

110TH CONGRESS
2D SESSION

H. R. 7038

To establish a Health Care Services Commission to enhance the quality, appropriateness, and effectiveness of health care services, and access to such services, through the establishment of a broad base of scientific research and through the promotion of improvements in clinical practice and in the organization, financing, and delivery of health care services.

IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 24, 2008

Mr. RYAN of Wisconsin 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

A BILL

To establish a Health Care Services Commission to enhance the quality, appropriateness, and effectiveness of health care services, and access to such services, through the establishment of a broad base of scientific research and through the promotion of improvements in clinical practice and in the organization, financing, and delivery of health care services.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

1 **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

2 (a) **SHORT TITLE.**—This Act may be cited as the
3 “Health Care Services Commission Act”.

4 (b) **TABLE OF CONTENTS.**—

Sec. 1. Short Title; table of Contents.

TITLE I—ESTABLISHMENT AND GENERAL DUTIES

Sec. 101. Establishment.

Sec. 102. General authorities and duties.

Sec. 103. Dissemination.

**TITLE II—FORUM FOR QUALITY AND EFFECTIVENESS IN
HEALTH CARE**

Sec. 201. Establishment of office.

Sec. 202. Membership.

Sec. 203. Duties.

Sec. 204. Adoption and enforcement of guidelines and standards.

Sec. 205. Additional requirements.

TITLE III—GENERAL PROVISIONS

Sec. 301. Certain administrative authorities.

Sec. 302. Funding.

Sec. 303. Definitions.

TITLE IV—TERMINATIONS AND TRANSITION

Sec. 401. Termination of Agency for Healthcare Research and Quality.

Sec. 402. Transition.

TITLE V—INDEPENDENT HEALTH RECORD TRUST

Sec. 501. Title V short title.

Sec. 502. Purpose.

Sec. 503. Definitions.

Sec. 504. Establishment, certification, and membership of independent health
record trusts.

Sec. 505. Duties of IHRT to IHRT participants.

Sec. 506. Availability and use of information from records in IHRT consistent
with privacy protections and agreements.

Sec. 507. Voluntary nature of trust participation and information sharing.

Sec. 508. Financing of activities.

Sec. 509. Regulatory oversight.

1 **TITLE I—ESTABLISHMENT AND**
2 **GENERAL DUTIES**

3 **SEC. 101. ESTABLISHMENT.**

4 (a) IN GENERAL.—There is hereby established a
5 Health Care Services Commission (in this Act, referred
6 to as the “Commission”) to be composed of five commis-
7 sioners (in this Act referred to as the “Commissioners”)
8 to be appointed by the President by and with the advice
9 and consent of the Senate. Not more than three of such
10 commissioners shall be members of the same political
11 party, and in making appointments members of different
12 political parties shall be appointed alternately as nearly
13 as may be practicable. No commissioner shall engage in
14 any other business, vocation, or employment than that of
15 serving as commissioner. Each commissioner shall hold of-
16 fice for a term of five years and until his successor is ap-
17 pointed and has qualified, except that he shall not so con-
18 tinue to serve beyond the expiration of the next session
19 of Congress subsequent to the expiration of said fixed
20 term of office, and except (1) any commissioner appointed
21 to fill a vacancy occurring prior to the expiration of the
22 term for which his predecessor was appointed shall be ap-
23 pointed for the remainder of such term, and (2) the terms
24 of office of the commissioners first taking office after the
25 enactment of this Act shall expire as designated by the

1 President at the time of nomination, one at the end of
2 one year, one at the end of two years, one at the end of
3 three years, one at the end of four years, and one at the
4 end of five years, after the date of the enactment of this
5 Act.

6 (b) PURPOSE.—The purpose of the Commission is to
7 enhance the quality, appropriateness, and effectiveness of
8 health care services, and access to such services, through
9 the establishment of a broad base of scientific research
10 and through the promotion of improvements in clinical
11 practice and in the organization, financing, and delivery
12 of health care services.

13 (c) APPOINTMENT OF CHAIRMAN.—The President
14 shall, from among the Commissioners appointed under
15 subsection (a), designate an individual to serve as the
16 Chairman of the Commission.

17 **SEC. 102. GENERAL AUTHORITIES AND DUTIES.**

18 (a) IN GENERAL.—In carrying out section 101(b),
19 the Commissioners shall conduct and support research,
20 demonstration projects, evaluations, training, guideline de-
21 velopment, and the dissemination of information, on
22 health care services and on systems for the delivery of
23 such services, including activities with respect to—

24 (1) the effectiveness, efficiency, and quality of
25 health care services;

1 (2) the outcomes of health care services and
2 procedures;

3 (3) clinical practice, including primary care and
4 practice-oriented research;

5 (4) health care technologies, facilities, and
6 equipment;

7 (5) health care costs, productivity, and market
8 forces;

9 (6) health promotion and disease prevention;

10 (7) health statistics and epidemiology; and

11 (8) medical liability.

