

111TH CONGRESS
1ST SESSION

H. R. 4216

To amend the Public Health Service Act and titles XVIII and XIX of the Social Security Act to establish guidelines to enhance the meaningful use and interoperability of electronic medical records with personal health records, including for purposes of Medicare and Medicaid payment incentives.

IN THE HOUSE OF REPRESENTATIVES

DECEMBER 7, 2009

Mr. KENNEDY (for himself and Mr. REICHERT) 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 amend the Public Health Service Act and titles XVIII and XIX of the Social Security Act to establish guidelines to enhance the meaningful use and interoperability of electronic medical records with personal health records, including for purposes of Medicare and Medicaid payment incentives.

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.**

2 This Act may be cited as the “Personal Health
3 Record Act of 2009”.

4 **SEC. 2. ENHANCING MEANINGFUL USE OF ELECTRONIC**
5 **HEALTH RECORDS THROUGH INTEROPER-**
6 **ABILITY.**

7 (a) DEFINITIONS.—

8 (1) IN GENERAL.—Section 3000 of the Public
9 Health Service Act (42 U.S.C. 300jj) is amended by
10 adding at the end the following:

11 “(15) ELECTRONIC EXCHANGE.—The term
12 ‘electronic exchange’ shall include the automated
13 transfer of individual health information between
14 electronic medical records and personal health
15 records, and between electronic medical records, per-
16 sonal health records, and other electronic systems.

17 “(16) PERSONAL HEALTH RECORD.—The term
18 ‘personal health record’ means an electronic record
19 of PHR identifiable health information (as defined
20 in section 13407(f)(2) of the HITECH Act) of an
21 individual that—

22 “(A) complies with appropriate data con-
23 tent standards;

24 “(B) enables the individual, an authorized
25 representative, vendor of personal health
26 records (as defined in section 318.2(j) of title

1 16, Code of Federal Regulations, as in effect as
2 of November 1, 2009), any covered entity (as
3 defined for purposes of HIPAA privacy and se-
4 curity law, as defined in section 3009(a)(2)), or
5 an entity to the extent that it engages in activi-
6 ties as a business associate (as defined for such
7 purposes) of such a covered entity, to retrieve
8 data from or input data into the electronic
9 record; and

10 “(C) is portable and capable of electronic
11 communication between such individual and the
12 relevant covered entity, business associate de-
13 scribed in subparagraph (B), or vendor of per-
14 sonal health records of such individual that is
15 managed, shared, and controlled by or primarily
16 for the individual.”.

17 (2) CONFORMING AMENDMENT.—Section
18 13400(11) of the HITECH Act (42 U.S.C.
19 17921(11)) is amended to read as follows:

20 “(11) PERSONAL HEALTH RECORD.—The term
21 ‘personal health record’ has the meaning given such
22 term in section 3000(16) of the Public Health Serv-
23 ice Act.”.

1 (b) ACCESS TO INDIVIDUALLY IDENTIFIABLE
2 HEALTH INFORMATION.—Section 3001(b) of the Public
3 Health Service Act (42 U.S.C. 300jj–11(b)) is amended—

4 (1) in the matter preceding paragraph (1), by
5 inserting “electronic” before “exchange”;

6 (2) in paragraph (6)—

7 (A) by inserting “individuals,” after “phy-
8 sician offices,”; and

9 (B) by inserting “electronic” before “ex-
10 change of health care information”;

11 (3) in paragraph (10), by striking at the end
12 “and”;

13 (4) in paragraph (11), by striking the period
14 and inserting “; and”; and

15 (5) by adding at the end the following new
16 paragraph:

17 “(12) allows for an individual to have access to
18 their individually identifiable health information.”.

19 (c) STRATEGIC PLAN RELATING TO PERSONAL
20 HEALTH RECORDS.—Section 3001(c)(3)(A) of the Public
21 Health Service Act (42 U.S.C. 300jj–11(c)(3)(A)) is
22 amended by adding at the end the following new clause:

23 “(ix) The interoperability of a per-
24 sonal health record with an electronic
25 health record.”.

