

110TH CONGRESS  
1ST SESSION

# H. R. 2991

To improve the availability of health information and the provision of health care by encouraging the creation, use, and maintenance of lifetime electronic health records of individuals in independent health record trusts and by providing a secure and privacy-protected framework in which such records are made available only by the affirmative consent of such individuals and are used to build a nationwide health information technology infrastructure.

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## IN THE HOUSE OF REPRESENTATIVES

JULY 11, 2007

Mr. MOORE of Kansas (for himself, Mr. RYAN of Wisconsin, Mr. BARROW, Mrs. BLACKBURN, Mr. BOUSTANY, Mr. BOYD of Florida, Mrs. BOYDA of Kansas, Mr. CLAY, Mr. CLEAVER, Mr. COOPER, Mr. CROWLEY, Mr. DAVIS of Alabama, Mr. LINCOLN DAVIS of Tennessee, Mr. DELAHUNT, Mr. DICKS, Mrs. EMERSON, Mr. ETHERIDGE, Mr. GRAVES, Mr. HELLER of Nevada, Mr. HERGER, Mr. HILL, Mr. HOLDEN, Mr. HOLT, Mrs. JONES of Ohio, Mr. LARSON of Connecticut, Mrs. MCCARTHY of New York, Mr. MITCHELL, Mr. MORAN of Kansas, Mr. PUTNAM, Mrs. MCMORRIS RODGERS, Mr. SENSENBRENNER, Mr. SESSIONS, Mr. SMITH of Washington, Mrs. TAUSCHER, Mr. TIAHRT, and Mr. BAIRD) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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## A BILL

To improve the availability of health information and the provision of health care by encouraging the creation, use, and maintenance of lifetime electronic health records of individuals in independent health record trusts and

by providing a secure and privacy-protected framework in which such records are made available only by the affirmative consent of such individuals and are used to build a nationwide health information technology infrastructure.

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; TABLE OF CONTENTS.**

4       (a) **SHORT TITLE.**—This Act may be cited as the  
 5 “Independent Health Record Trust Act of 2007”.

6       (b) **TABLE OF CONTENTS.**—The table of contents of  
 7 this Act is as follows:

Sec. 1. Short title; table of contents.

Sec. 2. Purpose.

Sec. 3. Definitions.

Sec. 4. Establishment, certification, and membership of independent health record trusts.

Sec. 5. Duties of IHRT to IHRT participants.

Sec. 6. Availability and use of information from records in IHRT consistent with privacy protections and agreements.

Sec. 7. Voluntary nature of trust participation and information sharing.

Sec. 8. Financing of activities.

Sec. 9. Regulatory oversight.

8 **SEC. 2. PURPOSE.**

9       It is the purpose of this Act to provide for the estab-  
 10 lishment of a nationwide health information technology  
 11 network that—

12           (1) improves health care quality, reduces med-  
 13 ical errors, increases the efficiency of care, and ad-  
 14 vances the delivery of appropriate, evidence-based  
 15 health care services;

1           (2) promotes wellness, disease prevention, and  
2           the management of chronic illnesses by increasing  
3           the availability and transparency of information re-  
4           lated to the health care needs of an individual;

5           (3) ensures that appropriate information nec-  
6           essary to make medical decisions is available in a us-  
7           able form at the time and in the location that the  
8           medical service involved is provided;

9           (4) produces greater value for health care ex-  
10          penditures by reducing health care costs that result  
11          from inefficiency, medical errors, inappropriate care,  
12          and incomplete information;

13          (5) promotes a more effective marketplace,  
14          greater competition, greater systems analysis, in-  
15          creased choice, enhanced quality, and improved out-  
16          comes in health care services;

17          (6) improves the coordination of information  
18          and the provision of such services through an effec-  
19          tive infrastructure for the secure and authorized ex-  
20          change and use of health information; and

21          (7) ensures that the health information privacy,  
22          security, and confidentiality of individually identifi-  
23          able health information is protected.

24 **SEC. 3. DEFINITIONS.**

25          In this Act:

1           (1) ACCESS.—The term “access” means, with  
2           respect to an electronic health record, entering infor-  
3           mation into such account as well as retrieving infor-  
4           mation from such account.