12 (b) **REQUIREMENTS WITH RESPECT TO RURAL**
13 **AREAS AND UNDERSERVED POPULATIONS.**—In carrying
14 out subsection (a), the Commissioners shall undertake and
15 support research, demonstration projects, and evaluations
16 with respect to—

17 (1) the delivery of health care services in rural
18 areas (including frontier areas); and

19 (2) the health of low-income groups, minority
20 groups, and the elderly.

21 **SEC. 103. DISSEMINATION.**

22 (a) **IN GENERAL.**—The Commissioners shall—

23 (1) promptly publish, make available, and oth-
24 erwise disseminate, in a form understandable and on
25 as broad a basis as practicable so as to maximize its

1 use, the results of research, demonstration projects,
2 and evaluations conducted or supported under this
3 Act and the guidelines, standards, and review cri-
4 teria developed under this Act;

5 (2) promptly make available to the public data
6 developed in such research, demonstration projects,
7 and evaluations; and

8 (3) as appropriate, provide technical assistance
9 to State and local government and health agencies
10 and conduct liaison activities to such agencies to fos-
11 ter dissemination.

12 (b) PROHIBITION AGAINST RESTRICTIONS.—Except
13 as provided in subsection (c), the Commissioners may not
14 restrict the publication or dissemination of data from, or
15 the results of, projects conducted or supported under this
16 Act.

17 (c) LIMITATION ON USE OF CERTAIN INFORMA-
18 TION.—No information, if an establishment or person sup-
19 plying the information or described in it is identifiable,
20 obtained in the course of activities undertaken or sup-
21 ported under this Act may be used for any purpose other
22 than the purpose for which it was supplied unless such
23 establishment or person has consented (as determined
24 under regulations of the Secretary) to its use for such
25 other purpose. Such information may not be published or

1 released in other form if the person who supplied the infor-
2 mation or who is described in it is identifiable unless such
3 person has consented (as determined under regulations of
4 the Secretary) to its publication or release in other form.

5 (d) CERTAIN INTERAGENCY AGREEMENT.—The
6 Commissioners and the Director of the National Library
7 of Medicine shall enter into an agreement providing for
8 the implementation of subsection (a)(1).

9 **TITLE II—FORUM FOR QUALITY**
10 **AND EFFECTIVENESS IN**
11 **HEALTH CARE**

12 **SEC. 201. ESTABLISHMENT OF OFFICE.**

13 There is established within the Commission an office
14 to be known as the Office of the Forum for Quality and
15 Effectiveness in Health Care. The office shall be headed
16 by a director (referred to in this Act as the “Director”)
17 who shall be appointed by the Commissioners.

18 **SEC. 202. MEMBERSHIP.**

19 (a) IN GENERAL.—The Office of the Forum for Qual-
20 ity and Effectiveness in Health Care shall be composed
21 of 15 individuals nominated by private sector health care
22 organizations and appointed by the Commission and shall
23 include representation from at least the following:

- 24 (1) Health insurance industry.
25 (2) Health care provider groups.

1 (3) Non-profit organizations.

2 (4) Rural health organizations.

3 (b) TERMS.—

4 (1) IN GENERAL.—Except as provided in para-
5 graph (2), members of the Office of the Forum for
6 Quality and Effectiveness in Health Care shall serve
7 for a term of 5 years.

8 (2) STAGGERED ROTATION.—Of the members
9 first appointed to the Office of the Forum for Qual-
10 ity and Effectiveness in Health Care, the Commis-
11 sion shall appoint 5 members to serve for a term of
12 2 years, 5 members to serve for a term of 3 years,
13 and 5 members to serve for a term of 4 years.

14 (c) TREATMENT OF OTHER EMPLOYMENT.—Each
15 member of the Office of the Forum for Quality and Effec-
16 tiveness in Health Care shall serve the Office independ-
17 ently from any other position of employment.

18 **SEC. 203. DUTIES.**

19 (a) ESTABLISHMENT OF FORUM PROGRAM.—The
20 Commissioners, acting through the Director, shall estab-
21 lish a program to be known as the Forum for Quality and
22 Effectiveness in Health Care. For the purpose of pro-
23 moting transparency in price, quality, appropriateness,
24 and effectiveness of health care, the Director, using the
25 process set forth in section 204, shall arrange for the de-

1 velopment and periodic review and updating of standards
2 of quality, performance measures, and medical review cri-
3 teria through which health care providers and other appro-
4 priate entities may assess or review the provision of health
5 care and assure the quality of such care.