1 (d) GUIDELINES RELATING TO PERSONAL HEALTH
2 RECORDS.—Section 3001(c) of the Public Health Service
3 Act (42 U.S.C. 300jj–11(c)) is amended by adding at the
4 end the following new paragraph:

5 “(9) GUIDELINES FOR PERSONAL HEALTH
6 RECORDS.—Not later than the date that is 12
7 months after the date of the enactment of the Per-
8 sonal Health Record Act of 2009, the National Co-
9 ordinator shall develop guidelines for making elec-
10 tronic health records interoperable with personal
11 health records for the purpose of improving health
12 care quality, reducing medical errors, and advancing
13 the delivery of patient-centered medical care and
14 health management. Such guidelines shall include—

15 “(A) standards based on the recommenda-
16 tions provided in section 3002(b)(2)(B)(ix), in-
17 cluding for purposes of requiring electronic
18 health records to be made available through
19 electronic exchange and interoperable with per-
20 sonal health records for purposes of dem-
21 onstrating meaningful use of an electronic
22 health record under sections 1848(o)(2)(A)(i),
23 1886(n)(3)(A)(i), and 1903(t)(6)(C)(i)(II) of
24 the Social Security Act;

1 “(B) recommendations for applying such a
2 requirement of making electronic health records
3 available, with respect to community and behav-
4 ioral health programs, in the form of personal
5 health records to improve the effective and effi-
6 cient electronic exchange and management of
7 information between the individual (or author-
8 ized representative of the individual), including
9 those in medically underserved communities (as
10 defined in section 799B(6)), and community
11 health centers and behavioral health service
12 providers;

13 “(C) required components of a personal
14 health record, which shall include—

15 “(i) information on medical history,
16 including diagnoses and procedures, includ-
17 ing updates if diagnosis or procedures
18 change after each provider encounter;

19 “(ii) information on recent laboratory
20 results, diagnostic examinations, and
21 radiologic procedures, if available in elec-
22 tronic format;

23 “(iii) information on medications and
24 prescriptions, both current and historical,

1 including updates if medications change
2 after each provider encounter;

3 “(iv) information on allergies, both
4 medication and environmental, including
5 the specific reaction;

6 “(v) privacy, security, and electronic
7 informed consents for disclosing individ-
8 ually identifiable health information;

9 “(vi) computer programming stand-
10 ards determined by the National Coordi-
11 nator that allow interoperability of individ-
12 ually identifiable health information and
13 communications between covered entities
14 (as defined for purposes of HIPAA privacy
15 and security law, as defined in section
16 3009(a)(2)), entities to the extent that
17 they engage in activities as business associ-
18 ates of such covered entities, individuals,
19 and vendors of personal health records;

20 “(vii) portability of the personal
21 health record by the individual between
22 covered entities, business associates de-
23 scribed in clause (vi), or vendors of per-
24 sonal health records;

1 “(viii) ability to use such record as
2 part of the patient intake process;

3 “(ix) accurate attribution of the
4 source of all data in the personal health
5 record, including the source of the infor-
6 mation, the date that such information was
7 entered into the personal health record,
8 and standards-based protection of data
9 provided by the health care provider (such
10 as health care provider clinic notes, labora-
11 tory results, diagnostic examinations, and
12 radiologic procedures) from changes;

13 “(x) notification of the individual in-
14 volved or the authorized representative of
15 such individual of the risks of withholding
16 medical information from a medical pro-
17 vider; and

18 “(xi) health services communication
19 tools, including those which offer online se-
20 cure communication with covered entities
21 (as defined for purposes of HIPAA privacy
22 and security law, as defined in section
23 3009(a)(2)) and entities to the extent that
24 they engage in activities as business associ-

1 ates (as defined for such purposes) of such
2 a covered entity;