5           (2) ACCOUNT.—The term “account” means an  
6           electronic health record of an individual contained in  
7           an independent health record trust.

8           (3) AFFIRMATIVE CONSENT.—The term “af-  
9           firmative consent” means, with respect to an elec-  
10          tronic health record of an individual contained in an  
11          IHRT, express consent given by the individual for  
12          the use of such record in response to a clear and  
13          conspicuous request for such consent or at the indi-  
14          vidual’s own initiative.

15          (4) AUTHORIZED EHR DATA USER.—The term  
16          “authorized EHR data user” means, with respect to  
17          an electronic health record of an IHRT participant  
18          contained as part of an IHRT, any entity (other  
19          than the participant) authorized (in the form of af-  
20          firmative consent) by the participant to access the  
21          electronic health record.

22          (5) CONFIDENTIALITY.—The term “confiden-  
23          tiality” means, with respect to individually identifi-  
24          able health information of an individual, the obliga-

1       tion of those who receive such information to respect  
2       the health information privacy of the individual.

3               (6) ELECTRONIC HEALTH RECORD.—The term  
4       “electronic health record” means a longitudinal col-  
5       lection of information concerning a single individual,  
6       including medical records and personal health infor-  
7       mation, that is stored electronically.

8               (7) HEALTH INFORMATION PRIVACY.—The  
9       term “health information privacy” means, with re-  
10      spect to individually identifiable health information  
11      of an individual, the right of such individual to con-  
12      trol the acquisition, uses, or disclosures of such in-  
13      formation.

14              (8) HEALTH PLAN.—The term “health plan”  
15      means a group health plan (as defined in section  
16      2208(1) of the Public Health Service Act (42 U.S.C.  
17      300bb–8(1))) as well as a plan that offers health in-  
18      surance coverage in the individual market.

19              (9) HIPAA PRIVACY REGULATIONS.—The term  
20      “HIPAA privacy regulations” means the regulations  
21      promulgated under section 264(c) of the Health In-  
22      surance Portability and Accountability Act of 1996  
23      (42 U.S.C. 1320d–2 note).

24              (10) INDEPENDENT HEALTH RECORD TRUST;  
25      IHRT.—The terms “independent health record trust”

1 and “IHRT” mean a legal arrangement under the  
2 administration of an IHRT operator that meets the  
3 requirements of this Act with respect to electronic  
4 health records of individuals participating in the  
5 trust or IHRT.

6 (11) IHRT OPERATOR.—The term “IHRT op-  
7 erator” means, with respect to an IHRT, the organi-  
8 zation that is responsible for the administration and  
9 operation of the IHRT in accordance with this Act.

10 (12) IHRT PARTICIPANT.—The term “IHRT  
11 participant” means, with respect to an IHRT, an in-  
12 dividual who has a participation agreement in effect  
13 with respect to the maintenance of the individual’s  
14 electronic health record by the IHRT.

15 (13) INDIVIDUALLY IDENTIFIABLE HEALTH IN-  
16 FORMATION.—The term “individually identifiable  
17 health information” has the meaning given such  
18 term in section 1171(6) of the Social Security Act  
19 (42 U.S.C. 1320d(6)).

20 (14) SECURITY.—The term “security” means,  
21 with respect to individually identifiable health infor-  
22 mation of an individual, the physical, technological,  
23 or administrative safeguards or tools used to protect  
24 such information from unwarranted access or disclo-  
25 sure.

1 **SEC. 4. ESTABLISHMENT, CERTIFICATION, AND MEMBER-**  
2 **SHIP OF INDEPENDENT HEALTH RECORD**  
3 **TRUSTS.**

4 (a) ESTABLISHMENT.—Not later than one year after  
5 the date of the enactment of this Act, the Federal Trade  
6 Commission, in consultation with the National Committee  
7 on Vital and Health Statistics, shall prescribe standards  
8 for the establishment, certification, operation, and inter-  
9 operability of IHRTs to carry out the purposes described  
10 in section 2 in accordance with the provisions of this Act.

11 (b) CERTIFICATION.—

12 (1) CERTIFICATION BY FTC.—The Federal  
13 Trade Commission shall provide for the certification  
14 of IHRTs. No IHRT may be certified unless the  
15 IHRT is determined to meet the standards for cer-  
16 tification established under subsection (a).

