

114TH CONGRESS
2D SESSION

S. _____

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

IN THE SENATE OF THE UNITED STATES

_____ introduced the following bill; which was read twice
and referred to the Committee on _____

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”.

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

8 (a) IN GENERAL.—Part 1 of subtitle A of title XIII
9 of the Health Information Technology for Economic and

1 Clinical Health Act (Public Law 111-5) is amended by
2 adding at the end the following:

3 **“SEC. 13103. ASSISTING DOCTORS AND HOSPITALS IN IM-**
4 **PROVING THE QUALITY OF CARE FOR PA-**
5 **TIENTS.**

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

15 “(1) establish a goal with respect to the reduc-
16 tion of regulatory or administrative burdens (such as
17 documentation requirements) relating to the use of
18 electronic health records;

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

21 “(3) develop recommendations for meeting the
22 goal established under paragraph (1).

23 “(b) STRATEGY AND RECOMMENDATIONS.—

24 “(1) IN GENERAL.—To achieve the goals estab-
25 lished under subsection (a)(1), the Secretary, in con-

1 sultation with the entities described in such sub-
2 section, shall, not later than 12 months after the
3 date of enactment of this section, develop a strategy
4 and recommendations to meet the goals in accord-
5 ance with this subsection.

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

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

19 “(B) health information technology certifi-
20 cation programs;

21 “(C) standards, and implementation speci-
22 fications, as appropriate;

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

1 “(E) activities related to protecting the
2 privacy of electronic health information;

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

5 “(G) activities related to facilitating health
6 and clinical research;

7 “(H) activities related to public health;

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

11 “(J) activities related to reporting clinical
12 data for administrative purposes; and

13 “(K) other areas determined appropriate
14 by the Secretary;

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

17 “(A) actions that improve the clinical doc-
18 umentation experience;

19 “(B) actions that improve patient care;

20 “(C) actions to be taken by the Secretary
21 and by other entities; and

22 “(D) other areas determined appropriate
23 by the Secretary to reduce the reporting burden
24 required of health care providers.

1 under subparagraph (A) for use in medical
2 specialties and sites of service for which no
3 such technology is available or where more
4 technological advancement or integration is
5 needed.

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

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

1 (under section 3004) to support the vol-
2 untary certification of health information
3 technology for use by pediatric health pro-
4 viders to support the health care of chil-
5 dren.”.

6 (c) MEANINGFUL USE STATISTICS.—

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

23 (2) AUTHORITY TO ALTER FORMAT.—The Sec-
24 retary of Health and Human Service may alter the
25 format of the reports on the attestation of eligible

1 health care professionals following the first perform-
2 ance year of the Merit-based Incentive Payment Sys-
3 tem to account for changes arising from the imple-
4 mentation of such payment system.

5 **SEC. 3. TRANSPARENT RATINGS ON USABILITY AND SECU-**
6 **RITY TO TRANSFORM INFORMATION TECH-**
7 **NOLOGY.**

8 (a) ENHANCEMENTS TO CERTIFICATION.—Section
9 3001(c)(5) of the Public Health Service Act (42 U.S.C.
10 300jj–11), as amended by section 2(b), is further amend-
11 ed—

12 (1) in subparagraph (A)—

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

15 “(i) VOLUNTARY CERTIFICATION PRO-
16 GRAM.—The National Coordinator”; and

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

18 “(ii) TRANSPARENCY OF PROGRAM.—

19 “(I) IN GENERAL.—To enhance
20 transparency in the compliance of
21 health information technology with
22 certification criteria and other re-
23 quirements adopted under this sub-
24 title, the National Coordinator, in co-
25 ordination with authorized certifi-

1 cation bodies, may make information
2 demonstrating how health information
3 technology meets such certification
4 criteria or other requirements publicly
5 available. Such information may in-
6 clude summaries, screenshots, video
7 demonstrations, or any other informa-
8 tion the National Coordinator deter-
9 mines appropriate.

