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2D SESSION

S. 3530

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 SENATE OF THE UNITED STATES

DECEMBER 8, 2016

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

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,*

3 **SECTION 1. SHORT TITLE.**

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

1 **SEC. 2. PROMOTION OF ACCESS TO DATA, VIA RESEARCH**
2 **AND USER FRIENDLY PRESENTATIONS AND**
3 **APPLICATIONS.**

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

8 **“PART 3—HEALTH CARE CLEARINGHOUSES;**
9 **DATA PROCESSING TO EMPOWER PATIENTS**
10 **AND IMPROVE THE HEALTH CARE SYSTEM**
11 **“SEC. 13451. MODERNIZING THE ROLE OF CLEARING-**
12 **HOUSES IN HEALTH CARE.**

13 “(a) EFFORTS TO PROMOTE ACCESS TO AND
14 LEVERAGING OF HEALTH INFORMATION.—

15 “(1) IN GENERAL.—The Secretary shall,
16 through the updating of existing policies and devel-
17 opment of policies that support dynamic technology
18 solutions, promote patient access to information re-
19 lated to their care, including real world outcomes
20 and economic data (including claims, eligibility, and
21 payment data), in a manner that would ensure that
22 such information is available in a form convenient
23 for the patient, in a reasonable manner, and without
24 burdening the health care provider involved.

25 “(2) REQUIREMENT.—Activities carried out
26 under paragraph (1) shall include the development

1 of policies to enable covered entities with access to
 2 health information to—

3 “(A) provide patient access to information
 4 related to their care, including real world out-
 5 comes and economic data; and

6 “(B) develop patient engagement tools, re-
 7 ports, analyses, and presentations based on
 8 population health, epidemiological, and health
 9 services outcomes data, that may demonstrate a
 10 fiscal or treatment benefit to the taxpayer.

11 “(b) TREATMENT AS COVERED ENTITY FOR SPECI-
 12 FIED FUNCTIONS.—

13 “(1) IN GENERAL.—With respect to the use
 14 and disclosure of protected health information, the
 15 Secretary shall—

16 “(A) not consider health care clearing-
 17 houses that engage in the functions described in
 18 paragraph (3) to be business associates under
 19 HIPAA-related provisions (as defined in sub-
 20 section (j)(3)) regardless of the role of such
 21 clearinghouses in collecting or receiving the in-
 22 formation; and

23 “(B) consider such clearinghouses to be
 24 covered entities under such provisions of law for
 25 all purposes.

1 Such clearinghouses shall not be considered business
2 associates for data translation, analytic, cloud com-
3 puting, or any other purpose.

4 “(2) DATA ACCURACY AND SECURITY REQUIRE-
5 MENT.—In order to use health data as authorized by
6 this section, a clearinghouse or other covered entity
7 engaging in activities authorized under this section
8 shall be certified to have the necessary expertise and
9 technical infrastructure to ensure the accuracy and
10 security of such claims, eligibility, and payment data
11 through receipt of an accreditation by the Electronic
12 Healthcare Network Accreditation Commission, or
13 by an equivalent accreditation program determined
14 appropriate by the Secretary.

15 “(3) ENHANCING TREATMENT, QUALITY IM-
16 PROVEMENT, RESEARCH, PUBLIC HEALTH EFFORTS
17 AND OTHER FUNCTIONS.—

18 “(A) EQUIVALENT AUTHORITY TO OTHER
19 COVERED ENTITIES.—Subject to paragraph (2),
20 a health care clearinghouse shall—

21 “(i) in addition to carrying out claims
22 processing functions, be permitted to use
23 and disclose protected health information
24 in the same manner as other covered enti-
25 ties, including for purposes of treatment,

1 payment, health care operations as per-
2 mitted by section 164.506 of title 45, Code
3 of Federal Regulations, research, and pub-
4 lic health as permitted by section 164.512
5 of title 45, Code of Federal Regulations,
6 and creating de-identified information as
7 permitted by section 164.502(d) of title
8 45, Code of Federal Regulations; and

9 “(ii) use or disclose protected health
10 information as required by section
11 164.502(a)(2) of title 45, Code of Federal
12 Regulations.

