

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

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the “Transparent Ratings on Usability and Security to Transform Information Technology (TRUST IT) Act of 2015”.

SEC. 2. DEFINITIONS.

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

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

(2) by inserting after paragraph (9) the following:

“(10) INFORMATION BLOCKING.—The term ‘information blocking’ means, with respect to the development, configuration, implementation, and use of qualified electronic health records and other qualified health information technology, business, technical, and organizational practices that—

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

“(B) the person knows or should know (as defined in section 1128A(i)(7) of the Social Security Act) are likely to interfere with the access, exchange, or use of electronic health information.

“(11) INTEROPERABILITY.—The term ‘interoperability’ means the ability of 2 or more health information systems or components to exchange clinical and other information and to use the information that has been exchanged using common standards to provide access to longitudinal or requested information to health care providers, patients, and other authorized users when such persons need such information in order to facilitate coordinated care and improved patient outcomes.”.

SEC. 3. ENHANCEMENTS TO TESTING AND CERTIFICATION.

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

(1) in subparagraph (A)—

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

“(i) VOLUNTARY CERTIFICATION PROGRAM.—The National Coordinator”; and

(B) by adding at the end the following:

“(ii) TRANSPARENCY OF PROGRAM.—

1 “(I) IN GENERAL.—To enhance transparency in the compliance of health
2 information technology with certification criteria adopted under this subtitle,
3 the National Coordinator, in coordination with authorized certification
4 bodies, may make information demonstrating how health information
5 technology meets such certification criteria publicly available. Such
6 information may include summaries, screenshots, video demonstrations, or
7 any other information the National Coordinator determines appropriate.

8 “(II) PROTECTION OF PROPRIETARY INFORMATION.—Nothing in this
9 paragraph shall be construed to require the release of trade secrets or any
10 other protection intellectual property.”;

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

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

18 “(C) CONDITIONS OF CERTIFICATION.—Beginning 1 year after the date of enactment
19 of the TRUST IT Act of 2015, the Secretary shall require that each vendor of health
20 information technology and entity seeking certification of health information
21 technology, as a condition of certification and maintenance of certification of such
22 technology, provide to the Secretary an attestation that—

23 “(i) the vendor or entity, unless for a legitimate purpose specified by the
24 Secretary, has not taken and will not take any action that constitutes information
25 blocking with respect to health information technology;

26 “(ii) the vendor or entity will not engage in business practices or impose
27 binding business relationship obligations that seek to intentionally limit
28 communication between health information technology users and an authorized
29 certification body regarding the usability, interoperability, security, business
30 practices, or other relevant information about the health information technology
31 or users’ experience with the health information technology; and

32 “(iii) health information from such technology may be exchanged, accessed,
33 and used through the use of application programming interfaces and other
34 standards without special effort, as authorized under applicable law.

35 “(D) INSPECTOR GENERAL AUTHORITY.—

36 “(i) IN GENERAL.—The Inspector General of the Department of Health and
37 Human Services may investigate any claim that—

38 “(I) a vendor of, or other entity offering, certified health information
39 technology—

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

41 “(bb) engaged in information blocking with respect to the use of such

health information technology by a health care provider, unless for a legitimate purpose specified by the Secretary;

“(II) a health care provider engaged in information blocking with respect to the use of certified health information technology, unless for a legitimate purpose specified by the Secretary;

“(III) a health information system provider engaged in information blocking with respect to the use of such certified health information technology, unless for a legitimate purpose specified by the Secretary.

“(ii) PENALTY.—Any person or entity determined by the Inspector General to have committed an act described in subclause (I), (II), or (III) of clause (i) shall be subject to a civil monetary penalty of not more than \$10,000 for each such act. The provisions of section 1128A of the Social Security Act (other than subsections (a) and (b)) shall apply to a civil money penalty applied under this subsection in the same manner as such provisions apply to a civil money penalty or proceeding under section 1128A(a).

SEC. 4. HEALTH INFORMATION TECHNOLOGY RATING PROGRAM.

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

“SEC. 3009A. HEALTH INFORMATION TECHNOLOGY RATING PROGRAM.

“(a) Establishment.—Not later than 6 months after the date of enactment of the TRUST IT Act of 2015, the Secretary shall recognize a development council made up of one representative from each of the authorized certification bodies and authorized testing laboratories and from the Office of the National Coordinator, for the purpose of establishing a health information technology rating program to evaluate, based on the methodology established under subsection (d), the field performance of certified health information technology with regard to interoperability, usability, and security, in accordance with the following:

“(1) 1 STAR RATING.—Certified health information technology shall receive a 1 star rating if an authorized certification body determines that the health information technology is less than satisfactory.

“(2) 2 STAR RATING.—Certified health information technology shall receive a 2 star rating if the authorized certification body determines that the health information technology is satisfactory.

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

“(b) Reporting Criteria.—

“(1) Not later than 1 year after the date of enactment of the TRUST IT Act of 2015, the

1 development council described in subsection (a) shall convene stakeholders as described in
2 paragraph (2) for the purpose of developing the reporting criteria in accordance with
3 paragraph (3).

4 “(2) DEVELOPMENT OF REPORTING CRITERIA.—The reporting criteria under this
5 subsection shall be developed through a public, transparent process that reflects input from
6 relevant stakeholders, including—

7 “(A) primary care and specialty care health care professionals;

8 “(B) hospitals;

9 “(C) health information technology vendors;

10 “(D) advocates for patients or consumers;

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

12 “(F) authorized certification bodies and testing laboratories;

13 “(G) security experts; and

14 “(H) other entities or persons, as the development council determines appropriate.

