

114TH CONGRESS
1ST SESSION

H. R. 2549

To amend the HITECH Act with respect to accessing, sharing, and using health data for research purposes.

IN THE HOUSE OF REPRESENTATIVES

MAY 21, 2015

Mrs. McMORRIS RODGERS introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To amend the HITECH Act with respect to accessing, sharing, and using health data for research purposes.

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. ACCESSING, SHARING, AND USING HEALTH**
4 **DATA FOR RESEARCH PURPOSES.**

5 (a) IN GENERAL.—The HITECH Act (title XIII of
6 division A of Public Law 111–5) is amended by adding
7 at the end of subtitle D of such Act (42 U.S.C. 17921
8 et seq.) the following:

1 **“PART 4—ACCESSING, SHARING, AND USING**
2 **HEALTH DATA FOR RESEARCH PURPOSES**

3 **“SEC. 13441. REFERENCES.**

4 “‘In this part:

5 “(a) THE RULE.—References to ‘the Rule’ refer to
6 part 160 or part 164, as appropriate, of title 45, Code
7 of Federal Regulations (or any successor regulation).

8 “(b) PART 164.—References to a specified section of
9 ‘part 164’, refer to such specified section of part 164 of
10 title 45, Code of Federal Regulations (or any successor
11 section).

12 **“SEC. 13442. DEFINING HEALTH DATA RESEARCH AS PART**
13 **OF HEALTH CARE OPERATIONS.**

14 “(a) IN GENERAL.—Subject to subsection (b), the
15 Secretary shall revise or clarify the rule to allow the use
16 and disclosure of protected health information by a cov-
17 ered entity for research purposes, including studies whose
18 purpose is to obtain generalizable knowledge, to be treated
19 as the use and disclosure of such information for health
20 care operations described in subparagraph (1) of the defi-
21 nition of health care operations in section 164.501 of part
22 164.

23 “(b) MODIFICATIONS TO RULES FOR DISCLOSURES
24 FOR HEALTH CARE OPERATIONS.—In applying section
25 164.506 of part 164 to the disclosure of protected health
26 information described in subsection (a)—

1 “(1) the Secretary shall revise or clarify the
2 Rule so that the disclosure may be made by the cov-
3 ered entity to only—

4 “(A) another covered entity for health care
5 operations (as defined in such section 164.501
6 of part 164);

7 “(B) a business associate that has entered
8 into a contract under section 164.504(e) of part
9 164 with a disclosing covered entity to perform
10 health care operations; or

11 “(C) a business associate that has entered
12 into a contract under section 164.504(e) of part
13 164 for the purpose of data aggregation (as de-
14 fined in such section 164.501 of part 164); and

15 “(2) the Secretary shall further revise or clarify
16 the Rule so that the limitation specified by section
17 164.506(e)(4) of part 164 does not apply to disclo-
18 sures that are described by subsection (a).

19 “(c) RULE OF CONSTRUCTION.—This section shall
20 not be construed as prohibiting or restricting a use or dis-
21 closure of protected health information for research pur-
22 poses that is otherwise permitted under part 164.

1 **“SEC. 13443. TREATING DISCLOSURES OF PROTECTED**
 2 **HEALTH INFORMATION FOR RESEARCH SIMI-**
 3 **LARLY TO DISCLOSURES OF SUCH INFORMA-**
 4 **TION FOR PUBLIC HEALTH PURPOSES.**

5 “(a) REMUNERATION.—The Secretary shall revise or
 6 clarify the Rule so that disclosures of protected health in-
 7 formation for research purposes are not subject to the lim-
 8 itation on remuneration described in section
 9 164.502(a)(5)(ii)(B)(2)(ii) of part 164.

10 “(b) PERMITTED USES AND DISCLOSURES.—The
 11 Secretary shall revise or clarify the Rule so that research
 12 activities, including comparative research activities, re-
 13 lated to the quality, safety, or effectiveness of a product
 14 or activity that is regulated by the Food and Drug Admin-
 15 istration are included as public health activities for pur-
 16 poses of which a covered entity may disclose protected
 17 health information to a person described in section
 18 164.512(b)(1)(iii) of part 164.

19 **“SEC. 13444. PERMITTING REMOTE ACCESS TO PROTECTED**
 20 **HEALTH INFORMATION BY RESEARCHERS.**

21 “The Secretary shall revise or clarify the Rule so that
 22 subparagraph (B) of section 164.512(i)(1)(ii) of part 164
 23 (prohibiting the removal of protected health information
 24 by a researcher) shall not prohibit remote access to health
 25 information by a researcher so long as—

1 “(1) appropriate security and privacy safe-
2 guards are maintained by the covered entity and the
3 researcher; and

4 “(2) the protected health information is not
5 copied or otherwise retained by the researcher.

6 **“SEC. 13445. ALLOWING ONE-TIME AUTHORIZATION OF USE**
7 **AND DISCLOSURE OF PROTECTED HEALTH**
8 **INFORMATION FOR RESEARCH PURPOSES.**

9 “(a) IN GENERAL.—The Secretary shall revise or
10 clarify the Rule to specify that an authorization for the
11 use or disclosure of protected health information, with re-
12 spect to an individual, for future research purposes shall
13 be deemed to contain a sufficient description of the pur-
14 pose of the use or disclosure if the authorization—

15 “(1) sufficiently describes the purposes such
16 that it would be reasonable for the individual to ex-
17 pect that the protected health information could be
18 used or disclosed for such future research;

19 “(2) either—

20 “(A) states that the authorization will ex-
21 pire on a particular date or on the occurrence
22 of a particular event; or

23 “(B) states that the authorization will re-
24 main valid unless and until it is revoked by the
25 individual; and

1 “(3) provides instruction to the individual on
2 how to revoke such authorization at any time.

3 “(b) REVOCATION OF AUTHORIZATION.—The Sec-
4 retary shall revise or clarify the Rule to specify that, if
5 an individual revokes an authorization for future research
6 purposes such as is described by subsection (a), the cov-
7 ered entity may not make any further uses or disclosures
8 based on that authorization, except, as provided in para-
9 graph (b)(5) of section 164.508 of part 164, to the extent
10 that the covered entity has taken action in reliance on the
11 authorization.”.

12 (b) REVISION OF REGULATIONS.—Not later than 12
13 months after the date of the enactment of this Act, the
14 Secretary of Health and Human Services shall revise and
15 clarify the provisions of title 45, Code of Federal Regula-
16 tions, for consistency with part 4 of subtitle D of the
17 HITECH Act, as added by subsection (a).

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