13 “(B) ADDITIONAL AUTHORITY.—Subject
14 to paragraph (2), a health care clearinghouse
15 and other covered entity shall, in addition to
16 claims processing functions, be permitted to—

17 “(i) provide individuals with access to
18 their own protected health information as
19 described in subsection (d);

20 “(ii) subject to subsection (c)(2), and
21 on behalf of both covered entities and non-
22 covered entities, use and disclose protected
23 health information for health care oper-
24 ations purposes (as defined by section
25 164.501 of title 45, Code of Federal Regu-

lations) without respect to whether the recipient of the information has or had a relationship with the individual;

“(iii) subject to subsection (c)(2), and upon the request of a covered entity, benchmark the operations of such covered entity against the operations of one or more other covered entities that have elected to participate in such benchmarking; and

“(iv) subject to subsection (c)(2), use protected health information to facilitate clinical trial recruitment.

“(c) AUTHORITIES RELATING TO DATA PROCESSING.—

“(1) IN GENERAL.—In carrying out HIPAA-related provisions, the Secretary shall permit a health care clearinghouse to aggregate protected health information that the clearinghouse possesses in order to carry out the functions described in subsection (b)(3). Subject to section 164.502(a)(5)(i) of title 45, Code of Federal Regulations, a health care clearinghouse may carry out the functions described in subsection (b)(3) without obtaining individual au-

1 thorization under section 164.508 of title 45, Code
2 of Federal Regulations.

3 “(2) PRIVACY.—For purposes of clauses (ii)
4 through (iv) of subsection (b)(3)(B), with respect to
5 any report, analysis, or presentation provided by the
6 clearinghouse to a third party, such report, analysis,
7 or presentation—

8 “(A) shall include only de-identified data;
9 or

10 “(B) if containing protected health infor-
11 mation, shall include such data that is subject
12 to a qualifying data use agreement (as defined
13 in subsection (j)).

14 “(3) FEE PERMITTED.—Nothing in this para-
15 graph shall be construed to prohibit an individual’s
16 right to access claims and payment records in
17 HIPAA standard format for a reasonable, cost-based
18 fee pursuant to section 164.524(c)(4) of title 45,
19 Code of Federal Regulations. In requesting access to
20 records held by a health care clearinghouse, the indi-
21 vidual shall identify the health care provider or pro-
22 viders that rendered care.

23 “(d) COMPREHENSIVE RECORDS AT THE REQUEST
24 OF AN INDIVIDUAL.—

1 “(1) IN GENERAL.—When a health care clear-
 2 inghouse receives a written request from an indi-
 3 vidual for the protected health information of the in-
 4 dividual, the clearinghouse shall provide to the indi-
 5 vidual a comprehensive record of such information
 6 (across health care providers and health plans and
 7 longitudinal in scope), unless the clearinghouse de-
 8 termines in its sole discretion that providing a com-
 9 prehensive record is not technologically feasible.

10 “(2) PURCHASE FROM OTHER CLEARING-
 11 HOUSES.—In preparing a comprehensive record for
 12 an individual under paragraph (1), a health care
 13 clearinghouse may, with the permission of the indi-
 14 vidual, purchase the protected health information of
 15 the individual from one or more other health clear-
 16 inghouses (and the cost of such purchase may be in-
 17 cluded in a fair-market fee charged to the individual
 18 as provided for under paragraph (1)).

19 “(e) SITUATIONS NOT INVOLVING DIRECT INTER-
 20 ACTION WITH INDIVIDUALS.—Sections 164.400 through
 21 164.414 (relating to breach notification) and sections
 22 164.520 through 164.528 (relating to individual rights)
 23 of title 45, Code of Federal Regulations, shall apply to
 24 a health care clearinghouse that engages in the functions
 25 described in subsection (b)(3) to the extent that such

1 clearinghouse has current contact information pursuant to
 2 direct interaction with the individual involved. In the case
 3 of each other individual, the clearinghouse shall provide
 4 notice to the covered entity of any breach of unsecured
 5 protected health information and provide a notice of pri-
 6 vacy practices on its website.

