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S. 2511

To improve Federal requirements relating to the development and use of electronic health records technology.

IN THE SENATE OF THE UNITED STATES

FEBRUARY 8, 2016

Mr. ALEXANDER (for himself, Mrs. MURRAY, Mr. CASSIDY, Mr. WHITEHOUSE, Mr. HATCH, and Mr. BENNET) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

APRIL 5, 2016

Reported by Mr. ALEXANDER, with an amendment

[Strike out all after the enacting clause and insert the part printed in italic]

A BILL

To improve Federal requirements relating to the development and use of electronic health records technology.

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 “Improving Health In-
5 formation Technology Act”.

1 **SEC. 2. ASSISTING DOCTORS AND HOSPITALS IN IMPROV-**
 2 **ING THE QUALITY OF CARE FOR PATIENTS.**

3 (a) IN GENERAL.—Part 1 of subtitle A of title XIII
 4 of the Health Information Technology for Economic and
 5 Clinical Health Act (Public Law 111–5) is amended by
 6 adding at the end the following:

7 **“SEC. 13103. ASSISTING DOCTORS AND HOSPITALS IN IM-**
 8 **PROVING THE QUALITY OF CARE FOR PA-**
 9 **TIENTS.**

10 **“(a) REDUCTION IN BURDENS GOAL.—**The Sec-
 11 retary of Health and Human Services (referred to in this
 12 section as the ‘Secretary’), in consultation with providers
 13 of health services, health care suppliers of services, health
 14 care payers, health professional societies, health informa-
 15 tion technology developers, health care quality organiza-
 16 tions, health care accreditation organizations, public
 17 health entities, States, and other appropriate entities,
 18 shall, in accordance with subsection (b)—

19 **“(1)** establish a goal with respect to the redu-
 20 tion of regulatory or administrative burdens (such as
 21 documentation requirements) relating to the use of
 22 electronic health records;

23 **“(2)** develop a strategy for meeting the goal es-
 24 tablished under paragraph (1); and

25 **“(3)** develop recommendations for meeting the
 26 goal established under paragraph (1).

1 “(b) STRATEGY AND RECOMMENDATIONS.—

2 “(1) IN GENERAL.—To achieve the goals estab-
3 lished under subsection (a)(1), the Secretary, in con-
4 sultation with the entities described in such sub-
5 section, shall, not later than 12 months after the
6 date of enactment of this section, develop a strategy
7 and recommendations to meet the goals in accord-
8 ance with this subsection.

9 “(2) STRATEGY.—The strategy developed under
10 paragraph (1) shall address the regulatory and ad-
11 ministration burdens (such as documentation re-
12 quirements) relating to the use of electronic health
13 records. Such strategy shall include broad public
14 comment and shall prioritize burdens related to—

15 “(A) the Medicare and Medicaid EHR
16 Meaningful Use Incentive programs or the
17 Merit-based Incentive Payment System, the Al-
18 ternative Payment Models, the Hospital Value-
19 Based Purchasing Program, and other value-
20 based payment programs determined appro-
21 priate by the Secretary;

22 “(B) health information technology certifi-
23 cation programs;

24 “(C) standards, and implementation speci-
25 fications, as appropriate;

1 “(D) activities that provide individuals ac-
2 cess to their electronic health information;

3 “(E) activities related to protecting the
4 privacy of electronic health information;

5 “(F) activities related to protecting the se-
6 curity of electronic health information;

7 “(G) activities related to facilitating health
8 and clinical research;

9 “(H) activities related to public health;

10 “(I) activities related to aligning and sim-
11 plifying quality measures across Federal pro-
12 grams and other payers;

13 “(J) activities related to reporting clinical
14 data for administrative purposes; and

15 “(K) other areas determined appropriate
16 by the Secretary.

17 “(3) RECOMMENDATIONS.—The recommenda-
18 tions developed under paragraph (1) shall address—

19 “(A) actions that improve the clinical doc-
20 umentation experience;

21 “(B) actions that improve patient care;

22 “(C) actions to be taken by the Secretary
23 and by other entities; and

1 “(D) other areas determined appropriate
2 by the Secretary to reduce the reporting burden
3 required of health care providers.

4 “(4) FACA.—The Federal Advisory Committee
5 Act (5 U.S.C. App.) shall not apply to the develop-
6 ment of the goal, strategies, or recommendations de-
7 scribed in this section.

8 “(e) APPLICATION OF CERTAIN REGULATORY RE-
9 QUIREMENTS.—A physician (as defined in section
10 1861(r)(1) of the Social Security Act) may delegate elec-
11 tronic medical record documentation requirements speci-
12 fied in regulations promulgated by the Department of
13 Health and Human Services to a person who is not such
14 physician if such physician has signed and verified the
15 documentation.”.

16 (b) CERTIFICATION OF HEALTH INFORMATION
17 TECHNOLOGY FOR MEDICAL SPECIALTIES AND SITES OF
18 SERVICE.—Section 3001(e)(5) of the Public Health Serv-
19 ice Act (42 U.S.C. 300jj-11(e)(5)) is amended by adding
20 at the end the following:

21 “(C) HEALTH INFORMATION TECHNOLOGY
22 FOR MEDICAL SPECIALTIES AND SITES OF
23 SERVICE.—

24 “(i) IN GENERAL.—The National Co-
25 ordinator shall encourage, keep, or recog-

1 nize, through existing authorities, the vol-
2 untary certification of health information
3 technology under the program developed
4 under subparagraph (A) for use in medical
5 specialties and sites of service for which no
6 such technology is available or where more
7 technological advancement or integration is
8 needed.

9 “(ii) SPECIFIC MEDICAL SPECIAL-
10 TIES.—The HIT Policy and Standards
11 Committees shall make recommendations
12 on specific medical specialties and sites of
13 service, in addition to those described in
14 clause (iii), applicable under this para-
15 graph.

16 “(iii) CERTIFIED HEALTH INFORMA-
17 TION TECHNOLOGY FOR PEDIATRICS.—Not
18 later than 18 months after the date of en-
19 actment of this subparagraph, the HIT
20 Policy and Standards Committees, in con-
21 sultation with relevant stakeholders, shall
22 make recommendations for the voluntary
23 certification of health information tech-
24 nology for use by pediatric health providers
25 to support the health care of children. Not

1 later than 24 months after the date of en-
2 actment of this subparagraph, the Sec-
3 retary shall adopt certification criteria
4 (under section 3004) to support the vol-
5 untary certification of health information
6 technology for use by pediatric health pro-
7 viders to support the health care of chil-
8 dren.”.

9 (c) MEANINGFUL USE STATISTICS.—

10 (1) IN GENERAL.—Not later than 6 months
11 after the date of enactment of this Act, the Sec-
12 retary of Health and Human Services shall submit
13 to the HIT Policy Committee of the Office of the
14 National Coordinator for Health Information Tech-
15 nology, a report concerning attestation statistics for
16 the Medicare and Medicaid EHR Meaningful Use
17 Incentive programs to assist in informing standards
18 adoption and related practices. Such statistics shall
19 include attestation information delineated by State,
20 including the number of providers who did not meet
21 the minimum criteria necessary to attest for the
22 Medicare and Medicaid EHR Meaningful Use Incen-
23 tive programs for a calendar year, and shall be made
24 publicly available on the Internet website of the Sec-
25 retary on at least a quarterly basis.

1 (2) **AUTHORITY TO ALTER FORMAT.**—The Sec-
 2 retary of Health and Human Services may alter the
 3 format of the reports on the attestation of eligible
 4 health care professionals following the first perform-
 5 ance year of the Merit-based Incentive Payment Sys-
 6 tem to account for changes arising from the imple-
 7 mentation of such payment system.

8 **SEC. 3. TRANSPARENT RATINGS ON USABILITY AND SECU-**
 9 **RITY TO TRANSFORM INFORMATION TECH-**
 10 **NOLOGY.**

11 (a) **ENHANCEMENTS TO CERTIFICATION.**—Section
 12 3001(e)(5) of the Public Health Service Act (42 U.S.C.
 13 300jj–11), as amended by section 2(b), is further amend-
 14 ed—

15 (1) in subparagraph (A)—

16 (A) by striking “The National Coordi-
 17 nator” and inserting the following:

18 “(i) **VOLUNTARY CERTIFICATION PRO-**
 19 **GRAM.**—The National Coordinator” and

20 (B) by adding at the end the following:

21 “(ii) **TRANSPARENCY OF PROGRAM.**—

22 “(I) **IN GENERAL.**—To enhance
 23 transparency in the compliance of
 24 health information technology with
 25 certification criteria and other re-

1 requirements adopted under this sub-
 2 title, the National Coordinator, in co-
 3 ordination with authorized certifi-
 4 cation bodies, may make information
 5 demonstrating how health information
 6 technology meets such certification
 7 criteria or other requirements publicly
 8 available. Such information may in-
 9 clude summaries, screenshots, video
 10 demonstrations, or any other informa-
 11 tion the National Coordinator deter-
 12 mines appropriate.

13 “(H) PROTECTION OF PROPRI-
 14 ETARY INFORMATION.—The National
 15 Coordinator shall take appropriate
 16 measures to ensure that there are in
 17 effect effective procedures to prevent
 18 the unauthorized disclosure of any
 19 trade secret or confidential informa-
 20 tion that is obtained by the Secretary
 21 pursuant to this section.”;

22 (2) in subparagraph (B), by adding at the end
 23 the following: “Beginning 18 months after reporting
 24 criteria are finalized under section 3009A, certifi-
 25 cation criteria shall include, in addition to criteria to

1 establish that the technology meets such standards
 2 and implementation specifications, criteria consistent
 3 with section 3009A(b) to establish that technology
 4 meets applicable security requirements, incorporates
 5 user-centered design, and achieves interoperability.”;
 6 and

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

8 “(D) CONDITIONS OF CERTIFICATION.—

9 Beginning 1 year after the date of enactment of
 10 the Improving Health Information Technology
 11 Act, the Secretary shall require, as a condition
 12 of certification and maintenance of certification
 13 for programs maintained or recognized under
 14 this paragraph, that—

15 “(i) the health information technology
 16 developer or entity does not take any ac-
 17 tion that constitutes information blocking
 18 with respect to health information tech-
 19 nology;

20 “(ii) the health information tech-
 21 nology developer or entity permits
 22 unimpeded communication among and be-
 23 tween health information technology users,
 24 and for the purposes of health information
 25 technology users communicating with an

1 authorized certification body, the Office of
2 the National Coordinator, and the Office of
3 the Inspector General, the health informa-
4 tion technology developer or entity permits
5 unimpeded communication regarding the
6 usability, interoperability, security, busi-
7 ness practices, or other relevant informa-
8 tion about the health information tech-
9 nology or users' experience with the health
10 information technology;

11 “(iii) health information from such
12 technology may be exchanged, accessed,
13 and used through the use of application
14 programming interfaces or successor tech-
15 nology or standard as provided for under
16 applicable law;

17 “(iv) the health information tech-
18 nology developer or entity provides to the
19 Secretary an attestation that the developer
20 or entity—

21 “(I) has not engaged in any of
22 the conduct described in clause (i);

23 “(II) allows for communication
24 as described in clause (ii); and

1 “(III) ensures that its technology
 2 allows for health information to be ex-
 3 changed, accessed, and used, in the
 4 manner described in clause (iii); and
 5 “(v) the health information technology
 6 developer or entity submits reporting cri-
 7 teria in accordance with section
 8 3009A(f).”.

9 (b) **HEALTH INFORMATION TECHNOLOGY RATING**
 10 **PROGRAM.**—Subtitle A of title XXX of the Public Health
 11 Service Act (42 U.S.C. 300jj–11 et seq.) is amended by
 12 adding at the end the following:

13 **“SEC. 3009A. HEALTH INFORMATION TECHNOLOGY RATING**
 14 **PROGRAM.**

15 “(a) **ESTABLISHMENT.**—Not later than 180 days
 16 after the date of enactment of the Improving Health Infor-
 17 mation Technology Act, the Secretary shall recognize a de-
 18 velopment council made up of one representative from
 19 each of the certification bodies authorized by the Office
 20 of the National Coordinator and the testing laboratories
 21 accredited under section 13201(b) of the Health Informa-
 22 tion Technology for Economic and Clinical Health Act (42
 23 U.S.C. 17911(b)), one representative from the National
 24 Institute of Standards and Technology, and one represent-
 25 ative from the Office of the National Coordinator. The de-

1 velopment council shall meet as needed for the purposes
 2 of carrying out its activities in accordance with this sec-
 3 tion.

4 “(b) REPORTING CRITERIA.—

5 “(1) IN GENERAL.—The Secretary shall, using
 6 the procedures prescribed in this subsection, issue
 7 rules establishing reporting criteria for health infor-
 8 mation technology products.

9 “(2) CONVENING OF STAKEHOLDERS.—Not
 10 later than 1 year after the date of enactment of the
 11 Improving Health Information Technology Act, the
 12 Secretary, in consultation with the development
 13 council described in subsection (a), shall convene
 14 stakeholders as described in paragraph (3) for the
 15 purpose of developing the reporting criteria in ac-
 16 cordance with paragraph (4).