3 “(D) other possible components for consid-
4 eration of a personal health record, including—

5 “(i) an audit trail to monitor who has
6 accessed the personal health record of the
7 individual;

8 “(ii) automated appointment, care re-
9 minders, and health self-management tools;

10 “(iii) the ability to provide education
11 tools;

12 “(iv) the ability of the individual or
13 authorized representative involved to anno-
14 tate (without changing) health care pro-
15 vider records, such as to provide feedback
16 to health care providers of the individual;

17 “(v) protection of clinical records in
18 the personal health record which are im-
19 ported from or exported to a covered enti-
20 ty, business associate described in clause
21 (i), or vendor of personal health records
22 from being changed by the individual, au-
23 thorized representative of the individual,
24 vendor of personal health records, the cov-
25 ered entity, or business associate;

1 “(vi) the ability to allow comments by
2 the individual, authorized representative,
3 and covered entity within an area of the
4 personal health record that is separate
5 from the clinical record imported from or
6 exported to a covered entity; and

7 “(vii) emergency access procedures for
8 medical personnel, with respect to the
9 record, for clinical care in cases that the
10 individual or authorized representative is
11 not able to give consent; and

12 “(E) security, privacy, and electronic in-
13 formed consents for disclosing individually iden-
14 tifiable health information for personal health
15 records, including the recommendations de-
16 scribed in paragraph (6)(F).

17 In the case that the Secretary determines that any
18 standard or component for personal health records
19 included under the guidance under this paragraph is
20 not adequate pursuant to the report submitted
21 under paragraph (6)(F), the Secretary shall notify
22 the National Coordinator and the HIT Standards
23 Committee in accordance with section 3004(a)(2)(B)
24 and the National Coordinator may revise such stand-
25 ard or component, respectively.”.

1 (e) REPORTS.—Section 3001(c)(6) of such Act (42
2 U.S.C. 300jj–11(c)(6)) is amended by adding at the end
3 the following new subparagraphs:

4 “(F) MONITORING PERSONAL HEALTH
5 RECORDS.—Not later than the date that is 24
6 months after the date of the enactment of the
7 Personal Health Record Act of 2009 and annu-
8 ally thereafter, the National Coordinator, in
9 consultation with the Administrator of the Cen-
10 ters for Medicare & Medicaid Services, shall
11 submit to the appropriate committees of juris-
12 diction of Congress an annual report on—

13 “(i) the extent to which personal
14 health records have been integrated into
15 the meaningful use of electronic health
16 records for purposes of sections
17 1848(o)(2), 1886(n)(3), and 1903(t)(6) of
18 the Social Security Act;

19 “(ii) the extent to which the use of
20 personal health records improve commu-
21 nication between individuals and covered
22 entities (as defined for purposes of HIPAA
23 privacy and security law, as defined in sec-
24 tion 3009(a)(2)) and improve patient
25 health management, including documenta-

1 tion of the extent to which there are cost
2 savings;

3 “(iii) the extent to which the use of
4 personal health records, with respect to
5 community health centers and behavioral
6 health services, improve the effective and
7 efficient exchange and management of in-
8 formation between the individual involved
9 (or authorized representative of the indi-
10 vidual), including those in medically under-
11 served communities, and community health
12 centers and behavioral health service pro-
13 viders;

14 “(iv) status of the standards imple-
15 mented in paragraph (9)(A) and the need
16 to revise or include new standards;

17 “(v) the adequacy of the components
18 of a personal health record described in
19 paragraph (9)(C); and

20 “(vi) the affect of having an individual
21 with full access to the medical records of
22 such individual through use of a personal
23 health record, including—

24 “(I) a prospective study ana-
25 lyzing health care utilization (includ-

1 ing the impact of personal health
2 records on health care provider effi-
3 ciency, health care provider reim-
4 bursement for time spent interacting
5 with individuals as a result of per-
6 sonal health records, and defensive
7 medicine practices);

8 “(II) the extent that such access
9 affects communications by means of
10 such records between various health
11 care providers of the individual (in-
12 cluding the use of provider notations);

13 “(III) a prospective study ana-
14 lyzing the affect of such access on the
15 patient-health care provider relation-
16 ship; and

17 “(IV) the risks and benefits of an
18 individual having full access to med-
19 ical records of the individual through
20 the use of personal health records.