6 (b) CERTAIN REQUIREMENTS.—Guidelines, stand-
7 ards, performance measures, and review criteria under
8 subsection (a) shall—

9 (1) be based on the best available research and
10 professional judgment regarding the effectiveness
11 and appropriateness of health care services and pro-
12 cedures; and

13 (2) be presented in formats appropriate for use
14 by physicians, health care practitioners, providers,
15 medical educators, and medical review organizations
16 and in formats appropriate for use by consumers of
17 health care.

18 (c) AUTHORITY FOR CONTRACTS.—In carrying out
19 this title, the Director may enter into contracts with public
20 or nonprofit private entities.

21 (d) PUBLIC DISCLOSURE OF RECOMMENDATIONS.—
22 For each fiscal year beginning with 2010, the Director
23 shall make publicly available the following:

24 (1) quarterly reports for public comment that
25 include proposed recommendations for guidelines,

1 standards, performance measures, and review cri-
2 teria under subsection (a) and any updates to such
3 guidelines, standards, performance measures, and
4 review criteria; and

5 (2) after consideration of such comments, a
6 final report that contains final recommendations for
7 such guidelines, standards, performance measures,
8 review criteria, and updates.

9 (e) DATE CERTAIN FOR INITIAL GUIDELINES AND
10 STANDARDS.—The Commissioners, by not later than Jan-
11 uary 1, 2012, shall assure the development of an initial
12 set of guidelines, standards, performance measures, and
13 review criteria under subsection (a).

14 **SEC. 204. ADOPTION AND ENFORCEMENT OF GUIDELINES**
15 **AND STANDARDS.**

16 (a) ADOPTION OF RECOMMENDATIONS OF FORUM
17 FOR QUALITY AND EFFECTIVENESS IN HEALTH CARE.—
18 For each fiscal year, the Commissioners shall adopt the
19 recommendations made for such year in the final report
20 under subsection (d)(2) of section 203 for guidelines,
21 standards, performance measures, and review criteria de-
22 scribed in subsection (a) of such section.

23 (b) ENFORCEMENT AUTHORITY.—The Commis-
24 sioners, in consultation with the Secretary of Health and
25 Human Services, have the authority to make recommenda-

1 tions to the Secretary to enforce compliance of health care
2 providers with the guidelines, standards, performance
3 measures, and review criteria adopted under subsection
4 (a). Such recommendations may include the following,
5 with respect to a health care provider who is not in compli-
6 ance with such guidelines, standards, measures, and cri-
7 teria:

8 (1) Exclusion from participation in Federal
9 health care programs (as defined in section
10 1128B(f) of the Social Security Act (42 U.S.C.
11 1320a-7b(f))).

12 (2) Imposition of a civil money penalty on such
13 provider.

14 **SEC. 205. ADDITIONAL REQUIREMENTS.**

15 (a) PROGRAM AGENDA.—The Commissioners shall
16 provide for an agenda for the development of the guide-
17 lines, standards, performance measures, and review cri-
18 teria described in section 203(a), including with respect
19 to the standards, performance measures, and review cri-
20 teria, identifying specific aspects of health care for which
21 the standards, performance measures, and review criteria
22 are to be developed and those that are to be given priority
23 in the development of the standards, performance meas-
24 ures, and review criteria.

1 **TITLE III—GENERAL**
2 **PROVISIONS**

3 **SEC. 301. CERTAIN ADMINISTRATIVE AUTHORITIES.**

4 The Commissioners, in carrying out this Act, may ac-
5 cept voluntary and uncompensated services.

6 **SEC. 302. FUNDING.**

7 For the purpose of carrying out this Act, there are
8 authorized to be appropriated such sums as may be nec-
9 essary for fiscal years 2010 through 2014.

10 **SEC. 303. DEFINITIONS.**

11 For purposes of this Act:

12 (1) The term “Commissioners” means the Com-
13 missioners of the Health Care Services Commission.

14 (2) The term “Commission” means the Health
15 Care Services Commission.

16 (3) The term “Director” means the Director of
17 the Office of the Forum for Quality and Effective-
18 ness in Health Care.

19 (4) The term “Secretary” means the Secretary
20 of Health and Human Services.

1 **TITLE IV—TERMINATIONS AND**
2 **TRANSITION**

3 **SEC. 401. TERMINATION OF AGENCY FOR HEALTHCARE RE-**
4 **SEARCH AND QUALITY.**

5 As of the date of the enactment of this Act, the Agen-
6 cy for Healthcare Research and Quality is terminated, and
7 title IX of the Public Health Service Act is repealed.

8 **SEC. 402. TRANSITION.**

9 All orders, grants, contracts, privileges, and other de-
10 terminations or actions of the Agency for Healthcare Re-
11 search and Quality that are effective as of the date before
12 the date of the enactment of this Act, shall be transferred
13 to the Secretary and shall continue in effect according to
14 their terms unless changed pursuant to law.