17 (2) DECERTIFICATION.—The Federal Trade  
18 Commission shall establish a process for the revoca-  
19 tion of certification of an IHRT under this section  
20 in the case that the IHRT violates the standards es-  
21 tablished under subsection (a).

22 (c) MEMBERSHIP.—

23 (1) IN GENERAL.—To be eligible to be a partic-  
24 ipant in an IHRT, an individual shall—

1 (A) submit to the IHRT information as re-  
2 quired by the IHRT to establish an electronic  
3 health record with the IHRT; and

4 (B) enter into a privacy protection agree-  
5 ment described in section 6(b)(1) with the  
6 IHRT.

7 The process to determine eligibility of an individual  
8 under this subsection shall allow for the establish-  
9 ment by such individual of an electronic health  
10 record as expeditiously as possible if such individual  
11 is determined so eligible.

12 (2) NO LIMITATION ON MEMBERSHIP.—Nothing  
13 in this subsection shall be construed to permit an  
14 IHRT to restrict membership, including on the basis  
15 of health condition.

16 **SEC. 5. DUTIES OF IHRT TO IHRT PARTICIPANTS.**

17 (a) FIDUCIARY DUTY OF IHRT; PENALTIES FOR  
18 VIOLATIONS OF FIDUCIARY DUTY.—

19 (1) FIDUCIARY DUTY.—With respect to the  
20 electronic health record of an IHRT participant  
21 maintained by an IHRT, the IHRT shall have a fi-  
22 duciary duty to act for the benefit and in the inter-  
23 ests of such participant and of the IHRT as a whole.  
24 Such duty shall include obtaining the affirmative  
25 consent of such participant prior to the release of in-

1 formation in such participant’s electronic health  
2 record in accordance with the requirements of this  
3 Act.

4 (2) PENALTIES.—If the IHRT knowingly or  
5 recklessly breaches the fiduciary duty described in  
6 paragraph (1), the IHRT shall be subject to the fol-  
7 lowing penalties:

8 (A) Loss of certification of the IHRT.

9 (B) A fine that is not in excess of \$50,000.

10 (C) A term of imprisonment for the indi-  
11 viduals involved of not more than 5 years.

12 (b) ELECTRONIC HEALTH RECORD DEEMED TO BE  
13 HELD IN TRUST BY IHRT.—With respect to an indi-  
14 vidual, an electronic health record maintained by an IHRT  
15 shall be deemed to be held in trust by the IHRT for the  
16 benefit of the individual and the IHRT shall have no legal  
17 or equitable interest in such electronic health record.

18 **SEC. 6. AVAILABILITY AND USE OF INFORMATION FROM**  
19 **RECORDS IN IHRT CONSISTENT WITH PRI-**  
20 **VACY PROTECTIONS AND AGREEMENTS.**

21 (a) PROTECTED ELECTRONIC HEALTH RECORDS  
22 USE AND ACCESS.—

23 (1) GENERAL RIGHTS REGARDING USES OF IN-  
24 FORMATION.—

1 (A) IN GENERAL.—With respect to the  
2 electronic health record of an IHRT participant  
3 maintained by an IHRT, subject to paragraph  
4 (2)(C), primary uses and secondary uses (de-  
5 scribed in subparagraphs (B) and (C), respec-  
6 tively) of information within such record (other  
7 than by such participant) shall be permitted  
8 only upon the authorization of such use, prior  
9 to such use, by such participant.

10 (B) PRIMARY USES.—For purposes of sub-  
11 paragraph (A) and with respect to an electronic  
12 health record of an individual, a primary use is  
13 a use for purposes of the individual’s self-care  
14 or care by health care professionals.

15 (C) SECONDARY USES.—For purposes of  
16 subparagraph (B) and with respect to an elec-  
17 tronic health record of an individual, a sec-  
18 ondary use is any use not described in subpara-  
19 graph (B) and includes a use for purposes of  
20 public health research or other related activi-  
21 ties. Additional authorization is required for a  
22 secondary use extending beyond the original  
23 purpose of the secondary use authorized by the  
24 IHRT participant involved. Nothing in this  
25 paragraph shall be construed as requiring au-

1           thorization for every secondary use that is with-  
2           in the authorized original purpose.

