

114TH CONGRESS
2D SESSION

H. R. 4805

To amend the Health Information Technology for Economic and Clinical Health Act to provide that information held by health care clearinghouses is subject to privacy protections that are equivalent to the protections that apply to information held by other types of covered entities under the HIPAA Privacy Rule, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MARCH 17, 2016

Mrs. MCMORRIS RODGERS (for herself and Mr. BYRNE) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

To amend the Health Information Technology for Economic and Clinical Health Act to provide that information held by health care clearinghouses is subject to privacy protections that are equivalent to the protections that apply to information held by other types of covered entities under the HIPAA Privacy Rule, and for other purposes.

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

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Ensuring Patient Ac-
3 cess to Healthcare Records Act of 2016”.

4 **SEC. 2. FINDINGS.**

5 The Congress finds as follows:

6 (1) The Health Insurance Portability and Ac-
7 countability Act of 1996 (“HIPAA”), through cer-
8 tain of its implementing regulations known as the
9 Privacy Rule, protects the health information of en-
10 rollees of health plans and other individuals (in this
11 section referred to as “protected health informa-
12 tion”).

13 (2) The HIPAA Privacy Rule applies to pro-
14 tected health information held by health care pro-
15 viders, plans, and clearinghouses, which are known
16 as “covered entities”. Such Rule also applies to ven-
17 dors that perform certain functions for covered enti-
18 ties and thereby come into possession of protected
19 health information. The HIPAA Privacy Rule refers
20 to these vendors as “business associates”.

21 (3) The HIPAA Privacy Rule applies both to
22 the internal use of protected health information by
23 covered entities and their business associates and to
24 the disclosure of such information to other parties.

25 (4) Covered entities and their business associ-
26 ates are subject to substantial civil and criminal pen-

1 alties if they use or disclose protected health infor-
2 mation in violation of the HIPAA Privacy Rule.

3 (5) Clearinghouses play a unique, central role
4 in the health care system, interacting with both
5 health care providers and plans. Clearinghouses con-
6 vert information from providers into claims-proc-
7 essing standard electronic formats and then submit
8 the claims to the plans and finally send providers
9 the plan payments.

10 (6) Claims and other data held by clearing-
11 houses could be analyzed longitudinally and geo-
12 graphically, providing powerful analytical tools that
13 could benefit the overall health care system and fa-
14 cilitate medical innovation in the 21st Century.

15 (7) Clearinghouses are unable to unlock the
16 benefits of such claims and other data because the
17 HIPAA Privacy Rule assigns clearinghouses a dual
18 role. Such clearinghouses are not only covered enti-
19 ties, but are also business associates. The latter role
20 substantially restricts the ability of clearinghouses to
21 analyze claims data.

22 (8) Clearinghouses should not be considered
23 business associates and should instead have the
24 same ability to use and disclose health-related data
25 as other types of covered entities.

1 (9) Eliminating the business-associate role of
2 clearinghouses would not affect the applicability of
3 the civil and criminal penalties that enforce the
4 HIPAA Privacy Rule. Clearinghouses would con-
5 tinue to be subject to such penalties in their role as
6 covered entities.

7 (10) In addition to the uses of health-related in-
8 formation that the HIPAA Privacy Rule currently
9 authorizes for covered entities, there are several par-
10 ticular analytical uses that should be authorized spe-
11 cifically for clearinghouses because of the unique
12 benefits that would result from authorizing those
13 uses. Although these particular new analytical uses
14 should be authorized for clearinghouses, the disclo-
15 sure of health information pursuant to these uses
16 should be subject to the protection principles cur-
17 rently underlying the HIPAA Privacy Rule, includ-
18 ing enforcement principles.

19 **SEC. 3. TREATMENT OF CERTAIN HIPAA-RELATED ACTIVI-**
20 **TIES OF HEALTH CARE CLEARINGHOUSES.**

21 (a) IN GENERAL.—Subtitle D of the Health Informa-
22 tion Technology for Economic and Clinical Health Act (42
23 U.S.C. 17921 et seq.) is amended by adding at the end
24 the following:

1 **“PART 5—HEALTH CARE CLEARINGHOUSES; ANA-**
2 **LYTICAL FUNCTIONS TOWARD IMPROVING**
3 **THE HEALTH CARE SYSTEM**

4 **“SEC. 13451. AUTHORITY REGARDING ANALYTICAL FUNC-**
5 **TIONS TOWARD IMPROVING THE HEALTH**
6 **CARE SYSTEM.**

7 “(a) IN GENERAL.—With respect to the use and dis-
8 closure of protected health information, the Secretary—

9 “(1) shall not consider health care clearing-
10 houses to be business associates under this subtitle,
11 part C of title XI of the Social Security Act, or the
12 regulations promulgated pursuant to section 264(c)
13 of the Health Insurance Portability and Account-
14 ability Act of 1996 for purposes of carrying out ac-
15 tivities described in section 1171(2) of the Social Se-
16 curity Act and subsections (b) and (c) of this sec-
17 tion; and

18 “(2) shall consider such clearinghouses to be
19 covered entities under such provisions of law for
20 such purposes.