15 **TITLE V—INDEPENDENT**
16 **HEALTH RECORD TRUST**

17 **SEC. 501. TITLE V SHORT TITLE.**

18 This title may be cited as the “Independent Health
19 Record Trust Act of 2008”.

20 **SEC. 502. PURPOSE.**

21 It is the purpose of this title to provide for the estab-
22 lishment of a nationwide health information technology
23 network that—

24 (1) improves health care quality, reduces med-
25 ical errors, increases the efficiency of care, and ad-

1 vances the delivery of appropriate, evidence-based
2 health care services;

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

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

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

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

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

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

1 **SEC. 503. DEFINITIONS.**

2 In this title:

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

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

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

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

24 (5) **CONFIDENTIALITY.**—The term “confiden-
25 tiality” means, with respect to individually identifi-
26 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 title 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 title.

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 dislo-
25 sure.

1 **SEC. 504. 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 502 in accordance with the provisions of this
11 title.

12 (b) CERTIFICATION.—

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

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

23 (c) MEMBERSHIP.—

24 (1) IN GENERAL.—To be eligible to be a partic-
25 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 506(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. 505. 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 title.

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. 506. 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 title shall prevent an IHRT from
12 disclosing information contained in an electronic
13 health record maintained by the IHRT when re-
14 quired for purposes of a lawful investigation or offi-
15 cial proceeding inquiring into a violation of, or fail-
16 ure to comply with, any criminal or civil statute or
17 any regulation, rule, or order issued pursuant to
18 such a 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 title.

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. 507. 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. 508. 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 ccessing electronic health records maintained in the
11 trust;

12 (3) the sale of information contained in the
13 trust (as provided for in section 506(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 506(a)(2)(C)(ii) by appropriate emergency respond-
3 ers.

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

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

12 **SEC. 509. REGULATORY OVERSIGHT.**

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

16 (b) ESTABLISHMENT OF INTERAGENCY STEERING
17 COMMITTEE.—

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

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

1 (3) MEMBERSHIP.—The members of the Inter-
2 agency Steering Committee shall consist of the At-
3 torney General, the Chairperson of the Federal
4 Trade Commission, the Chairperson for the National
5 Committee for Vital and Health Statistics, a rep-
6 resentative of the Federal Reserve, and other Fed-
7 eral officials determined appropriate by the Sec-
8 retary of Health and Human Services.

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

15 (c) FEDERAL ADVISORY COMMITTEE.—

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

1 (2) DUTIES.—The National Committee for
2 Vital and Health Statistics shall issue periodic re-
3 ports and review policies concerning IHRTs based
4 on each of the following factors:

5 (A) Privacy and security policies.

6 (B) Economic progress.

7 (C) Interoperability standards.

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

12 (1) provide assistance to encourage the growth
13 of independent health record trusts;

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

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

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

1 ardized collection and transmission of individual
2 health records (or portions of such records) to au-
3 thorized EHR data users through a common inter-
4 face and for the portability of such records among
5 independent health record trusts; and

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

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

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

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

23 (3) Requiring a delay in releasing sensitive
24 health care test results and other similar informa-

1 tion to patients directly in order to give physicians
2 time to contact the patient.

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

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

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

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

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

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

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

1 (9) Public disclosure of audits in a manner
2 similar to financial audits required for publicly trad-
3 ed stock companies.

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

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

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

1 (2) The number of enforcement actions under-
2 taken by the Commission against independent health
3 record trusts in response to complaints under para-
4 graph (1), which shall be divided by enforcement ac-
5 tions related to security breaches and enforcement
6 actions not related to security breaches and may in-
7 clude other categories as the Interagency Steering
8 Committee established under subsection (b) deter-
9 mines appropriate.

10 (3) The economic progress of the individual
11 owner or institution operator as achieved through
12 independent health record trust usage and existing
13 barriers to such usage.

14 (4) The progress in security auditing as pro-
15 vided for by the Interagency Steering Committee
16 council under subsection (b).

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

19 (g) INTERAGENCY MEMORANDUM OF UNDER-
20 STANDING.—The Interagency Steering Committee shall
21 ensure, through the execution of an interagency memo-
22 randum of understanding, that—

23 (1) regulations, rulings, and interpretations
24 issued by Federal officials relating to the same mat-
25 ter over which 2 or more such officials have respon-

1 sibility under this title are administered so as to
2 have the same effect at all times; and

3 (2) the memorandum provides for the coordina-
4 tion of policies related to enforcing the same require-
5 ments through such officials in order to have coordi-
6 nated enforcement strategy that avoids duplication
7 of enforcement efforts and assigns priorities in en-
8 forcement.

○