

114TH CONGRESS
1ST SESSION

S. 2141

To amend the Public Health Service Act with respect to health information technology.

IN THE SENATE OF THE UNITED STATES

OCTOBER 6, 2015

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

A BILL

To amend the Public Health Service Act with respect to health information 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 “Transparent Ratings
5 on Usability and Security to Transform Information Tech-
6 nology Act of 2015” or the “TRUST IT Act”.

7 **SEC. 2. DEFINITIONS.**

8 Section 3000 of the Public Health Service Act (42
9 U.S.C. 300jj) is amended—

1 (1) by redesignating paragraphs (10) through
2 (14) as paragraphs (12) through (16), respectively;
3 and

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

6 “(10) INFORMATION BLOCKING.—The term ‘in-
7 formation blocking’ means, with respect to the devel-
8 opment, configuration, implementation, and use of
9 qualified electronic health records and other health
10 information technology, business, technical, and or-
11 ganizational practices that—

12 “(A) except as required by law, prevent or
13 materially discourage the access, exchange, or
14 use of electronic health information; and

15 “(B) the person knows or should know (as
16 defined in section 1128A(i)(7) of the Social Se-
17 curity Act) are likely to interfere with the ac-
18 cess, exchange, or use of electronic health infor-
19 mation.

20 “(11) INTEROPERABILITY.—The term ‘inter-
21 operability’ means the ability of 2 or more health in-
22 formation systems or components to exchange clin-
23 ical and other information and to use the informa-
24 tion that has been exchanged using common stand-
25 ards to provide access to longitudinal or requested

1 information to health care providers, patients, and
2 other authorized users when such persons need such
3 information in order to facilitate coordinated care
4 and improved patient outcomes.”.

5 **SEC. 3. ENHANCEMENTS TO TESTING AND CERTIFICATION.**

6 Section 3001(c)(5) of the Public Health Service Act
7 (42 U.S.C. 300jj–11) is amended—

8 (1) in subparagraph (A)—

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

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

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

14 “(ii) TRANSPARENCY OF PROGRAM.—

15 “(I) IN GENERAL.—To enhance
16 transparency in the compliance of
17 health information technology with
18 certification criteria adopted under
19 this subtitle, the National Coordi-
20 nator, in coordination with authorized
21 certification bodies, may make infor-
22 mation demonstrating how health in-
23 formation technology meets such cer-
24 tification criteria publicly available.
25 Such information may include sum-

1 maries, screenshots, video demonstra-
2 tions, or any other information the
3 National Coordinator determines ap-
4 propriate.

5 “(II) PROTECTION OF PROPRI-
6 ETARY INFORMATION.—Nothing in
7 this paragraph shall be construed to
8 require the release of trade secrets or
9 any other protected intellectual prop-
10 erty.”;

11 (2) in subparagraph (B), by adding at the end
12 the following: “Beginning 18 months after reporting
13 criteria are finalized under section 3009A, certifi-
14 cation criteria shall include, in addition to criteria to
15 establish that the technology meets such standards
16 and implementation specifications, criteria consistent
17 with section 3009A(b) to establish that technology
18 meets applicable security requirements, incorporates
19 user-centered design, and achieves interoperability.”;
20 and

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

22 “(C) CONDITIONS OF CERTIFICATION.—
23 Beginning 1 year after the date of enactment of
24 the TRUST IT Act, the Secretary shall require
25 that each vendor of health information tech-

1 nology and entity seeking certification of health
2 information technology, as a condition of certifi-
3 cation and maintenance of certification of such
4 technology, provide to the Secretary an attesta-
5 tion that—

6 “(i) the vendor or entity, unless for a
7 legitimate purpose specified by the Sec-
8 retary, has not taken and will not take any
9 action that constitutes information block-
10 ing with respect to health information
11 technology;

12 “(ii) the vendor or entity will not en-
13 gage in business practices or impose bind-
14 ing business relationship obligations that
15 seek to intentionally limit communication
16 between health information technology
17 users and an authorized certification body
18 regarding the usability, interoperability, se-
19 curity, business practices, or other relevant
20 information about the health information
21 technology or users’ experience with the
22 health information technology; and

23 “(iii) health information from such
24 technology may be exchanged, accessed,
25 and used through the use of application

1 programming interfaces and other stand-
2 ards without special effort, as authorized
3 under applicable law.