17 “(3) DEVELOPMENT OF REPORTING CRI-
 18 TERIA.—The reporting criteria under this subsection
 19 shall be developed through a public, transparent
 20 process that reflects input from relevant stake-
 21 holders, including—

22 “(A) health care providers, including pri-
 23 mary care and specialty care health care profes-
 24 sionals;

25 “(B) hospitals and hospital systems;

1 “(C) health information technology devel-
2 opers;

3 “(D) patients, consumers, and their advo-
4 cates;

5 “(E) data sharing networks, such as health
6 information exchanges;

7 “(F) authorized certification bodies and
8 testing laboratories;

9 “(G) security experts;

10 “(H) relevant manufacturers of medical
11 devices;

12 “(I) experts in health information tech-
13 nology market economics;

14 “(J) public and private entities engaged in
15 the evaluation of health information technology
16 performance;

17 “(K) quality organizations, including the
18 consensus based entity described in section
19 1890 of the Social Security Act;

20 “(L) experts in human factors engineering
21 and the measurement of user-centered design;
22 and

23 “(M) other entities or persons, as the Sec-
24 retary, in consultation with the development
25 council, determines appropriate.

1 “(4) CONSIDERATIONS FOR REPORTING CRI-
2 TERIA.—The reporting criteria developed under this
3 subsection—

4 “(A) shall include measures that reflect
5 categories including, with respect to the tech-
6 nology—

7 “(i) security;

8 “(ii) usability and user-centered de-
9 sign;

10 “(iii) interoperability;

11 “(iv) conformance to certification test-
12 ing; and

13 “(v) other categories as appropriate to
14 measure the performance of health infor-
15 mation technology;

16 “(B) may include measures such as—

17 “(i) enabling the user to order and
18 view the results of laboratory tests, imag-
19 ing tests, and other diagnostic tests;

20 “(ii) submitting, editing, and retriev-
21 ing data from registries such as clinician-
22 led clinical data registries;

23 “(iii) accessing and exchanging infor-
24 mation and data from and through Health
25 Information Exchanges;

1 “(iv) accessing and exchanging infor-
2 mation and data from medical devices;

3 “(v) accessing and exchanging infor-
4 mation and data held by Federal, State,
5 and local agencies and other applicable en-
6 tities useful to a health care provider or
7 other applicable user in the furtherance of
8 patient care;

9 “(vi) accessing and exchanging infor-
10 mation from other health care providers or
11 applicable users;

12 “(vii) accessing and exchanging pa-
13 tient generated information;

14 “(viii) providing the patient or an au-
15 thorized designee with a complete copy of
16 their health information from an electronic
17 record in a computable format;

18 “(ix) providing accurate patient infor-
19 mation for the correct patient, including
20 exchanging such information, and avoiding
21 the duplication of patients records; and

22 “(x) other appropriate functionalities;
23 and

24 “(C) shall be designed to ensure that small
25 and start-up health information technology de-

1 velopers are not unduly disadvantaged by the
2 reporting criteria or rating scale methodology.

3 ~~“(5) CONSIDERATION OF DEVELOPMENT COUN-~~
4 ~~CIL RECOMMENDATIONS.—~~In promulgating proposed
5 rules under this subsection, including modifications
6 to such rules under subsection (e), the Secretary
7 may accept, reject, or modify the recommendations
8 of the development council, but may not promulgate
9 a proposed rule that does not represent a complete
10 recommendation of such council.

11 ~~“(6) PUBLIC COMMENT.—~~In promulgating pro-
12 posed rules under this subsection, the Secretary
13 shall conduct a public comment period of not less
14 than 60 days during which any member of the public
15 may provide comments on the proposed reporting
16 criteria and the methodology for the rating body (de-
17 fined in subsection (g)) to use in determining the
18 star ratings.

19 ~~“(7) FINAL RULES.—~~The final rule promul-
20 gated under this subsection shall be accompanied by
21 timely responses to the public comments described in
22 paragraph (6).

23 ~~“(8) FACA.—~~The Federal Advisory Committee
24 Act (5 U.S.C. App.) shall not apply to the develop-
25 ment council described in this section.

1 “(c) FEEDBACK.—

2 “(1) IN GENERAL.—The Secretary, in consulta-
3 tion with the development council, shall establish a
4 process for the rating body (described in subsection
5 (g)) to collect and verify confidential feedback
6 from—

7 “(A) health care providers, patients, and
8 other users of certified health information tech-
9 nology on the usability, security, and interoper-
10 ability of health information technology prod-
11 ucts; and

12 “(B) developers of certified health informa-
13 tion technology on practices of health informa-
14 tion technology users that may inhibit inter-
15 operability.

16 “(2) PAPERWORK REDUCTION ACT.—The Pa-
17 perwork Reduction Act (44 U.S.C. 3501 et seq.)
18 shall not apply to the collection of feedback de-
19 scribed in this subsection.

20 “(d) METHODOLOGY.—The Secretary, in consulta-
21 tion with the development council, shall develop a method-
22 ology to be used by the rating body described in subsection
23 (g) to calculate the star ratings for certified health infor-
24 mation technology described in subsection (a). The meth-
25 odology shall use the reporting criteria developed in sub-

1 section (b); and the confidential feedback collected under
2 subsection (e). In developing such methodology, the Sec-
3 retary, in consultation with the development council,
4 shall—

5 “(1) provide for appropriate weighting of user
6 feedback submitted under subsection (e) and report-
7 ing criteria submitted under subsection (f), including
8 consideration of the number of users who submitted
9 such feedback;

10 “(2) consider the impact of customization or
11 adaptation by users of certified health information
12 technology on performance;

13 “(3) account for the intended function, scope,
14 and type of certified health information technology;

15 “(4) in consultation with the development coun-
16 cil and after seeking comment from developers of
17 health information technology in a manner that en-
18 sures appropriate industry feedback, establish a
19 timeframe, but in no case less frequent than once
20 every 3 years, for the submission of reporting cri-
21 teria under subsection (f); and

22 “(5) establish a timeframe for incorporating
23 user feedback submitted under subsection (e) and
24 reporting criteria submitted under subsection (f)
25 into the star ratings for certified health information

1 technology that accounts for updates to such tech-
2 nology in order to encourage innovation and maxi-
3 mize the utility of the star ratings.

4 “(e) MODIFICATIONS.—

5 “(1) TO THE NUMBER OF STARS IN THE RAT-
6 ING PROGRAM.—The development council may mod-
7 ify the number of star ratings employed by the sys-
8 tem, but not more frequently than every 4 years. In
9 no case shall the rating system employ fewer than
10 3 stars.

11 “(2) TO THE REPORTING CRITERIA.—After the
12 final reporting criteria have been established under
13 this section, the Secretary, in consultation with the
14 development council, may convene stakeholders and
15 conduct a public reporting period for the purpose of
16 modifying the reporting criteria developed under
17 subsection (b) and methodology for determining the
18 star ratings proposed under subsection (e).

19 “(3) TO THE METHODOLOGY.—After the final
20 methodology to be used by the rating body is estab-
21 lished under subsection (e), the Secretary, in con-
22 sultation with the development council, may modify
23 the methodology used to calculate the star ratings
24 for certified health information technology using the
25 reporting criteria developed under subsection (b) and

1 the confidential feedback collected under subsection
2 (e).

3 “(4) CONSIDERATION OF GAO REPORT.—The
4 Secretary and the development council shall take
5 into account the recommendations from the Comp-
6 troller General under subsection (k), where available,
7 for the purposes of this paragraph.

8 “(f) PARTICIPATION.—As a condition of maintaining
9 their certification under section 3001(e)(5)(D), a devel-
10 oper of certified health information technology shall report
11 on the criteria developed under subsection (b) for all such
12 certified technology offered by such developer pursuant to
13 the timeframe established under subsection (d).

14 “(g) RATING BODY.—

15 “(1) IN GENERAL.—The National Coordinator
16 shall recognize an independent entity with appro-
17 priate expertise to carry out the rating program es-
18 tablished by the development council under sub-
19 section (a) and shall redetermine such recognition at
20 least every 4 years.

21 “(2) CONSULTATION.—The entity recognized
22 under paragraph (1) may consult with organizations
23 with expertise in the measurement of interoper-
24 ability, usability, and security of health information

1 technology in carrying out activities under this sec-
2 tion.

3 “(h) ONE STAR RATING.—Each health information
4 technology developer, or entity offering health information
5 technology for certification, that receives a 1 star rating
6 shall take action, through an improvement plan developed
7 with the rating body and approved by the Secretary, to
8 improve the health information technology rating within
9 a timeframe that the Secretary determines appropriate.

10 “(i) DECERTIFICATION.—

11 “(1) MANDATORY.—The Secretary shall decer-
12 tify health information technology if the developer or
13 entity offering health information technology does
14 not submit reporting criteria in accordance with sub-
15 section (f) within 90 days of the timeline established
16 under subsection (d).

17 “(2) OTHER DECERTIFICATION.—The Secretary
18 may decertify health information technology if—

19 “(A) the health information technology
20 does not improve from a one star rating within
21 the timeframe established under subsection (h);

22 or

23 “(B) in other circumstances, as the Sec-
24 retary determines appropriate.

1 “(j) GAO REPORTS.—During the 12-year period be-
2 ginning on the date of enactment of the Improving Health
3 Information Technology Act, the Comptroller General of
4 the United States shall submit to Congress a report every
5 4 years on the rating scale methodology developed pursu-
6 ant to subsection (d), providing observations on the appro-
7 priateness of the current methodology and recommenda-
8 tions for changes to the methodology. The Development
9 Council shall recommend to Congress and the Secretary
10 if additional reports are needed after the expiration of
11 such 12-year period.

12 “(k) INTERNET WEBSITE.—On the Internet website
13 of the Office of the National Coordinator, the Secretary
14 shall publish the criteria and methodology used to deter-
15 mine the star ratings, and, for each certified health infor-
16 mation technology, the final star rating, and a report out-
17 lining such technology’s performance with regard to the
18 reporting criteria developed under subsection (b), and if
19 an improvement plan has been administered. Following
20 the reporting described in subsection (f), the rating body
21 shall have 30 days to calculate and submit updated ratings
22 to the Secretary and each developer of health information
23 technology, and updated ratings shall be published on such
24 Internet website not later than 30 days following such sub-
25 mission, notwithstanding an appeal of a rating by a devel-

1 oper or entity through the process developed under sub-
 2 section (m).

3 “(l) **HARDSHIP EXEMPTION.**—Decertification of an
 4 adopted health information technology product under sub-
 5 section (i) shall be considered a significant hardship re-
 6 sulting in a blanket exemption from the payment adjust-
 7 ment pursuant to section 1848(a)(7)(B) of the Social Se-
 8 curity Act for eligible professionals, section
 9 1886(b)(3)(ix)(II) of such Act for eligible hospitals, and
 10 1814(l)(4)(C) of such Act for critical access hospitals.

11 “(m) **NOTIFICATION AND APPEALS.**—The Secretary
 12 shall establish a process whereby any health information
 13 technology developer, or entity offering health information
 14 technology, is notified not less than 30 days before being
 15 made public and can appeal—

16 “(1) the health information technology prod-
 17 uct’s star rating; or

18 “(2) the Secretary’s decision to decertify a
 19 product, as applicable.”.

20 **SEC. 4. INFORMATION BLOCKING.**

21 Subtitle C of title ~~XXX~~ of the Public Health Service
 22 Act (42 U.S.C. 300jj–51 et seq.) is amended by adding
 23 at the end the following:

24 **“SEC. 3022. INFORMATION BLOCKING.**

25 “(a) **DEFINITION.**—

1 “(1) IN GENERAL.—The term ‘information
2 blocking’ means—

3 “(A) with respect to a health information
4 technology developer, exchange, or network,
5 business, technical, or organizational practices
6 that—

7 “(i) except as required by law or spec-
8 ified by the Secretary, interferes with, pre-
9 vents, or materially discourages access, ex-
10 change, or use of electronic health informa-
11 tion; and

12 “(ii) the developer, exchange, or net-
13 work knows, or should know, are likely to
14 interfere with or prevent or materially dis-
15 courage the access, exchange, or use of
16 electronic health information; and

17 “(B) with respect to a health care pro-
18 vider, the person or entity knowingly and un-
19 reasonably restricts electronic health informa-
20 tion exchange for patient care or other prior-
21 ities as determined appropriate by the Sec-
22 retary.

23 “(2) RULEMAKING.—The Secretary shall,
24 through rulemaking—

1 “(A) identify reasonable and necessary ac-
2 tivities that do not constitute information block-
3 ing for purposes of paragraph (1)(A); and

4 “(B) identify actions that meet the defini-
5 tion of information blocking with respect to
6 health care providers for purposes of paragraph
7 (1)(B).

8 “(b) INSPECTOR GENERAL AUTHORITY.—

9 “(1) IN GENERAL.—The Inspector General of
10 the Department of Health and Human Services may
11 investigate any claim that—

12 “(A) a health information technology de-
13 veloper of, or other entity offering certified
14 health information technology—

15 “(i) submits a false attestation made
16 under section 3001(e)(5)(D); or

17 “(ii) engaged in information blocking
18 with respect to the use of such health in-
19 formation technology by a health care pro-
20 vider, unless for a legitimate purpose speci-
21 fied by the Secretary;

22 “(B) a health care provider engaged in in-
23 formation blocking with respect to access or ex-
24 change of certified health information tech-

1 nology, unless for a legitimate purpose specified
2 by the Secretary; and

3 “(C) a health information network or ex-
4 change provider engaged in information block-
5 ing with respect to the access, exchange, or use
6 of such certified health information technology,
7 unless for a legitimate purpose specified by the
8 Secretary.