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

19 (2) in subparagraph (B), by adding at the end
20 the following: “Beginning 18 months after reporting
21 criteria are finalized under section 3009A, certifi-
22 cation criteria shall include, in addition to criteria to
23 establish that the technology meets such standards
24 and implementation specifications, criteria consistent
25 with section 3009A(b) to establish that technology

1 meets applicable security requirements, incorporates
2 user-centered design, and achieves interoperability.”;
3 and

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

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

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

17 “(ii) the health information tech-
18 nology developer or entity permits
19 unimpeded communication among and be-
20 tween health information technology users,
21 and for the purposes of health information
22 technology users communicating with an
23 authorized certification body, the Office of
24 the National Coordinator, and the Office of
25 the Inspector General, the health informa-

1 “(v) the health information technology
2 developer or entity submits reporting cri-
3 teria in accordance with section
4 3009A(f).”.

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

9 **“SEC. 3009A. HEALTH INFORMATION TECHNOLOGY RATING**
10 **PROGRAM.**

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

25 “(b) REPORTING CRITERIA.—

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

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

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

18 “(A) health care providers, including pri-
19 mary care and specialty care health care profes-
20 sionals;

21 “(B) hospitals and hospital systems;

22 “(C) health information technology devel-
23 opers;

24 “(D) patients, consumers, and their advo-
25 cates;

1 “(E) data sharing networks, such as health
2 information exchanges;

3 “(F) authorized certification bodies and
4 testing laboratories;

5 “(G) security experts;

6 “(H) relevant manufacturers of medical
7 devices;

8 “(I) experts in health information tech-
9 nology market economics;

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

13 “(K) quality organizations, including the
14 consensus based entity described in section
15 1890 of the Social Security Act;

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

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

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

1 “(A) shall include measures that reflect
2 categories including, with respect to the tech-
3 nology—

4 “(i) security;

5 “(ii) usability and user-centered de-
6 sign;

7 “(iii) interoperability;

8 “(iv) conformance to certification test-
9 ing; and

10 “(v) other categories as appropriate to
11 measure the performance of health infor-
12 mation technology;

13 “(B) may include measures such as—

14 “(i) enabling the user to order and
15 view the results of laboratory tests, imag-
16 ing tests, and other diagnostic tests;

17 “(ii) submitting, editing, and retriev-
18 ing data from registries such as clinician-
19 led clinical data registries;

20 “(iii) accessing and exchanging infor-
21 mation and data from and through Health
22 Information Exchanges;

23 “(iv) accessing and exchanging infor-
24 mation and data from medical devices;

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

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

10 “(vii) accessing and exchanging pa-
11 tient generated information;

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

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

20 “(x) other appropriate functionalities;
21 and

22 “(C) shall be designed to ensure that small
23 and start-up health information technology de-
24 velopers are not unduly disadvantaged by the
25 reporting criteria or rating scale methodology.

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

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

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

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

24 “(c) FEEDBACK.—

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

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

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

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

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

1 subsection (c). In developing such methodology, the Sec-
2 retary, in consultation with the development council,
3 shall—

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

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

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

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

21 “(5) establish a timeframe for incorporating
22 user feedback submitted under subsection (e) and
23 reporting criteria submitted under subsection (f)
24 into the star ratings for certified health information
25 technology that accounts for updates to such tech-

1 nology in order to encourage innovation and maxi-
2 mize the utility of the star ratings.

3 “(e) MODIFICATIONS.—

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

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

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

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

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(c)(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 re-determine such recognition
20 at 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(c) of the Public Health Service
8 Act (42 U.S.C. 300jj-11(c)) 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 non-compliance with the
24 terms of the common agreement.

1 “(ii) TECHNICAL ASSISTANCE.—The
2 National Coordinator, in conjunction with
3 National Institute of Standards and Tech-
4 nology, shall provide technical assistance
5 on how to implement the trusted exchange
6 framework and common agreement under
7 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 disrup-
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 (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” 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 sec-
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 sion 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 CFR 164.524
17 et seq.), the Director of the Office for Civil
18 Rights, in consultation with the National Coor-
19 dinator, shall assist individuals and health care
20 providers in understanding a patient’s rights to
21 access and protect their personal health infor-
22 mation under the Health Insurance Portability
23 and Accountability Act of 1996 (Public Law
24 104–191), including providing best practices for
25 requesting personal health information in a

1 computable format, including using patient por-
2 tals or third-party applications and common
3 cases when a provider is permitted to exchange
4 and provide access to health information.

5 “(2) CERTIFYING USABILITY FOR PATIENTS.—

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

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

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

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