21 “(G) RECOMMENDATION RELATING TO SE-
22 CURITY AND PRIVACY OF PERSONAL HEALTH
23 RECORDS.—Not later than 6 months after the
24 date of the enactment of the Personal Health
25 Record Act of 2009, the National Coordinator

1 shall submit to the appropriate committees of
2 jurisdiction of Congress a report, including rec-
3 ommendations, on the technological,
4 medicolegal, medical safety, and other pertinent
5 issues related to an individual’s control of the
6 personal health record of such individual and
7 shall establish guidelines for such control. The
8 National Coordinator shall ensure the participa-
9 tion in such a report of health care consumers,
10 vendors of personal health records, and covered
11 entities (as defined for purposes of HIPAA pri-
12 vacy and security law, as defined in section
13 3009(a)(2)), along with other health care stake-
14 holders. The report shall encompass at least the
15 following issues:

16 “(i) the rights of an individual uti-
17 lizing a personal health record with respect
18 to the individual’s own individually identifi-
19 able health information contained in such;
20 and

21 “(ii) the security and privacy of an in-
22 dividual utilizing a personal health record,
23 including—

24 “(I) defining who has right of ac-
25 cess to an individual’s personal health

1 record in the case of a personal health
2 record provided by a covered entity;

3 “(II) security and privacy issues
4 following medical emergency access of
5 information in a personal health
6 record by health care providers;

7 “(III) the impact of an individual
8 restricting medical information access
9 in a personal health record of such in-
10 dividual to health care providers on
11 patient care and safety;

12 “(IV) the risks and benefits of
13 health care provider notification if the
14 personal health record of an individual
15 is restricted by the individual;

16 “(V) the uses and disclosures of
17 the information of an individual con-
18 tained in a personal health record that
19 should be authorized or required by a
20 vendor of personal health records pro-
21 viding and maintaining such record;

22 “(VI) electronic informed con-
23 sents for disclosing individually identi-
24 fiable health information;

1 “(VII) the use of an audit trail of
2 who has entered, removed, and
3 changed data within a personal health
4 record; and

5 “(VIII) the dissemination of ab-
6 normal laboratory results, diagnostic
7 examinations, and radiological proce-
8 dures into personal health records
9 prior to notification of the abnor-
10 mality by the health care provider.”.

11 (f) PERSONAL HEALTH RECORD STANDARDS IN-
12 CLUDED IN HIT POLICY COMMITTEE RECOMMENDA-
13 TIONS.—

14 (1) IN GENERAL.—Section 3002(b)(2)(B) of
15 the Public Health Service Act (42 U.S.C. 300jj-
16 12(b)(2)(B)) is amended by adding at the end the
17 following new clause:

18 “(ix) Standards and implementation
19 specifications for the interoperability of
20 personal health records and electronic
21 health records.”.

22 (2) CONFORMING CHANGES RELATING TO HIT
23 STANDARDS COMMITTEE RECOMMENDATIONS.—

24 (A) DEADLINE FOR SUBMISSION OF REC-
25 COMMENDATIONS TO NATIONAL COORDINATOR.—

1 Section 3003(b)(1)(A) of such Act (42 U.S.C.
2 300jj–13(b)(1)(A)) is amended by adding at the
3 end the following: “Not later than the date that
4 is 6 months after the date of the enactment of
5 the Personal Health Record Act of 2009, the
6 HIT Standards Committee shall recommend to
7 the National Coordinator standards and imple-
8 mentation specifications described in section
9 3002(b)(2)(B)(ix). The HIT Standards Com-
10 mittee shall update such recommendations and
11 make new recommendations as appropriate, in-
12 cluding in response to notification sent under
13 section 3004(a)(2)(B).”.