7 “(f) TRANSITION.—

8 “(1) IN GENERAL.—Nothing in this section
 9 shall be construed 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.

13 “(2) EXISTING AGREEMENTS.—With respect to
 14 agreements entered into by a health care clearing-
 15 house prior to the date of enactment of this section,
 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 LIABIL-
 22 ITY.—In the case of a health care clearinghouse that en-
 23 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-

1 vided data or data access to the clearinghouse shall not
2 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.—

7 “(1) APPLICATION OF HITECH RULE.—Section
8 13421 shall apply to this section in the same man-
9 ner as such section applies to parts 1 and 2, except
10 to the extent that such section 13421 concerns sec-
11 tion 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.

16 “(j) DEFINITIONS.—In this part:

17 “(1) DE-IDENTIFIED.—The term ‘de-identified’,
18 with respect to health information, means such in-
19 formation that is not individually identifiable as de-
20 termined in accordance with the standards under
21 section 164.514(b) of title 45, Code of Federal Reg-
22 ulations.

23 “(2) HEALTH CARE CLEARINGHOUSE.—The
24 term ‘health care clearinghouse’ has the meaning

1 given such term in section 1171 of the Social Secu-
2 rity Act.

3 “(3) HIPAA-RELATED PROVISION.—The term
4 ‘HIPAA-related provision’ means the provisions of
5 each of the following:

6 “(A) This subtitle.

7 “(B) Part C of title XI of the Social Secu-
8 rity Act.

9 “(C) Regulations promulgated pursuant to
10 sections 262(a) and 264(c) of the Health Insur-
11 ance Portability and Accountability Act of 1996
12 or this subtitle.

13 “(4) INDIVIDUAL.—The term ‘individual’, with
14 respect to protected health information, has the
15 meaning applicable under section 160.103 of title
16 45, Code of Federal Regulations.

17 “(5) QUALIFYING DATA USE AGREEMENT.—The
18 term ‘qualifying data use agreement’ means an
19 agreement, which may be electronic, that establishes
20 the permitted uses and disclosures of protected
21 health information by the recipient consistent with
22 this paragraph. A qualifying data use agreement be-
23 tween the health care clearinghouse and the data re-
24 cipient shall—

1 “(A) establish the permitted uses and dis-
2 closures of such information by the recipient
3 which shall be limited to the original purpose of
4 disclosure under subsection (b)(3)(B); and

5 “(B) provide that the data recipient will—

6 “(i) not use or further disclose the in-
7 formation other than as permitted by the
8 qualifying data use agreement or as other-
9 wise required by law;

10 “(ii) use appropriate safeguards to
11 prevent use or disclosure of the informa-
12 tion other than as provided for by the
13 qualifying data use agreement; and

14 “(iii) ensure that any agents to whom
15 it provides the data agree to the same re-
16 strictions and conditions that apply to the
17 data recipient with respect to such infor-
18 mation.”.

19 (b) REGULATIONS.—Not later than 30 days after the
20 date of the enactment of this Act, the Secretary of Health
21 and Human Services shall promulgate regulations to carry
22 out the amendment 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 receives

1 a standard transaction from another entity and processes
2 or facilitates the processing of health information into
3 nonstandard format or nonstandard data content for the
4 receiving entity. Such term also includes an entity that
5 carries out such processing functions, processes standard
6 health care claims, processes health care claim payments
7 or provides advice on such, and processes eligibility claims
8 relating to health plan transactions on behalf of a HIPAA
9 covered entity and in addition, engages in any of the func-
10 tions described in subsection (a) of section 13451 of the
11 Health Information Technology for Economic and Clinical
12 Health Act”.

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