## 115TH CONGRESS 1ST SESSION H.R. 4613

AUTHENTICATED U.S. GOVERNMENT INFORMATION

> To allow the use of claims, eligibility, and payment data to produce reports, analyses, and presentations to benefit Medicare, and other similar health insurance programs, entities, researchers, and health care providers, to help develop cost saving approaches, standards, and reference materials and to support medical care and improved payment models.

## IN THE HOUSE OF REPRESENTATIVES

DECEMBER 11, 2017

Mrs. MCMORRIS RODGERS (for herself, Mr. KELLY of Pennsylvania, Mr. HUDSON, Mrs. BLACKBURN, Mr. LONG, Mr. BISHOP of Michigan, Mr. PAULSEN, and Mr. KRISHNAMOORTHI) 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 allow the use of claims, eligibility, and payment data to produce reports, analyses, and presentations to benefit Medicare, and other similar health insurance programs, entities, researchers, and health care providers, to help develop cost saving approaches, standards, and reference materials and to support medical care and improved payment models.
  - 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 2017".

4 SEC. 2. PROMOTION OF ACCESS TO DATA, VIA RESEARCH
5 AND USER FRIENDLY PRESENTATIONS AND
6 APPLICATIONS.

7 (a) IN GENERAL.—Subtitle D of the Health Informa8 tion Technology for Economic and Clinical Health Act (42
9 U.S.C. 17921 et seq.) is amended by adding at the end
10 the following:

 PART 3—HEALTH CARE CLEARINGHOUSES;
 DATA PROCESSING TO EMPOWER PATIENTS
 AND IMPROVE THE HEALTH CARE SYSTEM
 "SEC. 13451. MODERNIZING THE ROLE OF CLEARING-HOUSES IN HEALTH CARE.

16 "(a) EFFORTS TO PROMOTE ACCESS TO AND17 LEVERAGING OF HEALTH INFORMATION.—

18 "(1) IN GENERAL.—The Secretary shall. 19 through the updating of existing policies and devel-20 opment of policies that support dynamic technology 21 solutions, promote patient access to information re-22 lated to their care, including real world outcomes 23 and economic data (including claims, eligibility, and 24 payment data), in a manner that would ensure that 25 such information is available in a form convenient

1	for the patient, in a reasonable manner, and without
2	burdening the health care provider involved.
3	"(2) Requirement.—Activities carried out
4	under paragraph (1) shall include the development
5	of policies to enable covered entities with access to
6	health information to—
7	"(A) provide patient access to information
8	related to their care, including real world out-
9	comes and economic data;
10	"(B) develop, in accordance with HIPAA-
11	related provisions (as defined in subsection $(j)$ ),
12	patient engagement tools, reports, analyses, and
13	presentations based on population health, epide-
14	miological, and health services outcomes data,
15	that may demonstrate a fiscal or treatment ben-
16	efit to patients and health plan enrollees; and
17	"(C) promote transparency regarding the
18	use and disclosure of health information by
19	health care clearinghouses in accordance with
20	the notice provisions of subsection (e).
21	"(b) TREATMENT AS COVERED ENTITY FOR SPECI-
22	FIED FUNCTIONS.—
23	"(1) IN GENERAL.—With respect to the use
24	and disclosure of protected health information, the
25	Secretary shall—

"(A) not consider health care clearinghouses that engage in the functions described in paragraph (3) to be business associates, includ-

paragraph (3) to be business associates, including subcontractor business associates, under HIPAA-related provisions (as defined in subsection (j)(3)) regardless of the role of such clearinghouses in collecting or receiving the information; and

9 "(B) consider such clearinghouses to be
10 covered entities under such provisions of law for
11 all purposes.

Such clearinghouses shall not be considered business
associates, or subcontractor business associates, for
translation of data into and out of standard format,
analytic, cloud computing, or any other purpose.