14 (B) FORUM.—Section 3003(b)(2) of such
15 Act (42 U.S.C. 300jj–13(b)(2)) is amended by
16 inserting before the period the following: “, in-
17 cluding for the adoption of interoperability of
18 personal health records and electronic health
19 records”.

20 (3) CONFORMING CHANGES RELATING TO
21 ADOPTION OF INITIAL SET OF STANDARDS.—Section
22 3004(b)(1) of such Act (42 U.S.C. 300jj–14(b)(1))
23 is amended by inserting “(other than clause (ix))”
24 after “section 3002(b)(2)(B)”.

1 (g) APPLICATION OF GUIDELINES TO MEANINGFUL
2 USE REQUIREMENTS OF ELECTRONIC MEDICAL RECORDS
3 UNDER MEDICARE.—

4 (1) ELIGIBLE PROFESSIONAL PAYMENT INCEN-
5 TIVES.—Section 1848(o)(2)(A)(i) of the Social Secu-
6 rity Act (42 U.S.C. 1395w-4(o)(2)(A)(i)) is amend-
7 ed by inserting before the period at the end the fol-
8 lowing: “and shall include demonstrating the avail-
9 ability of such technology to and use of such tech-
10 nology by individuals furnished items and services by
11 such professional in the form of electronic and per-
12 sonal health records consistent with guidelines estab-
13 lished by the National Coordinator under section
14 3001(c)(9)(A) of the Public Health Service Act”.

15 (2) ELIGIBLE HOSPITAL PAYMENT INCEN-
16 TIVES.—Section 1886(n)(3)(A)(i) of such Act (42
17 U.S.C. 1395ww(n)(3)(A)(i)) is amended by inserting
18 before the period at the end the following: “, which
19 shall include demonstrating the availability of such
20 technology to and use of such technology by individ-
21 uals furnished items and services by such hospital in
22 the form of electronic and personal health records
23 consistent with guidelines established by the Na-
24 tional Coordinator under section 3001(c)(9)(A) of
25 the Public Health Service Act”.

1 (h) APPLICATION OF GUIDELINES TO MEANINGFUL
2 EHR USE REQUIREMENTS UNDER MEDICAID.—Section
3 1903(t)(6)(C)(i)(II) of the Social Security Act (42 U.S.C.
4 1396b(t)(6)(C)(i)(II)) is amended—

5 (1) by striking “and” before “that may be
6 based”; and

7 (2) by inserting before the period at the end the
8 following: “, and which shall include demonstrating
9 the availability of such technology to and use of such
10 technology by individuals furnished items and serv-
11 ices by such Medicaid provider in the form of elec-
12 tronic and personal health records consistent with
13 guidelines established by the National Coordinator
14 under section 3001(c)(9)(A) of the Public Health
15 Service Act”.

16 (i) RELATIONSHIP TO OTHER LAWS.—Section 13421
17 of the HITECH Act (42 U.S.C. 17951) is amended by
18 adding at the end the following new subsection:

19 “(c) HEALTH INFORMATION PORTABILITY AND AC-
20 COUNTABILITY ACT, HEALTH CARE PROVIDERS, AND
21 PERSONAL HEALTH RECORDS.—Nothing in this subtitle
22 or the provisions of or amendments made by the Personal
23 Health Record Act of 2009 shall affect the ability of a
24 health care provider involved in the direct care of an indi-
25 vidual to obtain pertinent information on the medical his-

1 tory of such individual from another health care provider
2 involved in the medical care of the individual, in accord-
3 ance with HIPAA privacy and security law (as defined in
4 section 3009(a)(2) of the Public Health Service Act) as
5 in effect before the date of the enactment of the Personal
6 Health Record Act of 2009.”.

○