3           (2) RULES FOR PRIMARY USE OF RECORDS FOR  
4           HEALTH CARE PURPOSES.—With respect to the elec-  
5           tronic health record of an IHRT participant (or  
6           specified parts of such electronic health record)  
7           maintained by an IHRT standards for access to  
8           such record shall provide for the following:

9                   (A) ACCESS BY IHRT PARTICIPANTS TO  
10                   THEIR ELECTRONIC HEALTH RECORDS.—

11                           (i) OWNERSHIP.—The participant  
12                           maintains ownership over the entire elec-  
13                           tronic health record (and all portions of  
14                           such record) and shall have the right to  
15                           electronically access and review the con-  
16                           tents of the entire record (and any portion  
17                           of such record) at any time, in accordance  
18                           with this subparagraph.

19                           (ii) ADDITION OF PERSONAL INFOR-  
20                           MATION.—The participant may add per-  
21                           sonal health information to the health  
22                           record of that participant, except that such  
23                           participant shall not alter information that  
24                           is entered into the electronic health record  
25                           by any authorized EHR data user. Such

1 participant shall have the right to propose  
2 an amendment to information that is en-  
3 tered by an authorized EHR data user  
4 pursuant to standards prescribed by the  
5 Federal Trade Commission for purposes of  
6 amending such information.

7 (iii) IDENTIFICATION OF INFORMA-  
8 TION ENTERED BY PARTICIPANT.—Any ad-  
9 ditions or amendments made by the partic-  
10 ipant to the health record shall be identi-  
11 fied and disclosed within such record as  
12 being made by such participant.

13 (B) ACCESS BY ENTITIES OTHER THAN  
14 IHRT PARTICIPANT.—

15 (i) AUTHORIZED ACCESS ONLY.—Ex-  
16 cept as provided under subparagraph (C)  
17 and paragraph (4), access to the electronic  
18 health record (or any portion of the  
19 record)—

20 (I) may be made only by author-  
21 ized EHR data users and only to such  
22 portions of the record as specified by  
23 the participant; and

24 (II) may be limited by the partic-  
25 ipant for purposes of entering infor-

1                   mation into such record, retrieving in-  
2                   formation from such record, or both.

3                   (ii) IDENTIFICATION OF ENTITY THAT  
4                   ENTERS INFORMATION.—Any information  
5                   that is added by an authorized EHR data  
6                   user to the health record shall be identified  
7                   and disclosed within such record as being  
8                   made by such user.

9                   (iii) SATISFACTION OF HIPAA PRIVACY  
10                  REGULATIONS.—In the case of a record of  
11                  a covered entity (as defined for purposes of  
12                  HIPAA privacy regulations), with respect  
13                  to an individual, if such individual is an  
14                  IHRT participant with an independent  
15                  health record trust and such covered entity  
16                  is an authorized EHR data user, the re-  
17                  quirement under the HIPAA privacy regu-  
18                  lations for such entity to provide the  
19                  record to the participant shall be deemed  
20                  met if such entity, without charge to the  
21                  IHRT or the participant—

22                         (I) forwards to the trust an ap-  
23                         propriately formatted electronic copy  
24                         of the record (and updates to such  
25                         records) for inclusion in the electronic

1 health record of the participant main-  
2 tained by the trust;

3 (II) enters such record into the  
4 electronic health record of the partici-  
5 pant so maintained; or

6 (III) otherwise makes such  
7 record available for electronic access  
8 by the IHRT or the individual in a  
9 manner that permits such record to  
10 be included in the account of the indi-  
11 vidual contained in the IHRT.

12 (iv) NOTIFICATION OF SENSITIVE IN-  
13 FORMATION.—Any information, with re-  
14 spect to the participant, that is sensitive  
15 information, as specified by the Federal  
16 Trade Commission, shall not be forwarded  
17 or entered by an authorized EHR data  
18 user into the electronic health record of the  
19 participant maintained by the trust unless  
20 the user certifies that the participant has  
21 been notified of such information.