9 “(2) JURISDICTION OF THE INSPECTOR GEN-
10 ERAL.—For purposes of this section, the Office of
11 the Inspector General shall have jurisdiction with re-
12 spect to exchanges and networks, as well as any de-
13 veloper or entity offering health information tech-
14 nology for certification under a program or pro-
15 grams kept or recognized by the National Coordi-
16 nator under section 3001(c)(5). The National Coordi-
17 nator shall notify developers of health information
18 technology as appropriate regarding the jurisdiction
19 of the Inspector General under this paragraph.

20 “(3) PENALTY.—

21 “(A) DEVELOPERS, NETWORKS, AND EX-
22 CHANGES.—With respect to a health informa-
23 tion technology developer, exchange, or network,
24 a person or entity determined by the Inspector
25 General to have committed information blocking

1 as described in subparagraph (A) or (C) of
2 paragraph (1) shall be subject to a civil mone-
3 tary penalty in an amount determined, through
4 notice-and-comment rulemaking, by the Sec-
5 retary which may take into account factors such
6 as the extent and duration of the information
7 blocking and the number of patients and pro-
8 viders potentially affected.

9 “(B) PROVIDERS.—With respect to health
10 care providers, any person or entity determined
11 by the Inspector General to have committed in-
12 formation blocking as described in subpara-
13 graph (B) of paragraph (1) shall be subject to
14 appropriate incentives and disincentives using
15 authorities under applicable Federal law, as de-
16 termined appropriate by the Secretary through
17 notice and comment rulemaking.

18 “(C) PROCEDURE.—The provisions of sec-
19 tion 1128A of the Social Security Act (other
20 than subsections (a) and (b)) shall apply to a
21 civil money penalty applied under this sub-
22 section in the same manner as such provisions
23 apply to a civil money penalty or proceeding
24 under section 1128A(a).

1 “(D) RECOVERY OF FUNDS.—Notwith-
2 standing section 3302 of title 31, United States
3 Code, or any other provision of law affecting
4 the crediting of collections, the Inspector Gen-
5 eral of the Department of Health and Human
6 Services may receive and retain for current use
7 any amounts recovered under subparagraphs
8 (A) and (C). In addition to amounts otherwise
9 available to the Inspector General, funds re-
10 ceived by the Inspector General under this
11 paragraph shall be deposited, as an offsetting
12 collection, to the credit of any appropriation
13 available for purposes of carrying out this sub-
14 section and shall be available without fiscal year
15 limitation and without further appropriation.

16 “(4) RESOLUTION OF CLAIMS.—

17 “(A) IN GENERAL.—The Office of the In-
18 spector General, if such Office determines that
19 a simple consultation regarding the health pri-
20 vacy and security rules promulgated under sec-
21 tion 264(e) of the Health Insurance Portability
22 and Accountability Act of 1996 (42 U.S.C.
23 1320d-2 note) will resolve the claim at issue,
24 may refer instances of information blocking to

1 the Office for Civil Rights of the Department of
2 Health and Human Services for resolution.

3 “(B) LIMITATION ON LIABILITY.—If a
4 health information technology developer makes
5 information available based on a good faith reli-
6 ance on consultations with the Office for Civil
7 Rights of the Department of Health and
8 Human Services with respect to such informa-
9 tion, the developer shall not be liable for such
10 disclosure.

11 “(c) IDENTIFYING BARRIERS TO EXCHANGE OF CER-
12 TIFIED HEALTH INFORMATION TECHNOLOGY.—

13 “(1) TRUSTED EXCHANGE DEFINED.—In this
14 section, the term ‘trusted exchange’ with respect to
15 certified health information technology means that
16 the certified health information technology has the
17 technical capability to enable secure health informa-
18 tion exchange between users and multiple certified
19 health information technology systems.

20 “(2) GUIDANCE.—The National Coordinator, in
21 consultation with the Office for Civil Rights of the
22 Department of Health and Human Services, shall
23 issue guidance on common legal, governance, and se-
24 curity barriers that prevent the trusted exchange of
25 electronic health information.

1 “(3) REFERRAL.—The National Coordinator
 2 and the Office for Civil Rights of the Department of
 3 Health and Human Services may refer to the In-
 4 spector General instances or patterns of refusal to
 5 exchange health information with an individual or
 6 entity using certified health information technology
 7 that is technically capable of trusted exchange and
 8 under conditions when exchange is legally permis-
 9 sible.

10 “(4) HIT STANDARDS COMMITTEE CONSIDER-
 11 ATION.—Not later than 1 year after the date of en-
 12 actment of the Improving Health Information Tech-
 13 nology Act, the HIT Standards Committee shall
 14 begin consideration of issues related to trusted ex-
 15 change.”.

16 **SEC. 5. INTEROPERABILITY.**

17 (a) DEFINITION.—Section 3000 of the Public Health
 18 Service Act (42 U.S.C. 300jj) is amended—

19 (1) by redesignating paragraphs (10) through
 20 (14), as paragraphs (11) through (15), respectively;
 21 and

22 (2) by inserting after paragraph (9) the fol-
 23 lowing:

24 “(10) INTEROPERABILITY.—The term ‘inter-
 25 operability’ with respect to health information tech-

1 nology means such health information technology
 2 that has the ability to securely exchange electronic
 3 health information with and use electronic health in-
 4 formation from other health information technology
 5 without special effort on the part of the user.”.

6 (b) SUPPORT FOR INTEROPERABLE NETWORK EX-
 7 CHANGE.—Section 3001(e) of the Public Health Service
 8 Act (42 U.S.C. 300jj–11(e)) is amended by adding at the
 9 end the following:

10 “(9) SUPPORT FOR INTEROPERABLE NET-
 11 WORKS EXCHANGE.—

12 “(A) IN GENERAL.—The National Coordi-
 13 nator shall, in collaboration with the National
 14 Institute of Standards and Technology and
 15 other relevant agencies within the Department
 16 of Health and Human Services, for the purpose
 17 of ensuring full network-to-network exchange of
 18 health information, convene public-private and
 19 public-public partnerships to build consensus
 20 and develop a trusted exchange framework, in-
 21 cluding a common agreement among health in-
 22 formation networks nationally. Such convention
 23 may occur at a frequency determined appro-
 24 priate by the Secretary.

1 “(B) ESTABLISHING A TRUSTED EX-
2 CHANGE FRAMEWORK.—

3 “(i) IN GENERAL.—Not later than six
4 months after the date of enactment of this
5 paragraph, the National Coordinator shall
6 convene appropriate public and private
7 stakeholders to develop a trusted exchange
8 framework for trust policies and practices
9 and for a common agreement for exchange
10 between health information networks. The
11 common agreement may include—

12 “(I) a common method for au-
13 thenticating trusted health informa-
14 tion network participants;

15 “(II) a common set of rules for
16 trusted exchange;

17 “(III) organizational and oper-
18 ational policies to enable the exchange
19 of health information among net-
20 works, including minimum conditions
21 for such exchange to occur; and

22 “(IV) a process for filing and ad-
23 judicating noncompliance with the
24 terms of the common agreement.

1 “(ii) TECHNICAL ASSISTANCE.—The
2 National Coordinator, in conjunction with
3 the National Institute of Standards and
4 Technology, shall provide technical assist-
5 ance on how to implement the trusted ex-
6 change framework and common agreement
7 under this paragraph.

8 “(iii) PILOT TESTING.—The National
9 Coordinator, in collaboration with the Na-
10 tional Institute of Standards and Tech-
11 nology, shall provide for the pilot testing of
12 the trusted exchange framework and com-
13 mon agreement established under this sub-
14 section (as authorized under section 13201
15 of the Health Information Technology for
16 Economic and Clinical Health Act). The
17 National Coordinator, in collaboration with
18 the National Institute of Standards and
19 Technology, may delegate pilot testing ac-
20 tivities under this clause to independent
21 entities with appropriate expertise.

22 “(C) PUBLICATION OF A TRUSTED EX-
23 CHANGE FRAMEWORK AND COMMON AGREE-
24 MENT.—Not later than one year after con-
25 vening stakeholders under subparagraph (A),

1 the National Coordinator shall publish on its
2 public Internet website, and in the Federal reg-
3 ister, the trusted exchange framework and com-
4 mon agreement developed under subparagraph
5 (B). Such trusted exchange framework and
6 common agreement shall be published in a man-
7 ner that protects proprietary and security infor-
8 mation, including trade secrets and any other
9 protected intellectual property.

10 “(D) DIRECTORY OF PARTICIPATING
11 HEALTH INFORMATION NETWORKS.—

12 “(i) IN GENERAL.—Not later than
13 two years after convening stakeholders
14 under subparagraph (A), and annually
15 thereafter, the National Coordinator shall
16 publish on its public Internet website a list
17 of those health information networks that
18 have adopted the common agreement and
19 are capable of trusted exchange pursuant
20 to the common agreement developed under
21 paragraph (B).

22 “(ii) PROCESS.—The Secretary shall,
23 through notice-and-comment rulemaking,
24 establish a process for health information
25 networks that voluntarily elect to adopt the

1 trusted exchange framework and common
2 agreement to attest to such adoption of the
3 framework and agreement.

4 “(E) APPLICATION OF THE TRUSTED EX-
5 CHANGE FRAMEWORK AND COMMON AGREE-
6 MENT.—As appropriate, Federal agencies con-
7 tracting or entering into agreements with health
8 information exchange networks may require
9 that as each such network upgrades health in-
10 formation technology or trust and operational
11 practices, it may adopt, where available, the
12 trusted exchange framework and common
13 agreement published under subparagraph (C).

14 “(F) RULE OF CONSTRUCTION.—

15 “(i) GENERAL ADOPTION.—Nothing
16 in this paragraph shall be construed to re-
17 quire a health information network to
18 adopt the trusted exchange framework or
19 common agreement.

20 “(ii) ADOPTION WHEN EXCHANGE OF
21 INFORMATION IS WITHIN NETWORK.—
22 Nothing in this paragraph shall be con-
23 strued to require a health information net-
24 work to adopt the trusted exchange frame-
25 work or common agreement for the ex-

1 change of electronic health information be-
2 tween participants of the same network.

3 “(iii) EXISTING FRAMEWORKS AND
4 AGREEMENTS.—The trusted exchange
5 framework and common agreement pub-
6 lished under subparagraph (C) shall take
7 into account existing trusted exchange
8 frameworks and agreements used by health
9 information networks to avoid the disrupt-
10 tion of existing exchanges between partici-
11 pants of health information networks.

12 “(iv) APPLICATION BY FEDERAL
13 AGENCIES.—Notwithstanding clauses (i),
14 (ii), and (iii), Federal agencies may require
15 the adoption of the trusted exchange
16 framework and common agreement pub-
17 lished under subparagraph (C) for health
18 information exchanges contracting with or
19 entering into agreements pursuant to sub-
20 paragraph (E).

21 “(v) CONSIDERATION OF ONGOING
22 WORK.—In carrying out this paragraph,
23 the Secretary shall ensure the consider-
24 ation of activities carried out by public and
25 private organizations related to exchange

1 between health information exchanges to
2 avoid duplication of efforts.”.

3 (c) PROVIDER DIGITAL CONTACT INFORMATION
4 INDEX.—

5 (1) IN GENERAL.—Not later than 36 months
6 after the date of enactment of this Act, the Sec-
7 retary of Health and Human Services shall either di-
8 rectly, or through a partnership with a private enti-
9 ty, establish a provider digital contact information
10 index to provide digital contact information for
11 health professionals, health facilities, and other indi-
12 viduals or organizations.

13 (2) USE OF EXISTING INDEX.—In establishing
14 the initial index under paragraph (1), the Secretary
15 of Health and Human Services may utilize an exist-
16 ing provider directory to make such digital contact
17 information available.

18 (3) CONTACT INFORMATION.—An index estab-
19 lished under this subsection shall ensure that con-
20 tact information is available at the individual health
21 care provider level and at the health facility or prac-
22 tice level.

23 (4) RULE OF CONSTRUCTION.—

24 (A) IN GENERAL.—The purpose of this
25 subsection is to encourage the exchange of elec-

1 tronic health information by providing the most
 2 useful, reliable, and comprehensive index of pro-
 3 viders possible. In furthering such purpose, the
 4 Secretary of Health and Human Services shall
 5 include all health professionals, health facilities,
 6 and other individuals or organizations applica-
 7 ble to provide a useful, reliable, and comprehen-
 8 sive index for use in the exchange of health in-
 9 formation.

10 (B) LIMITATION.—In no case shall exclu-
 11 sion from the index of providers be used as a
 12 measure to achieve objectives other those de-
 13 scribed in subparagraph (A).

14 (d) STANDARDS DEVELOPMENT ORGANIZATIONS.—
 15 Section 3004 of the Public Health Service Act (42 U.S.C.
 16 300jj-14) is amended by adding at the end the following:

17 “(e) DEFERENCE TO STANDARDS DEVELOPMENT
 18 ORGANIZATIONS.—In adopting and implementing stand-
 19 ards under this section, the Secretary shall give deference
 20 to standards published by Standards Development Organi-
 21 zations and voluntary consensus-based standards bodies.”.