"(2) DATA ACCURACY AND SECURITY REQUIRE-16 17 MENT.—In order to use health data as authorized by 18 this section, a clearinghouse or other covered entity 19 engaging in activities authorized under this section 20 shall be certified to have the necessary expertise and 21 technical infrastructure to ensure the accuracy and 22 security of such claims, eligibility, and payment data 23 through receipt of an accreditation by the Electronic Healthcare Network Accreditation Commission, or 24

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1	by an equivalent accreditation program determined
2	appropriate by the Secretary.
3	"(3) Enhancing treatment, quality im-
4	PROVEMENT, RESEARCH, PUBLIC HEALTH EFFORTS
5	AND OTHER FUNCTIONS.—
6	"(A) Equivalent authority to other
7	COVERED ENTITIES.—Subject to paragraph (2),
8	a health care clearinghouse shall—
9	"(i) in addition to carrying out claims
10	processing functions, be permitted to use
11	and disclose protected health information
12	without obtaining individual authorization
13	to the same extent as other covered enti-
14	ties, including for purposes of treatment,
15	payment, health care operations as per-
16	mitted by section 164.506 of title 45, Code
17	of Federal Regulations, research, and pub-
18	lic health as permitted by section $164.512$
19	of title 45, Code of Federal Regulations,
20	and creating de-identified information as
21	permitted by section $164.502(d)$ of title
22	45, Code of Federal Regulations; and
23	"(ii) use or disclose protected health
24	information as required by section

1	164.502(a)(2) of title 45, Code of Federal
2	Regulations.
3	"(B) Additional Authority.—
4	"(i) A health care clearinghouse shall
5	be permitted to provide an individual or
6	the personal representative of such indi-
7	vidual access to the protected health infor-
8	mation of such individual as described in
9	subsection (d).
10	"(ii) All covered entities, including a
11	health care clearinghouse, shall, subject to
12	subsection (c)(2), be permitted to—
13	"(I) on behalf of covered entities,
14	use and disclose protected health in-
15	formation for health care operations
16	purposes (as defined by section
17	164.501 of title 45, Code of Federal
18	Regulations) without respect to
19	whether the recipient of the informa-
20	tion has or had a relationship with the
21	individual;
22	"(II) upon the request of a cov-
23	ered entity, benchmark (as defined by
24	the Secretary pursuant to rulemaking)
25	the operations of such covered entity

1	against the operations of one or more
2	other covered entities that have elect-
3	ed to participate in such benchmark-
4	ing; and
5	"(III) use and disclose protected
6	health information to facilitate clinical
7	trial recruitment, except that in the
8	case the covered entity provides a con-
9	sumer-facing portal or website that in-
10	forms individuals of clinical trials con-
11	ducted by the covered entity, the cov-
12	ered entity shall secure opt-in consent
13	from the individual, or the individual's
14	personal representative, prior to con-
15	tacting an individual regarding such
16	clinical trials unless such covered enti-
17	ty already has a relationship with the
18	individual.
19	"(C) CLARIFICATION.—Nothing in this
20	paragraph shall expand the authority of a
21	health care clearinghouse or any other covered
22	entity to use or disclose protected health infor-
23	mation for marketing purposes under sections
24	164.501 and 164.508(a)(3) of title 45, Code of
25	Federal Regulations.

1 "(c) Authorities Relating to Data Proc-2 essing.—

3 "(1) IN GENERAL.—In carrying out HIPAA-re-4 lated provisions, the Secretary shall permit a health 5 care clearinghouse to aggregate protected health in-6 formation, within the clearinghouse and among other 7 clearinghouses, that the clearinghouse possesses in 8 order to carry out the functions described in sub-9 section (b)(3). Subject to section 164.502(a)(5)(i) of 10 title 45, Code of Federal Regulations, a health care 11 clearinghouse may carry out the functions described 12 in subsection (b)(3) without obtaining individual au-13 thorization under section 164.508 of title 45, Code 14 of Federal Regulations.