21 “(b) CERTAIN FUNCTIONS.—The functions that may
22 be carried out by a health care clearinghouse pursuant to
23 subsection (a) include the following:

24 “(1) Promptly upon the request of individuals,
25 providing such individuals with access to their pro-
26 tected health information as permitted by section

1 164.502(a)(1)(i) of title 45, Code of Federal Regula-
2 tions. In carrying out the previous sentence, the
3 clearinghouse may charge such an individual a fee,
4 not to exceed the fair market value, for preparing
5 the record of such information involved.

6 “(2) Promptly upon the request of individuals,
7 providing such individuals with access to their pro-
8 tected health information as required by section
9 164.502(a)(2)(i) of title 45, Code of Federal Regula-
10 tions. In carrying out the previous sentence, the
11 clearinghouse may charge such an individual a fee,
12 not to exceed the fair market value, for preparing
13 the record of such information involved.

14 “(3) With respect to the access of patients to
15 experimental treatments and diagnostics, notifying
16 patients that they may be appropriate candidates as
17 subjects in clinical research, and conducting research
18 to identify such patients, pursuant to the pre-
19 paratory-research provisions of section 164.512(i) of
20 title 45, Code of Federal Regulations, and pursuant
21 to the regulations referred to in paragraph (1) of
22 this subsection.

23 “(4) Making public health disclosures author-
24 ized by sections 164.512(b) or 164.514(e) of title
25 45, Code of Federal Regulations, including notifying

1 manufacturers of drugs or devices about adverse
2 events related to their products pursuant to such
3 section 164.512(b).

4 “(5) Research as authorized by sections
5 164.512(i) or 164.514(e) of title 45, Code of Federal
6 Regulations.

7 “(6) Consistent with the applicable require-
8 ments of section 164.514 of title 45, Code of Fed-
9 eral Regulations, creating de-identified health infor-
10 mation or a limited data set.

11 “(c) ADDITIONAL FUNCTIONS.—

12 “(1) IN GENERAL.—In addition to the functions
13 that may be carried out by a health care clearing-
14 house pursuant to subsection (a), such a clearing-
15 house may, subject only to the privacy protections
16 under paragraph (2), aggregate, use, and disclose
17 data the clearinghouse possesses in order to carry
18 out the following functions:

19 “(A) Prepare reports, analyses, and pres-
20 entations on the quality and costs of health care
21 services, including in specific geographic areas,
22 in order to assist individuals select health care
23 services and providers.

24 “(B) Prepare reports, analyses, and pres-
25 entations of health-services outcomes data, in-

1 including presentations addressing outcomes of
2 various types of approaches to a particular dis-
3 ease, disorder, or other adverse health condi-
4 tion.

5 “(C) Prepare reports, analyses, and pres-
6 entations of epidemiological data to assist deci-
7 sionmaking in development programs for new
8 treatments or diagnostics.

9 “(D) Prepare reports, analyses, and pres-
10 entations on costs and charges for health care
11 products and services.

12 “(E) Upon the request of a covered entity,
13 prepare reports, analyses, and presentations
14 that benchmark the operations of such covered
15 entity against the operations of one or more
16 other covered entities that have elected to par-
17 ticipate in such benchmarking.

18 “(2) PRIVACY.—A health care clearinghouse
19 may carry out the functions described in paragraph
20 (1) without obtaining any authorizations under sec-
21 tion 164.508 of title 45, Code of Federal Regula-
22 tions. For purposes of such paragraph, with respect
23 to any report, analysis, or presentation provided by
24 the clearinghouse to a third party, such report, anal-
25 ysis, or presentation—

1 “(A) shall include only de-identified data;

2 or

3 “(B) if containing protected health infor-
4 mation, shall include such data that is—

5 “(i) subject to a qualifying data use
6 agreement (as defined in subsection (i)); or

7 “(ii) provided to the Food and Drug
8 Administration for purposes authorized by
9 law for such Administration, subject to
10 protected health information being dis-
11 closed to such Administration only to the
12 extent necessary for such purposes.