22 **SEC. 6. LEVERAGING HEALTH INFORMATION TECHNOLOGY**
 23 **TO IMPROVE PATIENT CARE.**

24 (a) REQUIREMENT RELATING TO REGISTRIES.—

1 (1) IN GENERAL.—To be certified in accordance
2 with title XXX of the Public Health Service Act,
3 health information technology (as defined by section
4 3000(5) of the Public Health Service Act (42 U.S.C.
5 300jj(5))) shall be capable of transmitting to, and
6 where applicable, receiving and accepting data from
7 registries in accordance with standards recognized
8 by the Office of the National Coordinator for Health
9 Information Technology, including clinician-led clin-
10 ical data registries, that are also certified to be tech-
11 nically capable of receiving and accepting from, and
12 where applicable, transmitting data to certified
13 health information technology in accordance with
14 such standards.

15 (2) RULE OF CONSTRUCTION.—Nothing in this
16 subsection shall be construed to require the certifi-
17 cation of registries beyond the technical capability to
18 exchange data in accordance with applicable en-
19 dorsed standards.

20 (b) DEFINITION.—For purposes of this Act (includ-
21 ing amendments made to title XXX of the Public Health
22 Service Act (42 U.S.C. 300jj et seq.)), the term “clinician-
23 led clinical data registry”²² means a clinical data reposi-
24 tory—

1 (1) that is established and operated by a clini-
2 cian-led or controlled, tax-exempt (pursuant to see-
3 tion 501(c) of the Internal Revenue Code of 1986),
4 professional society or other similar clinician-led or
5 -controlled organization, or such organization's con-
6 trolled affiliate, devoted to the care of a population
7 defined by a particular disease, condition, exposure
8 or therapy;

9 (2) that is designed to collect detailed, stand-
10 ardized data on an ongoing basis for medical proce-
11 dures, services, or therapies for particular diseases,
12 conditions, or exposures;

13 (3) that provides feedback to participants who
14 submit reports to the repository;

15 (4) that meets standards for data quality in-
16 cluding—

17 (A) systematically collecting clinical and
18 other health care data, using standardized data
19 elements and has procedures in place to verify
20 the completeness and validity of those data; and

21 (B) being subject to regular data checks or
22 audits to verify completeness and validity; and

23 (5) that provides ongoing participant training
24 and support.

1 (c) TREATMENT OF HEALTH INFORMATION TECH-
2 NOLOGY DEVELOPERS WITH RESPECT TO PATIENT SAFE-
3 TY ORGANIZATIONS.—

4 (1) IN GENERAL.—In applying part C of title
5 IX of the Public Health Service Act (42 U.S.C.
6 299b-21 et seq.), a health information technology
7 developer shall be treated as a provider (as defined
8 in section 921 of such Act) for purposes of reporting
9 and conducting patient safety activities concerning
10 improving clinical care through the use of health in-
11 formation technology that could result in improved
12 patient safety, health care quality, or health care
13 outcomes.

14 (2) REPORT.—Not later than 48 months after
15 the date of enactment of this Act, the Secretary of
16 Health and Human Services shall submit to the
17 Committee on Health, Education, Labor, and Pen-
18 sions of the Senate and the Committee on Energy
19 and Commerce of the House of Representatives, a
20 report concerning best practices and current trends
21 voluntarily provided, and without identifying indi-
22 vidual providers or disclosing or using protected
23 health information or individually identifiable infor-
24 mation, by Patient Safety Organizations to improve

1 the integration of health information technology into
 2 clinical practice.

3 **SEC. 7. EMPOWERING PATIENTS AND IMPROVING PATIENT**
 4 **ACCESS TO THEIR ELECTRONIC HEALTH IN-**
 5 **FORMATION.**

6 (a) USE OF HEALTH INFORMATION EXCHANGES FOR
 7 PATIENT ACCESS.—Section 3009 of the Public Health
 8 Service Act (42 U.S.C. 300jj–19) is amended by adding
 9 at the end the following:

10 “(c) PROMOTING PATIENT ACCESS TO ELECTRONIC
 11 HEALTH INFORMATION THROUGH HEALTH INFORMA-
 12 TION EXCHANGES.—

13 “(1) IN GENERAL.—The National Coordinator,
 14 in coordination with the Office for Civil Rights of
 15 the Department of Health and Human Services,
 16 shall use existing authorities to encourage partner-
 17 ships between health information exchange organiza-
 18 tions and networks and health care providers, health
 19 plans, and other appropriate entities to offer pa-
 20 tients access to their electronic health information in
 21 a single, longitudinal format that is easy to under-
 22 stand, secure, and may update such information
 23 automatically.

24 “(2) EDUCATION OF PROVIDERS.—The Na-
 25 tional Coordinator, in coordination with the Office

1 for Civil Rights of the Department of Health and
2 Human Services, shall—

3 “(A) educate health care providers on ways
4 in which to leverage the capabilities of health
5 information exchanges (or other relevant plat-
6 forms) to provide patients with access to their
7 electronic health information;

8 “(B) clarify misunderstandings by health
9 care providers about using health information
10 exchanges (or other relevant platforms) for pa-
11 tient access to electronic health information;
12 and

13 “(C) to the extent practicable, educate pro-
14 viders about health information exchanges (or
15 other relevant platforms) that employ some or
16 all of the capabilities described in paragraph
17 (1).

18 “(3) REQUIREMENTS.—In carrying out para-
19 graph (1), the National Coordinator, in coordination
20 with the Office for Civil Rights, shall issue guidance
21 to health information exchanges related to best prac-
22 tices to ensure that the electronic health information
23 provided to patients is—

24 “(A) private and secure;

25 “(B) accurate;

1 “(C) verifiable; and

2 “(D) where a patient’s authorization to ex-
3 change is required by law; easily exchanged
4 pursuant to such authorization.

5 “(4) RULE OF CONSTRUCTION.—Nothing in
6 this subsection shall be construed to preempt State
7 laws applicable to patient consent for the access of
8 information through a Health Information Exchange
9 (or other relevant platforms) that provide protec-
10 tions to patients that are greater than the protec-
11 tions otherwise provided for under applicable Fed-
12 eral law.

13 “(d) EFFORTS TO PROMOTE ACCESS TO HEALTH IN-
14 FORMATION.—The National Coordinator and the Office
15 for Civil Rights of the Department of Health and Human
16 Services shall jointly, through the development of policies
17 that support dynamic technology solutions; promote pa-
18 tient access to health information in a manner that would
19 ensure that such information is available in a form conven-
20 ient for the patient, in a reasonable manner, and without
21 burdening the health care provider involved.

22 “(e) ACCESSIBILITY OF PATIENT RECORDS.—

23 “(1) ACCESSIBILITY AND UPDATING OF INFOR-
24 MATION.—

1 “(A) IN GENERAL.—The Secretary, in con-
2 sultation with the National Coordinator, shall
3 promote policies that ensure that a patient’s
4 electronic health information is accessible to
5 that patient, and their designees, in a manner
6 that facilitates communication with the pa-
7 tient’s health care providers and such patient’s
8 consent, including with respect to research.

9 “(B) UPDATING EDUCATION ON ACCESS-
10 ING AND EXCHANGING PERSONAL HEALTH IN-
11 FORMATION.—To promote awareness that an
12 individual has a right of access to inspect, ob-
13 tain a copy of, and transmit to a third party a
14 copy of protected health information pursuant
15 to the Health Information Portability and Ac-
16 countability Act Privacy Rule (45 C.F.R.
17 164.524 et seq.), the Director of the Office for
18 Civil Rights, in consultation with the National
19 Coordinator, shall assist individuals and health
20 care providers in understanding a patient’s
21 rights to access and protect their personal
22 health information under the Health Insurance
23 Portability and Accountability Act of 1996
24 (Public Law 104–191), including providing best
25 practices for requesting personal health infor-

1 mation in a computable format, including using
2 patient portals or third-party applications and
3 common cases when a provider is permitted to
4 exchange and provide access to health informa-
5 tion.

6 “(2) CERTIFYING USABILITY FOR PATIENTS.—

7 In carrying out certification programs under section
8 3001(e)(5), the National Coordinator shall require,
9 where applicable, that such program or programs re-
10 quire the following:

11 “(A) That certification criteria support pa-
12 tient access to their electronic health informa-
13 tion, including in a single longitudinal format
14 that is easy to understand, secure, and may be
15 updated automatically.

16 “(B) That developers of health information
17 technology support patient access to an elec-
18 tronic health record in a longitudinal format
19 that is easy to understand, secure, and may be
20 updated automatically.

21 “(C) That certification criteria support pa-
22 tient access to their personal electronic health
23 information for research at the option of the
24 patient.

1 “(D) That certification criteria support pa-
2 tient and health care provider communication;
3 including—

4 “(i) the ability for the patient to elec-
5 tronically communicate patient reported in-
6 formation (such as family history and med-
7 ical history); and

8 “(ii) the ability for the patient to elec-
9 tronically share patient health information;
10 at the option of the patient.

11 “(E) That certified health information
12 technology used for health programs where cer-
13 tified health information technology is required;
14 include the function for patient access to their
15 own health information, including—

16 “(i) ensuring that, as a condition of
17 certification, health care providers have op-
18 tions for making such information acces-
19 sible for patients;

20 “(ii) ensuring that patients have op-
21 tions for accessing such information; and

22 “(iii) ensuring that patients have ac-
23 cess to information regarding their legal
24 rights and responsibilities, as well the op-

1 tions available to them for accessing their
2 electronic health information.

3 “(F) That the HIT Standards Committee
4 develop and prioritize standards, implementa-
5 tion specifications, and certification criteria re-
6 quired to help support patient access to elec-
7 tronic health information, patient usability, and
8 support for technologies that offer patients ac-
9 cess to their electronic health information in a
10 single, longitudinal format that is easy to un-
11 derstand, secure, and may be updated auto-
12 matically.”.

13 (b) ACCESS TO INFORMATION IN AN ELECTRONIC
14 FORMAT.—Section 13405(e) of the Health Information
15 Technology for Economic and Clinical Health Act (42
16 U.S.C. 17935) is amended—

17 (1) in paragraph (1), by striking “and” at the
18 end;

19 (2) by redesignating paragraph (2) as para-
20 graph (3); and

21 (3) by inserting after paragraph (1), the fol-
22 lowing:

23 “(2) if the individual makes a request to a busi-
24 ness associate for access to, or a copy of, protected
25 health information about the individual, or if an in-

1 dividual makes a request to a business associate to
2 grant such access to, or transmit such copy directly
3 to, a person or entity designated by the individual,
4 a business associate may provide the individual with
5 such access or copy, which may be in an electronic
6 form, or grant or transmit such access or copy to
7 such person or entity designated by the individual;
8 and”.

9 **SEC. 8. GAO STUDY ON PATIENT MATCHING.**

10 (a) **IN GENERAL.**—Not later than 1 year after the
11 date of enactment of this Act, the Comptroller General
12 of the United States shall conduct a study to review the
13 policies and activities of the Office of the National Coordi-
14 nator for Health Information Technology and other rel-
15 evant stakeholders to ensure appropriate patient matching
16 to protect patient privacy and security with respect to elec-
17 tronic health records and the exchange of electronic health
18 information.

19 (b) **AREAS OF CONCENTRATION.**—In conducting the
20 study under subsection (a), the Comptroller General
21 shall—

22 (1) evaluate current methods used in certified
23 electronic health records for patient matching based
24 on performance related to factors such as—

25 (A) the privacy of patient information;

1 (B) the security of patient information;

2 (C) improving matching rates;

3 (D) reducing matching errors; and

4 (E) reducing duplicate records; and

5 (2) determine whether the Office of the Na-
6 tional Coordinator for Health Information Tech-
7 nology could improve patient matching by taking
8 steps including—

9 (A) defining additional data elements to
10 assist in patient data matching;

11 (B) agreeing on a required minimum set of
12 elements that need to be collected and ex-
13 changed;

14 (C) requiring electronic health records to
15 have the ability to make certain fields required
16 and use specific standards; or

17 (D) other options recommended by the rel-
18 evant stakeholders consulted pursuant to sub-
19 section (a).

20 (e) REPORT.—Not later than 2 years after the date
21 of enactment of this Act, the Comptroller General shall
22 submit to the appropriate committees of Congress a report
23 concerning the findings of the study conducted under sub-
24 section (a).