22 (C) DEEMED AUTHORIZATION FOR ACCESS  
23 FOR EMERGENCY HEALTH CARE.—

24 (i) FINDINGS.—Congress finds that—

1 (I) given the size and nature of  
2 visits to emergency departments in  
3 the United States, readily available  
4 health information could make the dif-  
5 ference between life and death; and

6 (II) because of the case mix and  
7 volume of patients treated, emergency  
8 departments are well positioned to  
9 provide information for public health  
10 surveillance, community risk assess-  
11 ment, research, education, training,  
12 quality improvement, and other uses.

13 (ii) USE OF INFORMATION.—With re-  
14 spect to the electronic health record of an  
15 IHRT participant (or specified parts of  
16 such electronic health record) maintained  
17 by an IHRT, the participant shall be  
18 deemed as providing authorization (in the  
19 form of affirmative consent) for health  
20 care providers to access, in connection with  
21 providing emergency care services to the  
22 participant, a limited, authenticated infor-  
23 mation set concerning the participant for  
24 emergency response purposes, unless the  
25 participant specifies that such information

1 set (or any portion of such information  
2 set) may not be so accessed. Such limited  
3 information set may include information—

4 (I) patient identification data, as  
5 determined appropriate by the partici-  
6 pant;

7 (II) provider identification that  
8 includes the use of unique provider  
9 identifiers;

10 (III) payment information;

11 (IV) information related to the  
12 individual's vitals, allergies, and medi-  
13 cation history;

14 (V) information related to exist-  
15 ing chronic problems and active clin-  
16 ical conditions of the participant; and

17 (VI) information concerning  
18 physical examinations, procedures, re-  
19 sults, and diagnosis data.

20 (3) RULES FOR SECONDARY USES OF RECORDS  
21 FOR RESEARCH AND OTHER PURPOSES.—

22 (A) IN GENERAL.—With respect to the  
23 electronic health record of an IHRT participant  
24 (or specified parts of such electronic health  
25 record) maintained by an IHRT, the IHRT

1           may sell such record (or specified parts of such  
2           record) only if—

3                   (i) the transfer is authorized by the  
4                   participant pursuant to an agreement be-  
5                   tween the participant and the IHRT and is  
6                   in accordance with the privacy protection  
7                   agreement described in subsection (b)(1)  
8                   entered into between such participant and  
9                   such IHRT;

10                   (ii) such agreement includes param-  
11                   eters with respect to the disclosure of in-  
12                   formation involved and a process for the  
13                   authorization of the further disclosure of  
14                   information in such record;

15                   (iii) the information involved is to be  
16                   used for research or other activities only as  
17                   provided for in the agreement;

18                   (iv) the recipient of the information  
19                   provides assurances that the information  
20                   will not be further transferred or reused in  
21                   violation of such agreement; and

22                   (v) the transfer otherwise meets the  
23                   requirements and standards prescribed by  
24                   the Federal Trade Commission.

1           (B) TREATMENT OF PUBLIC HEALTH RE-  
2           PORTING.—Nothing in this paragraph shall be  
3           construed as prohibiting or limiting the use of  
4           health care information of an individual, includ-  
5           ing an individual who is an IHRT participant,  
6           for public health reporting (or other research)  
7           purposes prior to the inclusion of such informa-  
8           tion in an electronic health record maintained  
9           by an IHRT.

10          (4) LAW ENFORCEMENT CLARIFICATION.—  
11          Nothing in this Act shall prevent an IHRT from dis-  
12          closing information contained in an electronic health  
13          record maintained by the IHRT when required for  
14          purposes of a lawful investigation or official pro-  
15          ceeding inquiring into a violation of, or failure to  
16          comply with, any criminal or civil statute or any reg-  
17          ulation, rule, or order issued pursuant to such a  
18          statute.

19          (5) RULE OF CONSTRUCTION.—Nothing in this  
20          section shall be construed to require a health care  
21          provider that does not utilize electronic methods or  
22          appropriate levels of health information technology  
23          on the date of the enactment of this Act to adopt  
24          such electronic methods or technology as a require-  
25          ment for participation or compliance under this Act.