13 “(d) RELEVANT INFORMATION.—In the case of a
14 health care clearinghouse, the authority under subsections
15 (a) through (c) includes applicability with respect to pro-
16 tected health information collected from other covered en-
17 tities and includes applicability with respect to the aggre-
18 gation of such information between covered entities.

19 “(e) COMPREHENSIVE RECORDS PER REQUEST OF
20 INDIVIDUAL.—For purposes of subsection (b)(2), when a
21 health care clearinghouse receives a request from an indi-
22 vidual for the protected health information of the indi-
23 vidual, the clearinghouse shall provide to the individual a
24 comprehensive record of such information (across health
25 care providers and health plans), unless the clearinghouse

1 determines in its discretion that providing a comprehen-
2 sive record is not technologically feasible. In preparing
3 such record for the individual, the clearinghouse may, with
4 the permission of the individual, purchase the protected
5 health care information of the individual from one or more
6 other health care clearinghouses (and the cost of such pur-
7 chase may be included in the fee charged to the indi-
8 vidual).

9 “(f) SITUATIONS NOT INVOLVING DIRECT INTER-
10 ACTION WITH INDIVIDUALS.—Sections 164.400 through
11 164.414, sections 164.520 through 164.528, and 164.530
12 of title 45, Code of Federal Regulations, apply to a clear-
13 inghouse to the extent that it has current contact informa-
14 tion pursuant to direct interaction with the individual. In
15 the case of each other individual, the clearinghouse shall
16 carry out its functions under this subtitle, part C of title
17 XI of the Social Security Act, and the regulations promul-
18 gated pursuant to section 264(c) of the Health Insurance
19 Portability and Accountability Act of 1996 as if the clear-
20 inghouse were a business associate. The individuals to
21 whom the preceding sentence applies includes individuals
22 with respect to whom the sole clearinghouse function is
23 to process or facilitate the processing of nonstandard data
24 elements of health information into standard data ele-
25 ments.

1 “(g) TRANSITION.—With respect to agreements en-
2 tered into by a health care clearinghouse before the effec-
3 tive date of this section, a provision of an agreement that
4 conflicts with this section shall not have any legal force
5 or effect. The preceding sentence may not be construed
6 as affecting any provision of an agreement that does not
7 conflict with this section. A health care clearinghouse shall
8 provide notice of this subsection to each entity with which
9 the clearinghouse has an agreement that is affected by this
10 subsection.

11 “(h) ENFORCEMENT.—Section 13410(a)(2) applies
12 to this part in the same manner as such section applies
13 to parts 1 and 2.

14 “(i) DEFINITIONS.—For purposes of this part:

15 “(1) The term ‘de-identified’, with respect to
16 health information, means such information that is
17 not individually identifiable as determined in accord-
18 ance with the standards under section 164.514(b) of
19 title 45, Code of Federal Regulations.

20 “(2) The term ‘health care clearinghouse’ has
21 the meaning given such term in section 1171 of the
22 Social Security Act.

23 “(3) The term ‘individual’, with respect to pro-
24 tected health information, has the meaning that ap-

1 plies under section 160.103 of title 45, Code of Fed-
2 eral Regulations.

3 “(4) The term ‘qualifying data use agreement’
4 means an agreement that establishes the permitted
5 uses and disclosures of protected health information
6 by the recipient for one or more functions described
7 in subsection (c)(1) and restricts the use and disclo-
8 sure of the information by the recipient in the same
9 manner as applies under paragraphs (e)(4)(ii)(B)
10 and (e)(4)(ii)(C) (1)–(4) of section 164.514 of title
11 45, Code of Federal Regulations, but without regard
12 to the references to limited data sets.

13 “(j) RELATION TO OTHER LAWS.—Section 13421
14 applies to this part in the same manner as such section
15 applies to parts 1 and 2, except to the extent that such
16 section concerns section 1178(a)(2)(B) of the Social Secu-
17 rity Act.”.

18 (b) REGULATIONS.—Not later than the expiration of
19 the 90-day period beginning on the date of the enactment
20 of this Act, the Secretary of Health and Human Services
21 shall promulgate regulations to carry out the amendment
22 made by subsection (a).

23 (c) CONFORMING AMENDMENT.—Section 1171(2) of
24 the Social Security Act (42 U.S.C. 1320d(2)) is amended
25 by inserting before the period the following: “, or that car-

1 ries out such processing function and in addition any of
2 the functions authorized in section 13451 of the Health
3 Information Technology for Economic and Clinical Health
4 Act”.

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