4 “(D) INSPECTOR GENERAL AUTHORITY.—

5 “(i) IN GENERAL.—The Inspector
6 General of the Department of Health and
7 Human Services may investigate any claim
8 that—

9 “(I) a vendor of, or other entity
10 offering, certified health information
11 technology—

12 “(aa) violated an attestation
13 made under subparagraph (C); or

14 “(bb) engaged in informa-
15 tion blocking with respect to the
16 use of such health information
17 technology by a health care pro-
18 vider, unless for a legitimate pur-
19 pose specified by the Secretary;

20 “(II) a health care provider en-
21 gaged in information blocking with re-
22 spect to the use of certified health in-
23 formation technology, unless for a le-
24 gitimate purpose specified by the Sec-
25 retary;

1 “(III) a health information sys-
2 tem provider engaged in information
3 blocking with respect to the use of
4 such certified health information tech-
5 nology, unless for a legitimate purpose
6 specified by the Secretary.

7 “(ii) PENALTY.—Any person or entity
8 determined by the Inspector General to
9 have committed an act described in sub-
10 clause (I), (II), or (III) of clause (i) shall
11 be subject to a civil monetary penalty of
12 not more than \$10,000 for each such act.
13 The provisions of section 1128A of the So-
14 cial Security Act (other than subsections
15 (a) and (b)) shall apply to a civil money
16 penalty applied under this subsection in
17 the same manner as such provisions apply
18 to a civil money penalty or proceeding
19 under section 1128A(a).”.

20 **SEC. 4. HEALTH INFORMATION TECHNOLOGY RATING PRO-**
21 **GRAM.**

22 Subtitle A of title XXX of the Public Health Service
23 Act (42 U.S.C. 300jj–11 et seq.) is amended by adding
24 at the end the following:

1 **“SEC. 3009A. HEALTH INFORMATION TECHNOLOGY RATING**
2 **PROGRAM.**

3 “(a) ESTABLISHMENT.—Not later than 180 days
4 after the date of enactment of the TRUST IT Act, the
5 Secretary shall recognize a development council made up
6 of one representative from each of the accredited certifying
7 bodies accredited by the Office and the testing laboratories
8 accredited under section 13201(b) of the Health Informa-
9 tion Technology for Economic and Clinical Health Act (42
10 U.S.C. 17911(b)), and one representative from the Office
11 of the National Coordinator, for the purpose of estab-
12 lishing a health information technology rating program to
13 evaluate, based on the methodology established under sub-
14 section (d), the field performance of certified health infor-
15 mation technology with regard to interoperability,
16 usability, and security, in accordance with the following:

17 “(1) 1 STAR RATING.—Certified health informa-
18 tion technology shall receive a 1 star rating if an au-
19 thorized certification body determines that the
20 health information technology is less than satisfac-
21 tory.

22 “(2) 2 STAR RATING.—Certified health informa-
23 tion technology shall receive a 2 star rating if the
24 authorized certification body determines that the
25 health information technology is satisfactory.

1 “(3) 3 STAR RATING.—Certified health informa-
2 tion technology shall receive a 3 star rating if the
3 authorized certification body determines that the
4 health information technology is excellent.

5 “(b) REPORTING CRITERIA.—

6 “(1) Not later than 1 year after the date of en-
7 actment of the TRUST IT Act, the Secretary, in
8 consultation with the development council described
9 in subsection (a), shall convene stakeholders as de-
10 scribed in paragraph (2) for the purpose of devel-
11 oping the reporting criteria in accordance with para-
12 graph (3).

13 “(2) 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) primary care and specialty care
19 health care professionals;

20 “(B) hospitals;

21 “(C) health information technology ven-
22 dors;

23 “(D) advocates for patients or consumers;

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

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

3 “(G) security experts; and

4 “(H) other entities or persons, as the Sec-
5 retary, in consultation with the development
6 council, determines appropriate.