1 (b) PRIVACY PROTECTION AGREEMENT; TREATMENT  
2 OF STATE PRIVACY AND SECURITY LAWS.—

3 (1) PRIVACY PROTECTION AGREEMENT.—A pri-  
4 vacy protection agreement described in this sub-  
5 section is an agreement, with respect to an electronic  
6 health record of an IHRT participant to be main-  
7 tained by an independent health record trust, be-  
8 tween the participant and the trust—

9 (A) that is consistent with the standards  
10 described in subsection (a)(2);

11 (B) under which the participant specifies  
12 the portions of the record that may be accessed,  
13 under what circumstances such portions may be  
14 accessed, any authorizations for indicated au-  
15 thorized EHR data users to access information  
16 contained in the record, and the purposes for  
17 which the information (or portions of the infor-  
18 mation) in the record may be used;

19 (C) which provides a process for the au-  
20 thorization of the transfer of information con-  
21 tained in the record to a third party, including  
22 for the sale of such information for purposes of  
23 research, by an authorized EHR data user and  
24 reuse of such information by such third party,  
25 including a provision requiring that such trans-

1           fer and reuse is not in violation of any privacy  
2           or transfer restrictions placed by the partici-  
3           pant on the independent health record of such  
4           participant; and

5           (D) under which the trust provides assur-  
6           ances that the trust will not transfer, disclose,  
7           or provide access to the record (or any portion  
8           of the record) in violation of the parameters es-  
9           tablished in the agreement or to any person or  
10          entity who has not agreed to use and transfer  
11          such record (or portion of such record) in ac-  
12          cordance with such agreement.

13          (2) TREATMENT OF STATE LAWS.—

14          (A) IN GENERAL.—Except as provided  
15          under subparagraph (B), the provisions of a  
16          privacy protection agreement entered into be-  
17          tween an IHRT and an IHRT participant shall  
18          preempt any provision of State law (or any  
19          State regulation) relating to the privacy and  
20          confidentiality of individually identifiable health  
21          information or to the security of such health in-  
22          formation.

23          (B) EXCEPTION FOR PRIVILEGED INFOR-  
24          MATION.—The provisions of a privacy protec-  
25          tion agreement shall not preempt any provision

1 of State law (or any State regulation) that rec-  
2 ognizes privileged communications between phy-  
3 sicians, health care practitioners, and patients  
4 of such physicians or health care practitioners,  
5 respectively.

6 (C) STATE DEFINED.—For purposes of  
7 this section, the term “State” has the meaning  
8 given such term when used in title XI of the  
9 Social Security Act, as provided under section  
10 1101(a) of such Act (42 U.S.C. 1301(a)).

11 **SEC. 7. VOLUNTARY NATURE OF TRUST PARTICIPATION**  
12 **AND INFORMATION SHARING.**

13 (a) IN GENERAL.—Participation in an independent  
14 health record trust, or authorizing access to information  
15 from such a trust, is voluntary. No employer, health insur-  
16 ance issuer, group health plan, health care provider, or  
17 other person may require, as a condition of employment,  
18 issuance of a health insurance policy, coverage under a  
19 group health plan, the provision of health care services,  
20 payment for such services, or otherwise, that an individual  
21 participate in, or authorize access to information from, an  
22 independent health record trust.

23 (b) ENFORCEMENT.—The penalties provided for in  
24 subsection (a) of section 1177 of the Social Security Act  
25 (42 U.S.C. 1320d–6) shall apply to a violation of sub-

1 section (a) in the same manner as such penalties apply  
2 to a person in violation of subsection (a) of such section.

3 **SEC. 8. FINANCING OF ACTIVITIES.**

4 (a) IN GENERAL.—Except as provided in subsection  
5 (b), an IHRT may generate revenue to pay for the oper-  
6 ations of the IHRT through—

7 (1) charging IHRT participants account fees  
8 for use of the trust;

9 (2) charging authorized EHR data users for ac-  
10 cessing electronic health records maintained in the  
11 trust;

12 (3) the sale of information contained in the  
13 trust (as provided for in section 6(a)(3)(A)); and

14 (4) any other activity determined appropriate  
15 by the Federal Trade Commission.