1 **SECTION 1. SHORT TITLE.**

2 *This Act may be cited as the “Improving Health Infor-*
 3 *mation Technology Act”.*

4 **SEC. 2. ASSISTING DOCTORS AND HOSPITALS IN IMPROV-**
 5 **ING THE QUALITY OF CARE FOR PATIENTS.**

6 *(a) IN GENERAL.—Part 1 of subtitle A of title XIII*
 7 *of the Health Information Technology for Economic and*
 8 *Clinical Health Act (Public Law 111-5) is amended by add-*
 9 *ing at the end the following:*

10 **“SEC. 13103. ASSISTING DOCTORS AND HOSPITALS IN IM-**
 11 **PROVING THE QUALITY OF CARE FOR PA-**
 12 **TIENTS.**

13 *“(a) REDUCTION IN BURDENS GOAL.—The Secretary*
 14 *of Health and Human Services (referred to in this section*
 15 *as the ‘Secretary’), in consultation with providers of health*
 16 *services, health care suppliers of services, health care payers,*
 17 *health professional societies, health information technology*
 18 *developers, health care quality organizations, health care*
 19 *accreditation organizations, public health entities, States,*
 20 *and other appropriate entities, shall, in accordance with*
 21 *subsection (b)—*

22 *“(1) establish a goal with respect to the reduction*
 23 *of regulatory or administrative burdens (such as doc-*
 24 *umentation requirements) relating to the use of elec-*
 25 *tronic health records;*

1 “(2) *develop a strategy for meeting the goal es-*
2 *tablished under paragraph (1); and*

3 “(3) *develop recommendations for meeting the*
4 *goal established under paragraph (1).*

5 “(b) *STRATEGY AND RECOMMENDATIONS.—*

6 “(1) *IN GENERAL.—To achieve the goals estab-*
7 *lished under subsection (a)(1), the Secretary, in con-*
8 *sultation with the entities described in such sub-*
9 *section, shall, not later than 12 months after the date*
10 *of enactment of this section, develop a strategy and*
11 *recommendations to meet the goals in accordance with*
12 *this subsection.*

13 “(2) *STRATEGY.—The strategy developed under*
14 *paragraph (1) shall address the regulatory and ad-*
15 *ministration burdens (such as documentation require-*
16 *ments) relating to the use of electronic health records.*
17 *Such strategy shall include broad public comment*
18 *and shall prioritize burdens related to—*

19 “(A) *the Medicare and Medicaid EHR*
20 *Meaningful Use Incentive programs or the Merit-*
21 *based Incentive Payment System, the Alternative*
22 *Payment Models, the Hospital Value-Based Pur-*
23 *chasing Program, and other value-based pay-*
24 *ment programs determined appropriate by the*
25 *Secretary;*

1 “(B) health information technology certifi-
2 cation programs;

3 “(C) standards, and implementation speci-
4 fications, as appropriate;

5 “(D) activities that provide individuals ac-
6 cess to their electronic health information;

7 “(E) activities related to protecting the pri-
8 vacy of electronic health information;

9 “(F) activities related to protecting the se-
10 curity of electronic health information;

11 “(G) activities related to facilitating health
12 and clinical research;

13 “(H) activities related to public health;

14 “(I) activities related to aligning and sim-
15 plifying quality measures across Federal pro-
16 grams and other payers;

17 “(J) activities related to reporting clinical
18 data for administrative purposes; and

19 “(K) other areas determined appropriate by
20 the Secretary;

21 “(3) *RECOMMENDATIONS.*—*The recommenda-*
22 *tions developed under paragraph (1) shall address—*

23 “(A) actions that improve the clinical docu-
24 mentation experience;

25 “(B) actions that improve patient care;

1 “(C) actions to be taken by the Secretary
2 and by other entities; and

3 “(D) other areas determined appropriate by
4 the Secretary to reduce the reporting burden re-
5 quired of health care providers.

6 “(4) FACA.—The Federal Advisory Committee
7 Act (5 U.S.C. App.) shall not apply to the develop-
8 ment of the goal, strategies, or recommendations de-
9 scribed in this section.

10 “(c) APPLICATION OF CERTAIN REGULATORY RE-
11 QUIREMENTS.—A physician (as defined in section
12 1861(r)(1) of the Social Security Act) may delegate elec-
13 tronic medical record documentation requirements specified
14 in regulations promulgated by the Department of Health
15 and Human Service to a person who is not such physician
16 if such physician has signed and verified the documenta-
17 tion.”.

18 (b) CERTIFICATION OF HEALTH INFORMATION TECH-
19 NOLOGY FOR MEDICAL SPECIALTIES AND SITES OF SERV-
20 ICE.—Section 3001(c)(5) of the Public Health Service Act
21 (42 U.S.C. 300jj–11(c)(5)) is amended by adding at the end
22 the following:

23 “(C) HEALTH INFORMATION TECHNOLOGY
24 FOR MEDICAL SPECIALTIES AND SITES OF SERV-
25 ICE.—

1 “(i) *IN GENERAL.*—*The National Coor-*
2 *dinator shall encourage, keep, or recognize,*
3 *through existing authorities, the voluntary*
4 *certification of health information tech-*
5 *nology under the program developed under*
6 *subparagraph (A) for use in medical spe-*
7 *cialties and sites of service for which no*
8 *such technology is available or where more*
9 *technological advancement or integration is*
10 *needed.*

11 “(ii) *SPECIFIC MEDICAL SPECIAL-*
12 *TIES.*—*The HIT Policy and Standards*
13 *Committees shall make recommendations on*
14 *specific medical specialties and sites of serv-*
15 *ice, in addition to those described in clause*
16 *(iii), applicable under this paragraph.*

17 “(iii) *CERTIFIED HEALTH INFORMA-*
18 *TION TECHNOLOGY FOR PEDIATRICS.*—*Not*
19 *later than 18 months after the date of enact-*
20 *ment of this subparagraph, the HIT Policy*
21 *and Standards Committees, in consultation*
22 *with relevant stakeholders, shall make rec-*
23 *ommendations for the voluntary certifi-*
24 *cation of health information technology for*
25 *use by pediatric health providers to support*

1 the health care of children. Not later than
2 24 months after the date of enactment of
3 this subparagraph, the Secretary shall
4 adopt certification criteria (under section
5 3004) to support the voluntary certification
6 of health information technology for use by
7 pediatric health providers to support the
8 health care of children.”.

9 (c) *MEANINGFUL USE STATISTICS.*—

10 (1) *IN GENERAL.*—Not later than 6 months after
11 the date of enactment of this Act, the Secretary of
12 Health and Human Services shall submit to the HIT
13 Policy Committee of the Office of the National Coordi-
14 nator for Health Information Technology, a report
15 concerning attestation statistics for the Medicare and
16 Medicaid EHR Meaningful Use Incentive programs
17 to assist in informing standards adoption and related
18 practices. Such statistics shall include attestation in-
19 formation delineated by State, including the number
20 of providers who did not meet the minimum criteria
21 necessary to attest for the Medicare and Medicaid
22 EHR Meaningful Use Incentive programs for a cal-
23 endar year, and shall be made publicly available on
24 the Internet website of the Secretary on at least a
25 quarterly basis.

1 (2) *AUTHORITY TO ALTER FORMAT.*—*The Sec-*
 2 *retary of Health and Human Service may alter the*
 3 *format of the reports on the attestation of eligible*
 4 *health care professionals following the first perform-*
 5 *ance year of the Merit-based Incentive Payment Sys-*
 6 *tem to account for changes arising from the imple-*
 7 *mentation of such payment system.*

8 **SEC. 3. TRANSPARENT RATINGS ON USABILITY AND SECU-**
 9 **RITY TO TRANSFORM INFORMATION TECH-**
 10 **NOLOGY.**

11 (a) *ENHANCEMENTS TO CERTIFICATION.*—*Section*
 12 *3001(c)(5) of the Public Health Service Act (42 U.S.C.*
 13 *300jj–11), as amended by section 2(b), is further amend-*
 14 *ed—*

15 (1) *in subparagraph (A)—*

16 (A) *by striking “The National Coordinator”*
 17 *and inserting the following:*

18 “(i) *VOLUNTARY CERTIFICATION PRO-*
 19 *GRAM.—The National Coordinator”;* and

20 (B) *by adding at the end the following:*

21 “(ii) *TRANSPARENCY OF PROGRAM.—*

22 “(I) *IN GENERAL.—To enhance*
 23 *transparency in the compliance of*
 24 *health information technology with cer-*
 25 *tification criteria and other require-*

1 *ments adopted under this subtitle, the*
2 *National Coordinator, in coordination*
3 *with authorized certification bodies,*
4 *may make information demonstrating*
5 *how health information technology*
6 *meets such certification criteria or*
7 *other requirements publicly available.*
8 *Such information may include sum-*
9 *maries, screenshots, video demonstra-*
10 *tions, or any other information the Na-*
11 *tional Coordinator determines appro-*
12 *priate.*

13 *“(II) PROTECTION OF PROPRI-*
14 *ETARY INFORMATION.—The National*
15 *Coordinator shall take appropriate*
16 *measures to ensure that there are in ef-*
17 *fect effective procedures to prevent the*
18 *unauthorized disclosure of any trade*
19 *secret or confidential information that*
20 *is obtained by the Secretary pursuant*
21 *to this section.”;*

22 *(2) in subparagraph (B), by adding at the end*
23 *the following: “Beginning 18 months after reporting*
24 *criteria are finalized under section 3009A, certifi-*
25 *cation criteria shall include, in addition to criteria to*

1 *establish that the technology meets such standards and*
2 *implementation specifications, criteria consistent with*
3 *section 3009A(b) to establish that technology meets*
4 *applicable security requirements, incorporates user-*
5 *centered design, and achieves interoperability.”; and*

6 *(3) by adding at the end the following:*

7 *“(D) CONDITIONS OF CERTIFICATION.—Be-*
8 *ginning 1 year after the date of enactment of the*
9 *Improving Health Information Technology Act,*
10 *the Secretary shall require, as a condition of cer-*
11 *tification and maintenance of certification for*
12 *programs maintained or recognized under this*
13 *paragraph, that—*

14 *“(i) the health information technology*
15 *developer or entity does not take any action*
16 *that constitutes information blocking with*
17 *respect to health information technology;*

18 *“(ii) the health information technology*
19 *developer or entity permits unimpeded com-*
20 *munication among and between health in-*
21 *formation technology users, and for the pur-*
22 *poses of health information technology users*
23 *communicating with an authorized certifi-*
24 *cation body, the Office of the National Coor-*
25 *dinator, and the Office of the Inspector Gen-*

1 *eral, the health information technology de-*
2 *veloper or entity permits unimpeded com-*
3 *munication regarding the usability, inter-*
4 *operability, security, business practices, or*
5 *other relevant information about the health*
6 *information technology or users' experience*
7 *with the health information technology;*

8 *“(iii) health information from such*
9 *technology may be exchanged, accessed, and*
10 *used through the use of application pro-*
11 *gramming interfaces or successor technology*
12 *or standard as provided for under applica-*
13 *ble law;*

14 *“(iv) the health information technology*
15 *developer or entity provides to the Secretary*
16 *an attestation that the developer or entity—*

17 *“(I) has not engaged in any of the*
18 *conduct described in clause (i);*

19 *“(II) allows for communication as*
20 *described in clause (ii); and*

21 *“(III) ensures that its technology*
22 *allows for health information to be ex-*
23 *changed, accessed, and used, in the*
24 *manner described in clause (iii); and*

1 *rules establishing reporting criteria for health infor-*
2 *mation technology products.*

3 “(2) *CONVENING OF STAKEHOLDERS.*—*Not later*
4 *than 1 year after the date of enactment of the Improv-*
5 *ing Health Information Technology Act, the Sec-*
6 *retary, in consultation with the development council*
7 *described in subsection (a), shall convene stakeholders*
8 *as described in paragraph (3) for the purpose of de-*
9 *veloping the reporting criteria in accordance with*
10 *paragraph (4).*

11 “(3) *DEVELOPMENT OF REPORTING CRITERIA.*—
12 *The reporting criteria under this subsection shall be*
13 *developed through a public, transparent process that*
14 *reflects input from relevant stakeholders, including—*

15 “(A) *health care providers, including pri-*
16 *mary care and specialty care health care profes-*
17 *sionals;*

18 “(B) *hospitals and hospital systems;*

19 “(C) *health information technology devel-*
20 *opers;*

21 “(D) *patients, consumers, and their advo-*
22 *cates;*

23 “(E) *data sharing networks, such as health*
24 *information exchanges;*

1 “(F) authorized certification bodies and
2 testing laboratories;

3 “(G) security experts;

4 “(H) relevant manufacturers of medical de-
5 vices;

6 “(I) experts in health information tech-
7 nology market economics;

8 “(J) public and private entities engaged in
9 the evaluation of health information technology
10 performance;

11 “(K) quality organizations, including the
12 consensus based entity described in section 1890
13 of the Social Security Act;

14 “(L) experts in human factors engineering
15 and the measurement of user-centered design;
16 and

17 “(M) other entities or persons, as the Sec-
18 retary, in consultation with the development
19 council, determines appropriate.