7 “(3) CONSIDERATIONS FOR REPORTING CRI-
8 TERIA.—The reporting criteria developed under this
9 subsection—

10 “(A) may include measures that reflect
11 categories including, with respect to the tech-
12 nology—

13 “(i) security;

14 “(ii) usability and user-centered de-
15 sign;

16 “(iii) interoperability;

17 “(iv) conformance to certification test-
18 ing; and

19 “(v) other categories as appropriate to
20 measure the performance of health infor-
21 mation technology;

22 “(B) may include measures such as—

23 “(i) enabling the user to order and
24 view the results of laboratory tests, imag-
25 ing tests, and other diagnostic tests;

1 “(ii) submitting, editing, and retriev-
2 ing data from registries for quality of care,
3 such as physician registries;

4 “(iii) accessing and exchanging infor-
5 mation and data from medical devices;

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

12 “(v) accessing and exchanging infor-
13 mation from other health care providers or
14 applicable users;

15 “(vi) accessing and exchanging pa-
16 tient generated information;

17 “(vii) providing the patient with a
18 complete copy of their electronic record in
19 a computable format; and

20 “(viii) other appropriate functionali-
21 ties; and

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

1 “(4) PUBLIC COMMENT.—The Secretary shall
2 conduct a 60-day public comment period during
3 which any member of the public may provide com-
4 ments on the proposed reporting criteria and the
5 methodology for authorized certification bodies to
6 use in determining the star ratings. The Secretary
7 shall provide timely responses to such comments be-
8 fore issuing a final rule.

9 “(5) MODIFICATIONS.—After the reporting cri-
10 teria have been established, the Secretary, in con-
11 sultation with the development council, may convene
12 stakeholders and conduct a public reporting period
13 for the purpose of modifying the reporting criteria
14 developed in this subsection and methodology for de-
15 termining the star ratings proposed under subsection
16 (d).

17 “(6) CONSIDERATION OF DEVELOPMENT COUN-
18 CIL RECOMMENDATIONS.—In promulgating final
19 rules under this subsection, including modifications
20 to such rules under paragraph (5), the Secretary
21 may accept or reject the recommendations of the de-
22 velopment council, but may not promulgate a rule
23 that does not represent a complete recommendation
24 of such council.

1 “(c) COLLECTION OF FEEDBACK.—The Secretary, in
2 consultation with the development council, shall establish
3 a process for authorized certification bodies to collect and
4 verify confidential feedback from—

5 “(1) health care providers, patients, and other
6 users of health information technology on the
7 usability, security, and interoperability of health in-
8 formation technology products; and

9 “(2) vendors or other entities offering health in-
10 formation technology on practices of health informa-
11 tion technology users that may inhibit interoper-
12 ability.

13 “(d) METHODOLOGY.—The Secretary, in consulta-
14 tion with the development council, shall develop a method-
15 ology for authorized certification bodies to use to calculate
16 the star ratings for certified health information technology
17 described in subsection (a). The methodology shall use the
18 reporting criteria developed in subsection (b) and con-
19 fidential feedback collected under subsection (c).

20 “(e) PARTICIPATION.—Each vendor of, or entity of-
21 fering, health information technology that is certified
22 under section 3001(c)(5) of the Public Health Service Act
23 after the date of enactment of the TRUST IT Act shall
24 report on the criteria developed under subsection (b) on

1 the date that is 2 years after such certification and every
2 2 years thereafter.

3 “(f) ONE STAR RATING.—Each vendor of, or entity
4 offering, health information technology that receives a 1
5 star rating shall take action, through a corrective action
6 plan developed with the authorized certification body and
7 approved by the Secretary, to improve the health informa-
8 tion technology rating within a timeframe that the Sec-
9 retary determines appropriate.

10 “(g) ENFORCEMENT AUTHORITIES.—

11 “(1) IN GENERAL.—The Secretary may assess
12 fines on any vendor of, or entity offering, certified
13 health information technology and decertify health
14 information technology in accordance with para-
15 graphs (2) and (3).