15 "(2) PRIVACY.—For purposes of clauses (ii)
16 through (iv) of subsection (b)(3)(B), with respect to
17 any report, analysis, or presentation provided by the
18 covered entity to a third party, such report, analysis,
19 or presentation—

20 "(A) shall include only de-identified data;
21 or

22 "(B) shall include, subject to a qualifying
23 data use agreement (as defined in subsection
24 (j)), protected health information.

25 "(3) CLARIFICATION; FEE PERMITTED.—

1	"(A) IN GENERAL.—Nothing in this para-
2	graph shall be construed as affecting an individ-
3	ual's right to access claims and payment
4	records in HIPAA standard format, in accord-
5	ance with section 164.524 of title 45, Code of
6	Federal Regulations.
7	"(B) FEE PERMITTED.—If an individual
8	or a personal representative of the individual
9	requests a copy of records in HIPAA standard
10	format a health care clearinghouse may charge
11	a reasonable, cost-based fee so far as such fee
12	is in accordance with section $164.524(c)(4)$ of
13	title 45, Code of Federal Regulations.
14	"(d) Comprehensive Records at the Request
15	of an Individual.—
16	"(1) IN GENERAL.—When a health care clear-
17	inghouse receives a written request from an indi-
18	vidual or the personal representative of the indi-
19	vidual for the protected health information of the in-
20	dividual, the clearinghouse shall provide to the indi-
21	vidual a comprehensive record of such information
22	(across health care providers and health plans and
23	longitudinal in scope), unless the clearinghouse de-
24	termines in its sole discretion that providing a com-
25	prehensive record is not technologically feasible.

(2)PURCHASE 1 FROM OTHER CLEARING-2 HOUSES.—In preparing a comprehensive record for 3 an individual under paragraph (1), a health care 4 clearinghouse may, with the permission of the indi-5 vidual, purchase the protected health information of 6 the individual from one or more other health clear-7 inghouses (and the amount of such purchase may be 8 included in a fee that is fair market value, as de-9 fined in subsection (j)(2), charged to the individual. 10 "(e) SITUATIONS NOT INVOLVING DIRECT INTER-ACTION WITH INDIVIDUALS.—Sections 164.400 through 11 12 164.414 (relating to breach notification) and sections 13 164.520 through 164.528 (relating to individual rights) of title 45, Code of Federal Regulations, shall apply to 14 15 a health care clearinghouse that engages in the functions described in subsection (b)(3) to the extent that such 16 17 clearinghouse has current contact information pursuant to 18 direct interaction with the individual involved. If the clearinghouse does not have direct interaction with the indi-19 20 vidual involved, the clearinghouse shall provide notice of 21 any breach of unsecured protected health information to 22 the covered entity that does have direct interaction with 23 the individual involved. The clearinghouse shall not be re-24 quired to report a breach if the protected health information is rendered unusable, unreadable, or indecipherable 25

to unauthorized persons through the use of a technology
 or methodology specified by the Secretary in the guidance
 issued under section 13402(h)(2). The clearinghouse shall
 also provide a notice of privacy practices on its website.
 "(f) TRANSITION.—

6 "(1) IN GENERAL.—Except where specifically 7 stated, nothing in this section shall be construed to 8 apply to clearinghouses to the exclusion of other cov-9 ered entities or to provide a health care clearing-10 house greater authority to use and disclose protected 11 health information than that provided to another 12 covered entity.

"(2) EXISTING AGREEMENTS.—With respect to 13 14 agreements entered into by a health care clearinghouse prior to the date of enactment of this section, 15 16 a provision of such an agreement that conflicts with 17 this section shall not have any legal force or effect. 18 The preceding sentence may not be construed as af-19 fecting any provision of an agreement that does not 20 conflict with this section.

21 "(g) SAFE HARBOR AND CLARIFICATION OF LIABIL22 ITY.—In the case of a health care clearinghouse that en23 gages in a function described in subsection (b), only that
24 clearinghouse may be held liable for a violation of a
25 HIPAA-related provision (and a covered entity that pro-

vided data or data access to the clearinghouse shall not
 be liable for such violations).