20 “(4) CONSIDERATIONS FOR REPORTING CRI-
21 TERIA.—The reporting criteria developed under this
22 subsection—

23 “(A) shall include measures that reflect cat-
24 egories including, with respect to the tech-
25 nology—

1 “(i) security;

2 “(ii) usability and user-centered de-
3 sign;

4 “(iii) interoperability;

5 “(iv) conformance to certification test-
6 ing; and

7 “(v) other categories as appropriate to
8 measure the performance of health informa-
9 tion technology;

10 “(B) may include measures such as—

11 “(i) enabling the user to order and
12 view the results of laboratory tests, imaging
13 tests, and other diagnostic tests;

14 “(ii) submitting, editing, and retriev-
15 ing data from registries such as clinician-
16 led clinical data registries;

17 “(iii) accessing and exchanging infor-
18 mation and data from and through Health
19 Information Exchanges;

20 “(iv) accessing and exchanging infor-
21 mation and data from medical devices;

22 “(v) accessing and exchanging infor-
23 mation and data held by Federal, State,
24 and local agencies and other applicable en-
25 tities useful to a health care provider or

1 *other applicable user in the furtherance of*
2 *patient care;*

3 *“(vi) accessing and exchanging infor-*
4 *mation from other health care providers or*
5 *applicable users;*

6 *“(vii) accessing and exchanging pa-*
7 *tient generated information;*

8 *“(viii) providing the patient or an au-*
9 *thorized designee with a complete copy of*
10 *their health information from an electronic*
11 *record in a computable format;*

12 *“(ix) providing accurate patient infor-*
13 *mation for the correct patient, including ex-*
14 *changing such information, and avoiding*
15 *the duplication of patients records; and*

16 *“(x) other appropriate functionalities;*
17 *and*

18 *“(C) shall be designed to ensure that small*
19 *and start-up health information technology de-*
20 *velopers are not unduly disadvantaged by the re-*
21 *porting criteria or rating scale methodology.*

22 *“(5) CONSIDERATION OF DEVELOPMENT COUNCIL*
23 *RECOMMENDATIONS.—In promulgating proposed rules*
24 *under this subsection, including modifications to such*
25 *rules under subsection (e), the Secretary may accept,*

1 *reject, or modify the recommendations of the develop-*
2 *ment council, but may not promulgate a proposed*
3 *rule that does not represent a complete recommenda-*
4 *tion of such council.*

5 “(6) *PUBLIC COMMENT.*—*In promulgating pro-*
6 *posed rules under this subsection, the Secretary shall*
7 *conduct a public comment period of not less than 60*
8 *days during which any member of the public may*
9 *provide comments on the proposed reporting criteria*
10 *and the methodology for the rating body (defined in*
11 *subsection (g)) to use in determining the star ratings.*

12 “(7) *FINAL RULES.*—*The final rule promulgated*
13 *under this subsection shall be accompanied by timely*
14 *responses to the public comments described in para-*
15 *graph (6).*

16 “(8) *FACA.*—*The Federal Advisory Committee*
17 *Act (5 U.S.C. App.) shall not apply to the develop-*
18 *ment council described in this section.*

19 “(c) *FEEDBACK.*—

20 “(1) *IN GENERAL.*—*The Secretary, in consulta-*
21 *tion with the development council, shall establish a*
22 *process for the rating body (described in subsection*
23 *(g)) to collect and verify confidential feedback from—*

24 “(A) *health care providers, patients, and*
25 *other users of certified health information tech-*

1 *nology on the usability, security, and interoper-*
2 *ability of health information technology prod-*
3 *ucts; and*

4 *“(B) developers of certified health informa-*
5 *tion technology on practices of health informa-*
6 *tion technology users that may inhibit interoper-*
7 *ability.*

8 *“(2) PAPERWORK REDUCTION ACT.—The Paper-*
9 *work Reduction Act (44 U.S.C. 3501 et seq.) shall not*
10 *apply to the collection of feedback described in this*
11 *subsection.*

12 *“(d) METHODOLOGY.—The Secretary, in consultation*
13 *with the development council, shall develop a methodology*
14 *to be used by the rating body described in subsection (g)*
15 *to calculate the star ratings for certified health information*
16 *technology described in subsection (a). The methodology*
17 *shall use the reporting criteria developed in subsection (b),*
18 *and the confidential feedback collected under subsection (c).*
19 *In developing such methodology, the Secretary, in consulta-*
20 *tion with the development council, shall—*

21 *“(1) provide for appropriate weighting of user*
22 *feedback submitted under subsection (c) and reporting*
23 *criteria submitted under subsection (f), including con-*
24 *sideration of the number of users who submitted such*
25 *feedback;*

1 “(2) consider the impact of customization or ad-
2 aptation by users of certified health information tech-
3 nology on performance;

4 “(3) account for the intended function, scope,
5 and type of certified health information technology;

6 “(4) in consultation with the development coun-
7 cil and after seeking comment from developers of
8 health information technology in a manner that en-
9 sures appropriate industry feedback, establish a time-
10 frame, but in no case less frequent than once every 3
11 years, for the submission of reporting criteria under
12 subsection (f); and

13 “(5) establish a timeframe for incorporating user
14 feedback submitted under subsection (e) and reporting
15 criteria submitted under subsection (f) into the star
16 ratings for certified health information technology
17 that accounts for updates to such technology in order
18 to encourage innovation and maximize the utility of
19 the star ratings.

20 “(e) MODIFICATIONS.—

21 “(1) TO THE NUMBER OF STARS IN THE RATING
22 PROGRAM.—The development council may modify the
23 number of star ratings employed by the system, but
24 not more frequently than every 4 years. In no case
25 shall the rating system employ fewer than 3 stars.

1 “(2) *TO THE REPORTING CRITERIA.*—After the
2 *final reporting criteria have been established under*
3 *this section, the Secretary, in consultation with the*
4 *development council, may convene stakeholders and*
5 *conduct a public reporting period for the purpose of*
6 *modifying the reporting criteria developed under sub-*
7 *section (b) and methodology for determining the star*
8 *ratings proposed under subsection (e).*

9 “(3) *TO THE METHODOLOGY.*—After the final
10 *methodology to be used by the rating body is estab-*
11 *lished under subsection (e), the Secretary, in consulta-*
12 *tion with the development council, may modify the*
13 *methodology used to calculate the star ratings for cer-*
14 *tified health information technology using the report-*
15 *ing criteria developed under subsection (b) and the*
16 *confidential feedback collected under subsection (c).*

17 “(4) *CONSIDERATION OF GAO REPORT.*—The Sec-
18 *retary and the development council shall take into ac-*
19 *count the recommendations from the Comptroller Gen-*
20 *eral under subsection (k), where available, for the*
21 *purposes of this paragraph.*

22 “(f) *PARTICIPATION.*—As a condition of maintaining
23 *their certification under section 3001(c)(5)(D), a developer*
24 *of certified health information technology shall report on*
25 *the criteria developed under subsection (b) for all such cer-*

1 *tified technology offered by such developer pursuant to the*
2 *timeframe established under subsection (d).*

3 “(g) *RATING BODY.*—

4 “(1) *IN GENERAL.*—*The National Coordinator*
5 *shall recognize an independent entity with appro-*
6 *priate expertise to carry out the rating program es-*
7 *tablished by the development council under subsection*
8 *(a) and shall re-determine such recognition at least*
9 *every 4 years.*

10 “(2) *CONSULTATION.*—*The entity recognized*
11 *under paragraph (1) may consult with organizations*
12 *with expertise in the measurement of interoperability,*
13 *usability, and security of health information tech-*
14 *nology in carrying out activities under this section.*

15 “(h) *ONE STAR RATING.*—*Each health information*
16 *technology developer, or entity offering health information*
17 *technology for certification, that receives a 1 star rating*
18 *shall take action, through an improvement plan developed*
19 *with the rating body and approved by the Secretary, to im-*
20 *prove the health information technology rating within a*
21 *timeframe that the Secretary determines appropriate.*

22 “(i) *DECERTIFICATION.*—

23 “(1) *MANDATORY.*—*The Secretary shall decertify*
24 *health information technology if the developer or enti-*
25 *ty offering health information technology does not*

1 submit reporting criteria in accordance with sub-
2 section (f) within 90 days of the timeline established
3 under subsection (d).

4 “(2) *OTHER DECERTIFICATION.*—The Secretary
5 may decertify health information technology if—

6 “(A) the health information technology does
7 not improve from a one star rating within the
8 timeframe established under subsection (h); or

9 “(B) in other circumstances, as the Sec-
10 retary determines appropriate through notice
11 and comment rulemaking.

12 “(j) *GAO REPORTS.*—During the 12-year period be-
13 ginning on the date of enactment of the Improving Health
14 Information Technology Act, the Comptroller General of the
15 United States shall submit to Congress a report every 4
16 years on the rating scale methodology developed pursuant
17 to subsection (d), providing observations on the appro-
18 priateness of the current methodology and recommendations
19 for changes to the methodology. The Development Council
20 shall recommend to Congress and the Secretary if addi-
21 tional reports are needed after the expiration of such 12-
22 year period.

23 “(k) *INTERNET WEBSITE.*—On the Internet website of
24 the Office of the National Coordinator, the Secretary shall
25 publish the criteria and methodology used to determine the

1 *star ratings, and, for each certified health information tech-*
2 *nology, the final star rating, and a report outlining such*
3 *technology's performance with regard to the reporting cri-*
4 *teria developed under subsection (b), and if an improvement*
5 *plan has been administered. Following the reporting de-*
6 *scribed in subsection (f), the rating body shall have 30 days*
7 *to calculate and submit updated ratings to the Secretary*
8 *and each developer of health information technology, and*
9 *updated ratings shall be published on such Internet website*
10 *not later than 30 days following such submission, notwith-*
11 *standing an appeal of a rating by a developer or entity*
12 *through the process developed under subsection (m).*

13 “(l) *HARDSHIP EXEMPTION.—Decertification of an*
14 *adopted health information technology product under sub-*
15 *section (i) shall be considered a significant hardship result-*
16 *ing in a blanket exemption from the payment adjustment*
17 *pursuant to section 1848(a)(7)(B) of the Social Security*
18 *Act for eligible professionals, section 1886(b)(3)(ix)(II) of*
19 *such Act for eligible hospitals, and 1814(l)(4)(C) of such*
20 *Act for critical access hospitals.*

21 “(m) *NOTIFICATION AND APPEALS.—The Secretary*
22 *shall establish a process through rulemaking whereby any*
23 *health information technology developer, or entity offering*
24 *health information technology, is notified not less than 30*
25 *days before being made public and can appeal—*

1 “(1) *the health information technology product’s*
2 *star rating; or*

3 “(2) *the Secretary’s decision to decertify a prod-*
4 *uct, as applicable.”.*

5 **SEC. 4. INFORMATION BLOCKING.**

6 *Subtitle C of title XXX of the Public Health Service*
7 *Act (42 U.S.C. 300jj-51 et seq.) is amended by adding at*
8 *the end the following:*

9 **“SEC. 3022. INFORMATION BLOCKING.**

10 “(a) *DEFINITION.—*

11 “(1) *IN GENERAL.—The term ‘information block-*
12 *ing’ means—*

13 “(A) *with respect to a health information*
14 *technology developer, exchange, or network, busi-*
15 *ness, technical, or organizational practices*
16 *that—*

17 “(i) *except as required by law or speci-*
18 *fied by the Secretary, interferes with, pre-*
19 *vents, or materially discourages access, ex-*
20 *change, or use of electronic health informa-*
21 *tion; and*

22 “(ii) *the developer, exchange, or net-*
23 *work knows, or should know, are likely to*
24 *interfere with or prevent or materially dis-*

1 *courage the access, exchange, or use of elec-*
2 *tronic health information; and*

3 “(B) *with respect to a health care provider,*
4 *the person or entity knowingly and unreasonably*
5 *restricts electronic health information exchange*
6 *for patient care or other priorities as determined*
7 *appropriate by the Secretary.*

8 “(2) *RULEMAKING.—The Secretary shall,*
9 *through rulemaking—*

10 “(A) *identify reasonable and necessary ac-*
11 *tivities that do not constitute information block-*
12 *ing for purposes of paragraph (1)(A); and*

13 “(B) *identify actions that meet the defini-*
14 *tion of information blocking with respect to*
15 *health care providers for purposes of paragraph*
16 *(1)(B).*

17 “(b) *INSPECTOR GENERAL AUTHORITY.—*

18 “(1) *IN GENERAL.—The Inspector General of the*
19 *Department of Health and Human Services may in-*
20 *vestigate any claim that—*

21 “(A) *a health information technology devel-*
22 *oper of, or other entity offering certified health*
23 *information technology—*

24 “(i) *submits a false attestation made*
25 *under section 3001(c)(5)(D); or*

1 “(ii) engaged in information blocking
2 with respect to the use of such health infor-
3 mation technology by a health care pro-
4 vider, unless for a legitimate purpose speci-
5 fied by the Secretary;

6 “(B) a health care provider engaged in in-
7 formation blocking with respect to access or ex-
8 change of certified health information technology,
9 unless for a legitimate purpose specified by the
10 Secretary; and

11 “(C) a health information network or ex-
12 change provider engaged in information blocking
13 with respect to the access, exchange, or use of
14 such certified health information technology, un-
15 less for a legitimate purpose specified by the Sec-
16 retary.