16 (b) PROHIBITION AGAINST ACCESS FEES FOR  
17 HEALTH CARE PROVIDERS.—For purposes of providing  
18 incentives to health care providers to access information  
19 maintained in an IHRT, as authorized by the IHRT par-  
20 ticipants involved, the IHRT may not charge a fee for  
21 services specified by the IHRT. Such services shall include  
22 the transmittal of information from a health care provider  
23 to be included in an independent electronic health record  
24 maintained by the IHRT (or permitting such provider to  
25 input such information into the record), including the

1 transmission of or access to information described in sec-  
2 tion 6(a)(2)(C)(ii) by appropriate emergency responders.

3 (c) **REQUIRED DISCLOSURES.**—The sources and  
4 amounts of revenue derived under subsection (a) for the  
5 operations of an IHRT shall be fully disclosed to each  
6 IHRT participant of such IHRT and to the public.

7 (d) **TREATMENT OF INCOME.**—For purposes of the  
8 Internal Revenue Code of 1986, any revenue described in  
9 subsection (a) shall not be included in gross income of any  
10 IHRT, IHRT participant, or authorized EHR data user.

11 **SEC. 9. REGULATORY OVERSIGHT.**

12 (a) **IN GENERAL.**—In carrying out this Act, the Fed-  
13 eral Trade Commission shall promulgate regulations for  
14 independent health record trusts.

15 (b) **ESTABLISHMENT OF INTERAGENCY STEERING**  
16 **COMMITTEE.**—

17 (1) **IN GENERAL.**—The Secretary of Health and  
18 Human Services shall establish an Interagency  
19 Steering Committee in accordance with this sub-  
20 section.

21 (2) **CHAIRPERSON.**—The Secretary of Health  
22 and Human Services shall serve as the chairperson  
23 of the Interagency Steering Committee.

24 (3) **MEMBERSHIP.**—The members of the Inter-  
25 agency Steering Committee shall consist of the At-

1       torney General, the Chairperson of the Federal  
2       Trade Commission, the Chairperson for the National  
3       Committee for Vital and Health Statistics, a rep-  
4       resentative of the Federal Reserve, and other Fed-  
5       eral officials determined appropriate by the Sec-  
6       retary of Health and Human Services.

7               (4) DUTIES.—The Interagency Steering Com-  
8       mittee shall coordinate the implementation of this  
9       Act, including the implementation of policies de-  
10      scribed in subsection (d) based upon the rec-  
11      ommendations provided under such subsection, and  
12      regulations promulgated under this Act.

13      (c) FEDERAL ADVISORY COMMITTEE.—

14              (1) IN GENERAL.—The National Committee for  
15      Vital and Health Statistics shall serve as an advisory  
16      committee for the IHRTs. The membership of such  
17      advisory committee shall include a representative  
18      from the Federal Trade Commission and the chair-  
19      person of the Interagency Steering Committee. Not  
20      less than 60 percent of such membership shall con-  
21      sist of representatives of nongovernment entities, at  
22      least one of whom shall be a representative from an  
23      organization representing health care consumers.

24              (2) DUTIES.—The National Committee for  
25      Vital and Health Statistics shall issue periodic re-

1 ports and review policies concerning IHRTs based  
2 on each of the following factors:

3 (A) Privacy and security policies.

4 (B) Economic progress.

5 (C) Interoperability standards.

6 (d) POLICIES RECOMMENDED BY FEDERAL TRADE  
7 COMMISSION.—The Federal Trade Commission, in con-  
8 sultation with the National Committee for Vital and  
9 Health Statistics, shall recommend policies to—

10 (1) provide assistance to encourage the growth  
11 of independent health record trusts;

12 (2) track economic progress as it pertains to  
13 operators of independent health records trusts and  
14 individuals receiving nontaxable income with respect  
15 to accounts;

16 (3) conduct public education activities regarding  
17 the creation and usage of the independent health  
18 records trusts;

19 (4) establish standards for the interoperability  
20 of health information technology to ensure that in-  
21 formation contained in such record may be shared  
22 between the trust involved, the participant, and au-  
23 thorized EHR data users, including for the stand-  
24 ardized collection and transmission of individual  
25 health records (or portions of such records) to au-

1       thorized EHR data users through a common inter-  
2       face and for the portability of such records among  
3       independent health record trusts; and

4             (5) carry out any other activities determined  
5       appropriate by the Federal Trade Commission.