16 “(2) FINES.—

17 “(A) IN GENERAL.—The Secretary may
18 assess fines against such a vendor or entity if
19 the vendor or entity—

20 “(i) does not meet the requirements of
21 the corrective action plan described in sub-
22 section (f);

23 “(ii) does not improve from a one star
24 rating in accordance with subsection (f); or

1 “(iii) does not report on criteria in ac-
2 cordance with subsection (e).

3 “(B) FINE AMOUNTS.—Not later than 1
4 year after the date of enactment of the TRUST
5 IT Act, the Secretary shall establish fine
6 amounts for violations of clauses (i), (ii), and
7 (iii) of subparagraph (A). In setting such
8 amounts, the Secretary shall consider the
9 amounts necessary to reimburse, in part or in
10 full, the users of decertified health information
11 technology for the amounts invested in pur-
12 chasing new certified health information tech-
13 nology, as applicable.

14 “(3) DECERTIFICATION.—The Secretary may
15 decertify health information technology if—

16 “(A) the health information technology
17 does not improve from a one star rating within
18 the timeframe established under subsection (f);

19 “(B) does not report on criteria in accord-
20 ance with subsection (b); or

21 “(C) in other circumstances, as the Sec-
22 retary determines appropriate.

23 “(h) GAO REPORTS.—The Comptroller General of
24 the United States shall submit to Congress a report every
25 4 years on the rating scale methodology developed pursu-

1 ant to subsection (b), providing observations on the appro-
2 priateness of the current methodology and recommenda-
3 tions for changes to the methodology.

4 “(i) INTERNET WEBSITE.—The Secretary shall pub-
5 lish the star rating for each certified health information
6 technology and methodology to determine the star rating
7 on the Internet website of the Office of the National Coor-
8 dinator. Following the biannual reporting described in
9 subsection (e), authorized certified bodies shall have 30
10 days to calculate and submit updated ratings to the Sec-
11 retary, and updated ratings shall be published on such
12 Internet website not later than 30 days following such sub-
13 mission.

14 “(j) USER COMPENSATION FUND.—The Secretary
15 shall establish a revolving user compensation fund in
16 which amounts collected under subsection (g)(2) shall be
17 directed and used to assist users of health information
18 technology that are decertified under subsection (g)(3) to
19 reimburse users for the costs of purchasing new certified
20 health information technology products.

21 “(k) HARDSHIP EXEMPTION.—The Secretary shall,
22 on a case-by-case basis, exempt an eligible professional,
23 eligible hospital, or critical access hospital from the appli-
24 cation of the payment adjustment under the Meaningful
25 Use of Certified EHR Technology program under sections

1 1848(a)(7)(A), 1886(b)(3)(B)(ix)(I), and 1814(l)(4), re-
 2 spectively, of the Social Security Act for 1 year if the eligi-
 3 ble professional, eligible hospital, or critical access hospital
 4 uses health information technology that becomes decerti-
 5 fied under subsection (g)(3), to help such eligible profes-
 6 sional, eligible hospital, or critical access hospital transi-
 7 tion to a new certified electronic health record technology.

8 “(1) APPEALS.—The Secretary shall establish a proc-
 9 ess whereby any vendor of, or entity offering, health infor-
 10 mation technology can appeal—

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

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

15 **SEC. 5. UPDATING INFORMATION ON ACCESSING PER-**
 16 **SONAL HEALTH INFORMATION.**

17 Subtitle A of title XXX of the Public Health Service
 18 Act (42 U.S.C. 300jj–11 et seq.), as amended by section
 19 4, is further amended by adding at the end the following:

20 **“SEC. 3009B. UPDATING INFORMATION ON ACCESSING PER-**
 21 **SONAL HEALTH INFORMATION.**

22 “The National Coordinator, in consultation with the
 23 Director of the Office of Civil Rights, shall, as appro-
 24 priate, update the Internet website of the Office with in-
 25 formation to assist individuals in understanding their

1 rights to access and protect their personal health informa-
2 tion under the Health Insurance Portability and Account-
3 ability Act of 1996 (Public Law 104–191), including best
4 practices for requesting their personal health information
5 in a computable format and using patient portals, among
6 other information.”.