17 “(2) JURISDICTION OF THE INSPECTOR GEN-
18 ERAL.—For purposes of this section, the Office of the
19 Inspector General shall have jurisdiction with respect
20 to exchanges and networks, as well as any developer
21 or entity offering health information technology for
22 certification under a program or programs kept or
23 recognized by the National Coordinator under section
24 3001(c)(5). The National Coordinator shall notify de-
25 velopers of health information technology as appro-

1 *appropriate regarding the jurisdiction of the Inspector Gen-*
2 *eral under this paragraph.*

3 *“(3) PENALTY.—*

4 *“(A) DEVELOPERS, NETWORKS, AND EX-*
5 *CHANGES.—With respect to a health information*
6 *technology developer, exchange, or network, a*
7 *person or entity determined by the Inspector*
8 *General to have committed information blocking*
9 *as described in subparagraph (A) or (C) of para-*
10 *graph (1) shall be subject to a civil monetary*
11 *penalty in an amount determined, through no-*
12 *tice-and-comment rulemaking, by the Secretary*
13 *which may take into account factors such as the*
14 *extent and duration of the information blocking*
15 *and the number of patients and providers poten-*
16 *tially affected.*

17 *“(B) PROVIDERS.—With respect to health*
18 *care providers, any person or entity determined*
19 *by the Inspector General to have committed in-*
20 *formation blocking as described in subparagraph*
21 *(B) of paragraph (1) shall be subject to appro-*
22 *priate incentives and disincentives using au-*
23 *thorities under applicable Federal law, as deter-*
24 *mined appropriate by the Secretary through no-*
25 *tice and comment rulemaking.*

1 “(C) *PROCEDURE.*—The provisions of sec-
2 tion 1128A of the Social Security Act (other
3 than subsections (a) and (b)) shall apply to a
4 civil money penalty applied under this sub-
5 section in the same manner as such provisions
6 apply to a civil money penalty or proceeding
7 under section 1128A(a).

8 “(D) *RECOVERY OF FUNDS.*—Notwith-
9 standing section 3302 of title 31, United States
10 Code, or any other provision of law affecting the
11 crediting of collections, the Inspector General of
12 the Department of Health and Human Services
13 may receive and retain for current use any
14 amounts recovered under subparagraphs (A) and
15 (C). In addition to amounts otherwise available
16 to the Inspector General, funds received by the
17 Inspector General under this paragraph shall be
18 deposited, as an offsetting collection, to the credit
19 of any appropriation available for purposes of
20 carrying out this subsection and shall be avail-
21 able without fiscal year limitation and without
22 further appropriation.

23 “(4) *RESOLUTION OF CLAIMS.*—

24 “(A) *IN GENERAL.*—The Office of the In-
25 specter General, if such Office determines that a

1 *simple consultation regarding the health privacy*
2 *and security rules promulgated under section*
3 *264(c) of the Health Insurance Portability and*
4 *Accountability Act of 1996 (42 U.S.C. 1320d-2*
5 *note) will resolve the claim at issue, may refer*
6 *instances of information blocking to the Office*
7 *for Civil Rights of the Department of Health and*
8 *Human Services for resolution.*

9 “(B) *LIMITATION ON LIABILITY.—If a*
10 *health information technology developer makes*
11 *information available based on a good faith reli-*
12 *ance on consultations with the Office for Civil*
13 *Rights of the Department of Health and Human*
14 *Services with respect to such information, the de-*
15 *veloper shall not be liable for such disclosure.*

16 “(c) *IDENTIFYING BARRIERS TO EXCHANGE OF CER-*
17 *TIFIED HEALTH INFORMATION TECHNOLOGY.—*

18 “(1) *TRUSTED EXCHANGE DEFINED.—In this*
19 *section, the term ‘trusted exchange’ with respect to*
20 *certified health information technology means that the*
21 *certified health information technology has the tech-*
22 *nical capability to enable secure health information*
23 *exchange between users and multiple certified health*
24 *information technology systems.*

1 “(2) *GUIDANCE.*—*The National Coordinator, in*
2 *consultation with the Office for Civil Rights of the*
3 *Department of Health and Human Services, shall*
4 *issue guidance on common legal, governance, and se-*
5 *curity barriers that prevent the trusted exchange of*
6 *electronic health information.*

7 “(3) *REFERRAL.*—*The National Coordinator and*
8 *the Office for Civil Rights of the Department of*
9 *Health and Human Services may refer to the Inspec-*
10 *tor General instances or patterns of refusal to ex-*
11 *change health information with an individual or enti-*
12 *ty using certified health information technology that*
13 *is technically capable of trusted exchange and under*
14 *conditions when exchange is legally permissible.*

15 “(4) *HIT STANDARDS COMMITTEE CONSIDER-*
16 *ATION.*—*Not later than 1 year after the date of enact-*
17 *ment of the Improving Health Information Tech-*
18 *nology Act, the HIT Standards Committee shall begin*
19 *consideration of issues related to trusted exchange.”.*

20 **SEC. 5. INTEROPERABILITY.**

21 “(a) *DEFINITION.*—*Section 3000 of the Public Health*
22 *Service Act (42 U.S.C. 300jj) is amended—*

23 (1) *by redesignating paragraphs (10) through*
24 (14), *as paragraphs (11) through (15), respectively;*
25 *and*

1 (2) by inserting after paragraph (9) the fol-
2 lowing:

3 “(10) *INTEROPERABILITY*.—The term ‘interoper-
4 ability’ with respect to health information technology
5 means such health information technology that has
6 the ability to securely exchange electronic health in-
7 formation with and use electronic health information
8 from other health information technology without spe-
9 cial effort on the part of the user.”.

10 (b) *SUPPORT FOR INTEROPERABLE NETWORK EX-*
11 *CHANGE*.—Section 3001(c) of the Public Health Service Act
12 (42 U.S.C. 300jj-11(c)) is amended by adding at the end
13 the following:

14 “(9) *SUPPORT FOR INTEROPERABLE NETWORKS*
15 *EXCHANGE*.—

16 “(A) *IN GENERAL*.—The National Coordi-
17 nator shall, in collaboration with the National
18 Institute of Standards and Technology and other
19 relevant agencies within the Department of
20 Health and Human Services, for the purpose of
21 ensuring full network-to-network exchange of
22 health information, convene public-private and
23 public-public partnerships to build consensus
24 and develop a trusted exchange framework, in-
25 cluding a common agreement among health in-

1 *formation networks nationally. Such convention*
2 *may occur at a frequency determined appro-*
3 *priate by the Secretary.*

4 “(B) *ESTABLISHING A TRUSTED EXCHANGE*
5 *FRAMEWORK.—*

6 “(i) *IN GENERAL.—Not later than six*
7 *months after the date of enactment of this*
8 *paragraph, the National Coordinator shall*
9 *convene appropriate public and private*
10 *stakeholders to develop a trusted exchange*
11 *framework for trust policies and practices*
12 *and for a common agreement for exchange*
13 *between health information networks. The*
14 *common agreement may include—*

15 “(I) *a common method for au-*
16 *thenticating trusted health information*
17 *network participants;*

18 “(II) *a common set of rules for*
19 *trusted exchange;*

20 “(III) *organizational and oper-*
21 *ational policies to enable the exchange*
22 *of health information among networks,*
23 *including minimum conditions for*
24 *such exchange to occur; and*

1 “(IV) a process for filing and ad-
2 judicating non-compliance with the
3 terms of the common agreement.

4 “(ii) *TECHNICAL ASSISTANCE.*—The
5 National Coordinator, in conjunction with
6 National Institute of Standards and Tech-
7 nology, shall provide technical assistance on
8 how to implement the trusted exchange
9 framework and common agreement under
10 this paragraph.

11 “(iii) *PILOT TESTING.*—The National
12 Coordinator, in collaboration with the Na-
13 tional Institute of Standards and Tech-
14 nology, shall provide for the pilot testing of
15 the trusted exchange framework and com-
16 mon agreement established under this sub-
17 section (as authorized under section 13201
18 of the Health Information Technology for
19 Economic and Clinical Health Act). The
20 National Coordinator, in collaboration with
21 the National Institute of Standards and
22 Technology, may delegate pilot testing ac-
23 tivities under this clause to independent en-
24 tities with appropriate expertise.

1 “(C) *PUBLICATION OF A TRUSTED EX-*
2 *CHANGE FRAMEWORK AND COMMON AGREE-*
3 *MENT.—Not later than one year after convening*
4 *stakeholders under subparagraph (A), the Na-*
5 *tional Coordinator shall publish on its public*
6 *Internet website, and in the Federal register, the*
7 *trusted exchange framework and common agree-*
8 *ment developed under subparagraph (B). Such*
9 *trusted exchange framework and common agree-*
10 *ment shall be published in a manner that pro-*
11 *tects proprietary and security information, in-*
12 *cluding trade secrets and any other protected in-*
13 *tellectual property.*

14 “(D) *DIRECTORY OF PARTICIPATING*
15 *HEALTH INFORMATION NETWORKS.—*

16 “(i) *IN GENERAL.—Not later than two*
17 *years after convening stakeholders under*
18 *subparagraph (A), and annually thereafter,*
19 *the National Coordinator shall publish on*
20 *its public Internet website a list of those*
21 *health information networks that have*
22 *adopted the common agreement and are ca-*
23 *pable of trusted exchange pursuant to the*
24 *common agreement developed under para-*
25 *graph (B).*

1 “(ii) *PROCESS.*—*The Secretary shall,*
2 *through notice-and-comment rulemaking, es-*
3 *tablish a process for health information net-*
4 *works that voluntarily elect to adopt the*
5 *trusted exchange framework and common*
6 *agreement to attest to such adoption of the*
7 *framework and agreement.*

8 “(E) *APPLICATION OF THE TRUSTED EX-*
9 *CHANGE FRAMEWORK AND COMMON AGREE-*
10 *MENT.*—*As appropriate, Federal agencies con-*
11 *tracting or entering into agreements with health*
12 *information exchange networks may require that*
13 *as each such network upgrades health informa-*
14 *tion technology or trust and operational prac-*
15 *tices, it may adopt, where available, the trusted*
16 *exchange framework and common agreement*
17 *published under subparagraph (C).*

18 “(F) *RULE OF CONSTRUCTION.*—

19 “(i) *GENERAL ADOPTION.*—*Nothing in*
20 *this paragraph shall be construed to require*
21 *a health information network to adopt the*
22 *trusted exchange framework or common*
23 *agreement.*

24 “(ii) *ADOPTION WHEN EXCHANGE OF*
25 *INFORMATION IS WITHIN NETWORK.*—*Noth-*

1 *ing in this paragraph shall be construed to*
2 *require a health information network to*
3 *adopt the trusted exchange framework or*
4 *common agreement for the exchange of elec-*
5 *tronic health information between partici-*
6 *pants of the same network.*

7 *“(iii) EXISTING FRAMEWORKS AND*
8 *AGREEMENTS.—The trusted exchange frame-*
9 *work and common agreement published*
10 *under subparagraph (C) shall take into ac-*
11 *count existing trusted exchange frameworks*
12 *and agreements used by health information*
13 *networks to avoid the disruption of existing*
14 *exchanges between participants of health in-*
15 *formation networks.*

16 *“(iv) APPLICATION BY FEDERAL AGEN-*
17 *CIES.—Notwithstanding clauses (i), (ii),*
18 *and (iii), Federal agencies may require the*
19 *adoption of the trusted exchange framework*
20 *and common agreement published under*
21 *subparagraph (C) for health information ex-*
22 *changes contracting with or entering into*
23 *agreements pursuant to subparagraph (E).*

24 *“(v) CONSIDERATION OF ONGOING*
25 *WORK.—In carrying out this paragraph, the*

1 *Secretary shall ensure the consideration of*
2 *activities carried out by public and private*
3 *organizations related to exchange between*
4 *health information exchanges to avoid du-*
5 *plication of efforts.”.*

6 (c) *PROVIDER DIGITAL CONTACT INFORMATION*
7 *INDEX.—*

8 (1) *IN GENERAL.—Not later than 36 months*
9 *after the date of enactment of this Act, the Secretary*
10 *of Health and Human Services shall either directly,*
11 *or through a partnership with a private entity, estab-*
12 *lish a provider digital contact information index to*
13 *provide digital contact information for health profes-*
14 *sionals, health facilities, and other individuals or or-*
15 *ganizations.*

16 (2) *USE OF EXISTING INDEX.—In establishing*
17 *the initial index under paragraph (1), the Secretary*
18 *of Health and Human Services may utilize an exist-*
19 *ing provider directory to make such digital contact*
20 *information available.*

21 (3) *CONTACT INFORMATION.—An index estab-*
22 *lished under this subsection shall ensure that contact*
23 *information is available at the individual health care*
24 *provider level and at the health facility or practice*
25 *level.*

1 (4) *RULE OF CONSTRUCTION.*—

2 (A) *IN GENERAL.*—*The purpose of this sub-*
3 *section is to encourage the exchange of electronic*
4 *health information by providing the most useful,*
5 *reliable, and comprehensive index of providers*
6 *possible. In furthering such purpose, the Sec-*
7 *retary of Health and Human Service shall in-*
8 *clude all health professionals, health facilities,*
9 *and other individuals or organizations applica-*
10 *ble to provide a useful, reliable, and comprehen-*
11 *sive index for use in the exchange of health infor-*
12 *mation.*

13 (B) *LIMITATION.*—*In no case shall exclusion*
14 *from the index of providers be used as a measure*
15 *to achieve objectives other those described in sub-*
16 *paragraph (A).*

17 (d) *STANDARDS DEVELOPMENT ORGANIZATIONS.*—

18 *Section 3004 of the Public Health Service Act (42 U.S.C.*
19 *300jj-14) is amended by adding at the end the following:*

20 “(c) *DEFERENCE TO STANDARDS DEVELOPMENT OR-*
21 *GANIZATIONS.*—*In adopting and implementing standards*
22 *under this section, the Secretary shall give deference to*
23 *standards published by Standards Development Organiza-*
24 *tions and voluntary consensus-based standards bodies.”.*