15 “(3) CONSIDERATIONS FOR REPORTING CRITERIA.—The reporting criteria developed under
16 this subsection—

17 “(A) may include measures that reflect categories including, with respect to the
18 technology—

19 “(i) security;

20 “(ii) usability and user-centered design;

21 “(iii) interoperability;

22 “(iv) conformance to certification testing; and

23 “(v) other categories as appropriate to measure the performance of health
24 information technology;

25 “(B) may include measures such as—

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

28 “(ii) submitting, editing, and retrieving data from registries for quality of care,
29 such as physician registries;

30 “(iii) accessing and exchanging information and data from medical devices;

31 “(iv) accessing and exchanging information and data held by Federal, State,
32 and local agencies and other applicable entities useful to a health care provider or
33 other applicable user in the furtherance of patient care;

34 “(v) accessing and exchanging information from other health care providers or
35 applicable users;

36 “(vi) accessing and exchanging patient generated information;

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

3 “(viii) other appropriate functionalities; and

4 “(C) shall be designed to ensure that small and start up venders of health information
5 technology are not unduly disadvantaged by the reporting criteria or rating scale
6 methodology.

7 “(4) PUBLIC COMMENT.—The development council shall conduct a 60-day public
8 comment period during which any member of the public may provide comments on the
9 proposed reporting criteria and the methodology for authorized certification bodies to use in
10 determining the star ratings. The development council shall provide timely responses to
11 such comments before issuing a final proposal.

12 “(5) MODIFICATIONS.—In future years, the development council may convene
13 stakeholders and conduct a public reporting period for the purpose modifying the reporting
14 criteria developed in this subsection and methodology for determining the star ratings
15 proposed under subsection (d).

16 “(c) Collection of Feedback.—The development council shall establish a process for
17 authorized certification bodies to collect and verify confidential feedback from—

18 “(1) health care providers, patients, and other users of health information technology on
19 the usability, security, and interoperability of health information technology products; and

20 “(2) venders or other entities offering health information technology on practices of
21 health information technology users that may inhibit interoperability.

22 “(d) Methodology.—The development council shall develop a methodology for authorized
23 certification bodies to use to calculate the star ratings for certified health information technology
24 described in subsection (a). The methodology shall use the reporting criteria developed in
25 subsection (b) and confidential feedback collected under subsection (c).

26 “(e) Participation.—Each vender of, or entity offering, health information technology that is
27 certified under section 3001(c)(5) of the Public Health Service Act after the date of enactment of
28 the TRUST IT Act of 2015 shall report on the criteria developed under subsection (b) on the date
29 that is 2 years after such certification and every 2 years thereafter.

30 “(f) One Star Rating.—Each vender of, or entity offering, health information technology that
31 receives a 1 star rating shall take action, through a corrective action plan developed with the
32 authorized certification body and approved by the Secretary, to improve the health information
33 technology rating within a timeframe that the Secretary determines appropriate.

34 “(g) Enforcement Authorities.—

35 “(1) IN GENERAL.—The Secretary may assess fines on any vendor of, or entity offering,
36 certified health information technology and decertify health information technology in
37 accordance with paragraphs (2) and (3).

38 “(2) FINES.—

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

“(i) does not meet the requirements of the corrective action plan described in subsection (f);

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

“(iii) does not report on criteria in accordance with subsection (e).

“(B) FINE AMOUNTS.—Not later than 1 year after the date of enactment of the TRUST IT Act of 2015 the Secretary shall establish fine amounts for violations of clauses (i), (ii), and (iii) of subparagraph (A). In setting such amounts, the Secretary shall consider the amounts necessary to reimburse, in part or in full, the users of decertified health information technology for the amounts invested in purchasing new certified health information technology, as applicable.

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

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

“(B) does not report on criteria in accordance with subsection (b); or

“(C) in other circumstances, as the Secretary determines appropriate.

“(h) GAO Reports.—The Comptroller General of the United States shall submit to Congress a report every 4 years on the rating scale methodology developed pursuant to subsection (b), providing observations on the appropriateness of the current methodology and recommendations for changes to the methodology.

“(i) Internet Website.—The Secretary shall publish the star rating for each certified health information technology and methodology to determine the star rating on the Internet website of the Office of the National Coordinator. Following the biannual reporting described in subsection (e), authorized certified bodies shall have 30 days to calculate and submit updated ratings to the Secretary, and updated ratings shall be published on such Internet website not later than 30 days following such submission.

“(j) User Compensation Fund.—The Secretary shall establish a revolving user compensation fund in which amounts collected under subsection (g)(2) shall be directed and used to assist users of health information technology whose technology was decertified under subsection (g)(3) to reimburse users for the costs of purchasing new certified health information technology products.

“(k) Hardship Exemption.—The Secretary shall, on a case-by-case basis, exempt an eligible professional or eligible hospital from the application of the payment adjustment under the Meaningful Use of Certified EHR Technology program under section 1848(o) of the Social Security Act for 1 year if the eligible professional or eligible hospital uses health information technology that becomes decertified under subsection (g)(3), to help such eligible professional or eligible hospital transition to a new certified electronic health record technology.

“(l) Appeals.—The Secretary shall establish a process whereby any vendor of, or entity offering, health information technology can appeal—

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

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

1 SEC. 5. UPDATING INFORMATION ON ACCESSING
2 PERSONAL HEALTH INFORMATION.

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

5 “SEC. 3009B. UPDATING INFORMATION ON ACCESSING
6 PERSONAL HEALTH INFORMATION.

7 “The National Coordinator, in consultation with the Director of the Office of Civil Rights,
8 shall, as appropriate, update the Internet website of the Office with information to assist
9 individuals in understanding their rights to access and protect their personal health information
10 under the Health Insurance Portability and Accountability Act of 1996 (Public Law 104–191),
11 including best practices for requesting their personal health information in a computable format
12 and using patient portals, among other information.”.
13