6       (e) REGULATIONS PROMULGATED BY FEDERAL  
7 TRADE COMMISSION.—The Federal Trade Commission  
8 shall promulgate regulations based on, at a minimum, the  
9 following factors:

10            (1) Requiring that an IHRT participant, who  
11       has an electronic health record that is maintained by  
12       an IHRT, be notified of a security breach with re-  
13       spect to such record, and any corrective action taken  
14       on behalf of the participant.

15            (2) Requiring that information sent to, or re-  
16       ceived from, an IHRT that has been designated as  
17       high-risk should be authenticated through the use of  
18       methods such as the periodic changing of passwords,  
19       the use of biometrics, the use of tokens or other  
20       technology as determined appropriate by the council.

21            (3) Requiring a delay in releasing sensitive  
22       health care test results and other similar informa-  
23       tion to patients directly in order to give physicians  
24       time to contact the patient.

1           (4) Recommendations for entities operating  
2           IHRTs, including requiring analysis of the potential  
3           risk of health transaction security breeches based on  
4           set criteria.

5           (5) The conduct of audits of IHRTs to ensure  
6           that they are in compliance with the requirements  
7           and standards established under this Act.

8           (6) Disclosure to IHRT participants of the  
9           means by which such trusts are financed, including  
10          revenue from the sale of patient data.

11          (7) Prevention of certification of an entity seek-  
12          ing independent health record trust certification  
13          based on—

14                 (A) the potential for conflicts between the  
15                 interests of such entity and the security of the  
16                 health information involved; and

17                 (B) the involvement of the entity in any  
18                 activity that is contrary to the best interests of  
19                 a patient.

20          (8) Prevention of the use of revenue sources  
21          that are contrary to a patient's interests.

22          (9) Public disclosure of audits in a manner  
23          similar to financial audits required for publicly trad-  
24          ed stock companies.

1           (10) Requiring notification to a participating  
2           entity that the information contained in such record  
3           may not be representative of the complete or accu-  
4           rate electronic health record of such account holder.

5           (f) COMPLIANCE REPORT.—Not later than 1 year  
6           after the date of the enactment of this Act, and annually  
7           thereafter, the Commission shall submit to the Committee  
8           on Health, Education, Labor, and Pensions and the Com-  
9           mittee on Finance of the Senate and the Committee on  
10          Energy and Commerce and the Committee on Ways and  
11          Means of the House of Representatives, a report on com-  
12          pliance by and progress of independent health record  
13          trusts with this Act. Such report shall describe the fol-  
14          lowing:

15           (1) The number of complaints submitted about  
16          independent health record trusts, which shall be di-  
17          vided by complaints related to security breaches, and  
18          complaints not related to security breaches, and may  
19          include other categories as the Interagency Steering  
20          Committee established under section (b) determines  
21          appropriate.

22           (2) The number of enforcement actions under-  
23          taken by the Commission against independent health  
24          record trusts in response to complaints under para-  
25          graph (1), which shall be divided by enforcement ac-

1 tions related to security breaches and enforcement  
2 actions not related to security breaches and may in-  
3 clude other categories as the Interagency Steering  
4 Committee established under section (b) determines  
5 appropriate.

6 (3) The economic progress of the individual  
7 owner or institution operator as achieved through  
8 independent health record trust usage and existing  
9 barriers to such usage.

10 (4) The progress in security auditing as pro-  
11 vided for by the Interagency Steering Committee  
12 council under subsection (b).

13 (5) The other core responsibilities of the Com-  
14 mission as described in subsection (a).

15 (g) INTERAGENCY MEMORANDUM OF UNDER-  
16 STANDING.—The Interagency Steering Committee shall  
17 ensure, through the execution of an interagency memo-  
18 randum of understanding, that—

19 (1) regulations, rulings, and interpretations  
20 issued by Federal officials relating to the same mat-  
21 ter over which 2 or more such officials have respon-  
22 sibility under this Act are administered so as to have  
23 the same effect at all times; and

24 (2) the memorandum provides for the coordina-  
25 tion of policies related to enforcing the same require-

1       ments through such officials in order to have coordi-  
2       nated enforcement strategy that avoids duplication  
3       of enforcement efforts and assigns priorities in en-  
4       forcement.

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