3 "(h) ENFORCEMENT.—Section 13410(a)(2) shall
4 apply to this section in the same manner as such section
5 applies to parts 1 and 2.

6 "(i) Relation to Other Laws.—

"(1) APPLICATION OF HITECH RULE.—Section
13421 shall apply to this section in the same manner as such section applies to parts 1 and 2, except
to the extent that such section 13421 concerns section 1178(a)(2)(B) of the Social Security Act.

12 "(2) STATE LAWS REGARDING UNFAIR OR DE-13 CEPTIVE ACTS OR PRACTICES.—This part shall not 14 be construed to preempt the law of any State that 15 prohibits unfair or deceptive acts or practices or 16 limit the authority of State attorneys general to en-17 force such laws.

18 "(j) DEFINITIONS.—In this part:

19 "(1) DE-IDENTIFIED.—The term 'de-identified',
20 with respect to health information, means such in21 formation that is not individually identifiable as de22 termined in accordance with the standards under
23 section 164.514(b) of title 45, Code of Federal Reg24 ulations.

1	"(2) FAIR MARKET VALUE.—The term 'fair
2	market value' means the price that a person reason-
3	ably knowledgeable and interested in buying a given
4	product or service would pay to a person reasonably
5	knowledgeable and interested in selling the product
6	or service.
7	"(3) Health care clearinghouse.—The
8	term 'health care clearinghouse' has the meaning
9	given such term in section 1171 of the Social Secu-
10	rity Act.
11	"(4) HIPAA-RELATED PROVISION.—The term
12	'HIPAA-related provision' means the provisions of
13	each of the following:
14	"(A) This subtitle.
15	"(B) Part C of title XI of the Social Secu-
16	rity Act.
17	"(C) Regulations promulgated pursuant to
18	sections 262(a) and 264(c) of the Health Insur-
19	ance Portability and Accountability Act of 1996
20	or this subtitle.
21	"(5) INDIVIDUAL.—The term 'individual', with
22	respect to protected health information, has the
23	meaning applicable under section 160.103 of title
24	45, Code of Federal Regulations.

1	"(6) QUALIFYING DATA USE AGREEMENT.—The
2	term 'qualifying data use agreement' means an
3	agreement, which may be electronic, that—
4	"(A) establishes the permitted uses and
5	disclosures of protected health information by
6	the recipient;
7	"(B) limits such uses and disclosures to
8	the original purpose of disclosure under sub-
9	section $(b)(3)(B)$ ; and
10	"(C) provides that the data recipient will—
11	"(i) not use or further disclose the in-
12	formation other than as permitted by the
13	qualifying data use agreement or as other-
14	wise required by law;
15	"(ii) use appropriate safeguards to
16	prevent use or disclosure of the informa-
17	tion other than as provided for by the
18	qualifying data use agreement; and
19	"(iii) ensure that any agents to whom
20	it provides the data agree to the same re-
21	strictions and conditions that apply to the
22	data recipient with respect to such infor-
23	mation.".
24	(b) REGULATIONS.—Not later than 180 days after
25	the date of the enactment of this Act, the Secretary of

Health and Human Services shall promulgate regulations
 to carry out the amendment made by subsection (a).

3 (c) CONFORMING AMENDMENT.—Section 1171(2) of 4 the Social Security Act (42 U.S.C. 1320d(2)) is amended by inserting before the period the following: "or receives 5 6 a standard transaction from another entity and processes 7 or facilitates the processing of health information into 8 nonstandard format or nonstandard data content for the 9 receiving entity. Such term also includes an entity that 10 carries out such processing functions, transmits standard health care claims, transmits health care claim payments 11 12 or provides advice on such, and transmits any standard 13 transactions on behalf of a HIPAA-covered entity and in 14 addition, engages in any authority of such entity described 15 in subsection (b)(3) of section 13451 of the Health Information Technology for Economic and Clinical Health 16 17 Act".