1 **SEC. 6. LEVERAGING HEALTH INFORMATION TECHNOLOGY**
2 **TO IMPROVE PATIENT CARE.**

3 *(a) REQUIREMENT RELATING TO REGISTRIES.—*

4 *(1) IN GENERAL.—To be certified in accordance*
5 *with title XXX of the Public Health Service Act,*
6 *health information technology (as defined by section*
7 *3000(5) of the Public Health Service Act (42 U.S.C.*
8 *300jj(5))) shall be capable of transmitting to, and*
9 *where applicable, receiving and accepting data from*
10 *registries in accordance with standards recognized by*
11 *the Office of the National Coordinator for Health In-*
12 *formation Technology, including clinician-led clinical*
13 *data registries, that are also certified to be technically*
14 *capable of receiving and accepting from, and where*
15 *applicable, transmitting data to certified health infor-*
16 *mation technology in accordance with such standards.*

17 *(2) RULE OF CONSTRUCTION.—Nothing in this*
18 *subsection shall be construed to require the certifi-*
19 *cation of registries beyond the technical capability to*
20 *exchange data in accordance with applicable endorsed*
21 *standards.*

22 *(b) DEFINITION.—For purposes of this Act (including*
23 *amendments made to title XXX of the Public Health Service*
24 *Act (42 U.S.C. 300jj et seq.), the term “clinician-led clinical*
25 *data registry” means a clinical data repository—*

1 (1) *that is established and operated by a clini-*
2 *cian-led or controlled, tax-exempt (pursuant to section*
3 *501(c) of the Internal Revenue Code of 1986), profes-*
4 *sional society or other similar clinician-led or -con-*
5 *trolled organization, or such organization's controlled*
6 *affiliate, devoted to the care of a population defined*
7 *by a particular disease, condition, exposure or ther-*
8 *apy;*

9 (2) *that is designed to collect detailed, standard-*
10 *ized data on an ongoing basis for medical procedures,*
11 *services, or therapies for particular diseases, condi-*
12 *tions, or exposures;*

13 (3) *that provides feedback to participants who*
14 *submit reports to the repository;*

15 (4) *that meets standards for data quality includ-*
16 *ing—*

17 (A) *systematically collecting clinical and*
18 *other health care data, using standardized data*
19 *elements and has procedures in place to verify*
20 *the completeness and validity of those data; and*

21 (B) *being subject to regular data checks or*
22 *audits to verify completeness and validity; and*

23 (5) *that provides ongoing participant training*
24 *and support.*

1 (c) *TREATMENT OF HEALTH INFORMATION TECH-*
2 *NOLOGY DEVELOPERS WITH RESPECT TO PATIENT SAFETY*
3 *ORGANIZATIONS.—*

4 (1) *IN GENERAL.—In applying part C of title IX*
5 *of the Public Health Service Act (42 U.S.C. 299b-21*
6 *et seq.), a health information technology developer*
7 *shall be treated as a provider (as defined in section*
8 *921 of such Act) for purposes of reporting and con-*
9 *ducting patient safety activities concerning improv-*
10 *ing clinical care through the use of health information*
11 *technology that could result in improved patient safe-*
12 *ty, health care quality, or health care outcomes.*

13 (2) *REPORT.—Not later than 48 months after the*
14 *date of enactment of this Act, the Secretary of Health*
15 *and Human Services shall submit to the Committee*
16 *on Health, Education, Labor, and Pension of the Sen-*
17 *ate and the Committee on Energy and Commerce of*
18 *the House of Representatives, a report concerning best*
19 *practices and current trends voluntarily provided,*
20 *and without identifying individual providers or dis-*
21 *closing or using protected health information or indi-*
22 *vidually identifiable information, by Patient Safety*
23 *Organizations to improve the integration of health in-*
24 *formation technology into clinical practice.*

1 **SEC. 7. EMPOWERING PATIENTS AND IMPROVING PATIENT**
2 **ACCESS TO THEIR ELECTRONIC HEALTH IN-**
3 **FORMATION.**

4 (a) *USE OF HEALTH INFORMATION EXCHANGES FOR*
5 *PATIENT ACCESS.*—Section 3009 of the Public Health Serv-
6 ice Act (42 U.S.C. 300jj-19) is amended by adding at the
7 end the following:

8 “(c) *PROMOTING PATIENT ACCESS TO ELECTRONIC*
9 *HEALTH INFORMATION THROUGH HEALTH INFORMATION*
10 *EXCHANGES.*—

11 “(1) *IN GENERAL.*—The National Coordinator,
12 in coordination with the Office for Civil Rights of the
13 Department of Health and Human Services, shall use
14 existing authorities to encourage partnerships between
15 health information exchange organizations and net-
16 works and health care providers, health plans, and
17 other appropriate entities to offer patients access to
18 their electronic health information in a single, longi-
19 tudinal format that is easy to understand, secure, and
20 may update such information automatically.

21 “(2) *EDUCATION OF PROVIDERS.*—The National
22 Coordinator, in coordination with the Office for Civil
23 Rights of the Department of Health and Human
24 Services, shall—

25 “(A) educate health care providers on ways
26 in which to leverage the capabilities of health in-

1 *formation exchanges (or other relevant plat-*
2 *forms) to provide patients with access to their*
3 *electronic health information;*

4 “(B) *clarify misunderstandings by health*
5 *care providers about using health information*
6 *exchanges (or other relevant platforms) for pa-*
7 *tient access to electronic health information; and*

8 “(C) *to the extent practicable, educate pro-*
9 *viders about health information exchanges (or*
10 *other relevant platforms) that employ some or all*
11 *of the capabilities described in paragraph (1).*

12 “(3) *REQUIREMENTS.—In carrying out para-*
13 *graph (1), the National Coordinator, in coordination*
14 *with the Office for Civil Rights, shall issue guidance*
15 *to health information exchanges related to best prac-*
16 *tices to ensure that the electronic health information*
17 *provided to patients is—*

18 “(A) *private and secure;*

19 “(B) *accurate;*

20 “(C) *verifiable; and*

21 “(D) *where a patient’s authorization to ex-*
22 *change is required by law, easily exchanged pur-*
23 *suant to such authorization.*

24 “(4) *RULE OF CONSTRUCTION.—Nothing in this*
25 *subsection shall be construed to preempt State laws*

1 *applicable to patient consent for the access of infor-*
2 *mation through a Health Information Exchange (or*
3 *other relevant platforms) that provide protections to*
4 *patients that are greater than the protections other-*
5 *wise provided for under applicable Federal law.*

6 “(d) *EFFORTS TO PROMOTE ACCESS TO HEALTH IN-*
7 *FORMATION.—The National Coordinator and the Office for*
8 *Civil Rights of the Department of Health and Human Serv-*
9 *ices shall jointly, through the development of policies that*
10 *support dynamic technology solutions, promote patient ac-*
11 *cess to health information in a manner that would ensure*
12 *that such information is available in a form convenient for*
13 *the patient, in a reasonable manner, and without burdening*
14 *the health care provider involved.*

15 “(e) *ACCESSIBILITY OF PATIENT RECORDS.—*

16 “(1) *ACCESSIBILITY AND UPDATING OF INFORMA-*
17 *TION.—*

18 “(A) *IN GENERAL.—The Secretary, in con-*
19 *sultation with the National Coordinator, shall*
20 *promote policies that ensure that a patient’s elec-*
21 *tronic health information is accessible to that*
22 *patient, and their designees, in a manner that*
23 *facilitates communication with the patient’s*
24 *health care providers and such patient’s consent,*
25 *including with respect to research.*

1 “(B) *UPDATING EDUCATION ON ACCESSING*
2 *AND EXCHANGING PERSONAL HEALTH INFORMA-*
3 *TION.—To promote awareness that an individual*
4 *has a right of access to inspect, obtain a copy of,*
5 *and transmit to a third party a copy of pro-*
6 *ected health information pursuant to the Health*
7 *Information Portability and Accountability Act*
8 *Privacy Rule (45 CFR 164.524 et seq.), the Di-*
9 *rector of the Office for Civil Rights, in consulta-*
10 *tion with the National Coordinator, shall assist*
11 *individuals and health care providers in under-*
12 *standing a patient’s rights to access and protect*
13 *their personal health information under the*
14 *Health Insurance Portability and Accountability*
15 *Act of 1996 (Public Law 104–191), including*
16 *providing best practices for requesting personal*
17 *health information in a computable format, in-*
18 *cluding using patient portals or third-party ap-*
19 *plications and common cases when a provider is*
20 *permitted to exchange and provide access to*
21 *health information.*

22 “(2) *CERTIFYING USABILITY FOR PATIENTS.—In*
23 *carrying out certification programs under section*
24 *3001(c)(5), the National Coordinator shall require,*

1 *where applicable, that such program or programs re-*
2 *quire the following:*

3 “(A) *That certification criteria support pa-*
4 *tient access to their electronic health informa-*
5 *tion, including in a single longitudinal format*
6 *that is easy to understand, secure, and may be*
7 *updated automatically.*

8 “(B) *That developers of health information*
9 *technology support patient access to an electronic*
10 *health record in a longitudinal format that is*
11 *easy to understand, secure, and may be updated*
12 *automatically.*

13 “(C) *That certification criteria support pa-*
14 *tient access to their personal electronic health in-*
15 *formation for research at the option of the pa-*
16 *tient.*

17 “(D) *That certification criteria support pa-*
18 *tient and health care provider communication,*
19 *including—*

20 “(i) *the ability for the patient to elec-*
21 *tronically communicate patient reported in-*
22 *formation (such as family history and med-*
23 *ical history); and*

1 “(ii) the ability for the patient to elec-
2 tronically share patient health information,
3 at the option of the patient.

4 “(E) That certified health information tech-
5 nology used for health programs where certified
6 health information technology is required, in-
7 clude the function for patient access to their own
8 health information, including—

9 “(i) ensuring that, as a condition of
10 certification, health care providers have op-
11 tions for making such information accessible
12 for patients;

13 “(ii) ensuring that patients have op-
14 tions for accessing such information; and

15 “(iii) ensuring that patients have ac-
16 cess to information regarding their legal
17 rights and responsibilities, as well the op-
18 tions available to them for accessing their
19 electronic health information.

20 “(F) That the HIT Standards Committee
21 develop and prioritize standards, implementa-
22 tion specifications, and certification criteria re-
23 quired to help support patient access to elec-
24 tronic health information, patient usability, and
25 support for technologies that offer patients access

1 to their electronic health information in a single,
2 longitudinal format that is easy to understand,
3 secure, and may be updated automatically.”.

4 (b) *ACCESS TO INFORMATION IN AN ELECTRONIC FOR-*
5 *MAT.*—Section 13405(e) of the Health Information Tech-
6 *nology for Economic and Clinical Health Act (42 U.S.C.*
7 *17935) is amended—*

8 (1) in paragraph (1), by striking “and” at the
9 end;

10 (2) by redesignating paragraph (2) as para-
11 graph (3); and

12 (3) by inserting after paragraph (1), the fol-
13 lowing:

14 “(2) if the individual makes a request to a busi-
15 ness associate for access to, or a copy of, protected
16 health information about the individual, or if an in-
17 dividual makes a request to a business associate to
18 grant such access to, or transmit such copy directly
19 to, a person or entity designated by the individual, a
20 business associate may provide the individual with
21 such access or copy, which may be in an electronic
22 form, or grant or transmit such access or copy to such
23 person or entity designated by the individual; and”.

1 **SEC. 8. GAO STUDY ON PATIENT MATCHING.**

2 (a) *IN GENERAL.*—Not later than 1 year after the date
3 of enactment of this Act, the Comptroller General of the
4 United States shall conduct a study to review the policies
5 and activities of the Office of the National Coordinator for
6 Health Information Technology and other relevant stake-
7 holders to ensure appropriate patient matching to protect
8 patient privacy and security with respect to electronic
9 health records and the exchange of electronic health infor-
10 mation.

11 (b) *AREAS OF CONCENTRATION.*—In conducting the
12 study under subsection (a), the Comptroller General shall—

13 (1) evaluate current methods used in certified
14 electronic health records for patient matching based
15 on performance related to factors such as—

16 (A) the privacy of patient information;

17 (B) the security of patient information;

18 (C) improving matching rates;

19 (D) reducing matching errors; and

20 (E) reducing duplicate records; and

21 (2) determine whether the Office of the National
22 Coordinator for Health Information Technology could
23 improve patient matching by taking steps includ-
24 ing—

25 (A) defining additional data elements to as-
26 sist in patient data matching;

1 (B) agreeing on a required minimum set of
2 elements that need to be collected and exchanged;

3 (C) requiring electronic health records to
4 have the ability to make certain fields required
5 and use specific standards; or

6 (D) other options recommended by the rel-
7 evant stakeholders consulted pursuant to sub-
8 section (a).

9 (c) *REPORT.*—Not later than 2 years after the date of
10 enactment of this Act, the Comptroller General shall submit
11 to the appropriate committees of Congress a report con-
12 cerning the findings of the study conducted under subsection
13 (a).

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114TH CONGRESS
2^D SESSION

S. 2511

A BILL

To improve Federal requirements relating to the development and use of electronic health records technology.

APRIL 5, 2016

Reported with an amendment