal or
2 State court or any Federal or State administrative
3 proceeding as evidence of fault, liability, or occur-
4 rence of an adverse health event.

5 “(5) ANNUAL REPORT.—The agency designated
6 under paragraph (1) shall use the database estab-
7 lished under such paragraph to submit to Congress
8 an annual report regarding the use and safety of
9 health information technology.”.

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