[DISCUSSION DRAFT]

SEC. ___. ENSURING INTEROPERABILITY OF QUALIFIED ELECTRONIC HEALTH RECORDS.

(a) DEVELOPMENT OF AND RECOMMENDATIONS FOR METHODS TO MEASURE INTEROPERABILITY.—

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

"SEC. 3010. ENSURING INTEROPERABILITY OF QUALIFIED ELECTRONIC HEALTH RECORDS.

(a) INTEROPERABILITY.—In order for a qualified electronic health record to be considered interoperable, such record must satisfy the following criteria:

“(1) OPEN ACCESS.—The record allows authorized users access to the entirety of a patient’s data from any and all qualified electronic health records without restriction.

“(2) COMPLETE ACCESS TO HEALTH DATA.—The record allows authorized users access to the entirety of a patient’s data in one location, without the need for multiple interfaces (such as sign on systems)."
“(3) Does not block access to other qualified electronic health records.—The record does not prevent end users from interfacing with other qualified electronic health records.

“(4) [Other criteria?]

“(b) Determining methods in which to measure if qualified electronic health records are interoperable.—

“(1) In general.—The Secretary shall adopt, in accordance with this section—

“(A) methods in which to measure if qualified electronic health records satisfy the criteria described in subsection (a); and

“(B) modifications (including additions) to such methods, as appropriate.

“(2) Role of charter organization.—

“(A) In general.—Except as provided in subparagraph (B), any method adopted under this subsection shall be a method that has been recommended by the Charter Organization established under subsection (c).

“(B) Special rules.—

“(i) Different methods.—The Secretary may adopt a method that is dif-
different from any method recommended by
the Charter Organization, if—

“(I) the different method will
substantially reduce administrative
costs to health care providers and
health plans compared to the alter-
 natives; and

“(II) the method is promulgated
in accordance with the rulemaking
procedures of subchapter III of chap-
ter 5 of title 5, United States Code.

“(ii) NO STANDARD BY CHARTER OR-
gANIZATION.—If the Charter Organization
under subsection (c) has not recommended
any method relating to a criteria described
in subsection (a)—

“(I) subparagraph (A) shall not
apply; and

“(II) paragraph (3) shall apply.

“(C) CONSULTATION REQUIREMENT.—

“(i) IN GENERAL.—The Secretary, in
complying with paragraph (3), may not
adopt under this subsection a method that
has not been recommended by the Charter
Organization under subsection (e) unless
the Secretary consulted with each of the organizations described in clause (ii) before adopting the method.

“(ii) Organizations described.—The organizations referred to in clause (i) are the following: [Please review what organizations should be included.]

“(3) Assistance to the Secretary.—In complying with the requirements of this subsection, the Secretary shall rely on the recommendations of the National Committee on Vital and Health Statistics established under section 306(k) of the Public Health Service Act (42 U.S.C. 242k(k)), and shall consult with appropriate Federal and State agencies and private organizations. The Secretary shall publish in the Federal Register any recommendation of the National Committee on Vital and Health Statistics regarding the adoption of a method under this subsection.

“(4) Application to modification of methods.—Paragraphs (2) and (3) shall apply to a modification to a method (including an addition to a method) adopted under paragraph (1)(B) in the same manner as such paragraphs apply to an initial method adopted under paragraph (1)(A).
“(5) METHODS.—

“(e) CHARTER ORGANIZATION.—

“(1) ESTABLISHMENT.—Not later than 180 days after the date of the enactment of this section, the Secretary shall establish a committee to be known as the ‘Charter Organization’ to provide to the Secretary recommendations for methods in which to measure if qualified electronic health records satisfy the criteria described in subsection (a).

“(2) RECOMMENDATIONS.—

“(A) INITIAL METHODS.—Not later than one year after the date of the enactment of this section, the Charter Organization shall submit to the Secretary recommendations for an initial set of methods described in paragraph (1).

“(B) MODIFICATIONS AND ADDITIONS.—

“(i) EVALUATIONS AND REPORTS.—

“(I) HEARINGS.—Not later than three years after the date of the enactment of this section, and not less than biennially thereafter, the Secretary, acting through the Charter Organization, shall conduct hearings to
evaluate and review the adopted methods under this section.

“(II) REPORT.—Not later than five years after the date of the enactment of this section, and not less than biennially thereafter, the Charter Organization shall provide recommendations for updating and improving such methods.

“(ii) INTERIM FINAL RULEMAKING.—

“(I) IN GENERAL.—Subject to subclause (III) and subsection (b)(2)(B), any recommendations to amend adopted methods that have been approved by the Charter Organization and submitted to the Secretary under clause (i)(II) shall be adopted by the Secretary through promulgation of an interim final rule not later than 90 days after receipt of the organization’s submission.

“(II) PUBLIC COMMENT.—The Secretary shall accept and consider public comments on any interim final rule published under this clause for
60 days after the date of such publication.

[(III) AUTHORITY NOT TO ADOPT.—The Secretary, after the period of public comment described in subclause (II), may determine not to adopt a recommendation to amend an adopted method if [______]. [Not later than [____ days] after the date of such determination, the Secretary shall publish in the Federal Register the reason for such determination not to adopt such recommendation.]

“(IV) EFFECTIVE DATE.—The effective date of any amendment to existing methods that is adopted through an interim final rule published under this paragraph shall be 25 months following the close of the public comment period described in subclause (II).

“(3) MEMBERSHIP.—The Charter Organization shall consist of the following members:

“(A) STANDARDS DEVELOPMENT ORGANIZATIONS.—One representative from each of the
standards development organizations accredited
by the American National Standards Institute,
appointed by the Committee on Energy and
Commerce of the House of Representatives and
the Committee on Health, Education, Labor,
and Pensions of the Senate.

“(B) Stakeholders.—Twelve representatives of health care providers, qualified electronic health records developers, health insurance issuers and group health plans, and other appropriate stakeholders—

“(i) six of whom shall be appointed by
the Speaker and minority leader of the
House of Representatives; and

“(ii) six of whom shall be appointed
by the majority leader and minority leader
of the Senate.

“(4) Application of FACA.—The Federal Advisory Committee Act (5 U.S.C. App.), other than section 14, shall apply to the Charter Organization.

“(d) Harmonization.—In carrying out this section,
the Secretary shall recognize methods, with respect to interoperability of qualified electronic health records, from an entity or entities for the purpose of harmonizing or
updating methods in order to achieve uniform and consistent implementation of the methods.

“(e) Pilot Testing of Methods.—In the development, harmonization, or recognition of methods under this section, the Secretary shall, as appropriate, provide for the testing of such methods by the National Institute for Standards and Technology under section 13201(a) of the Health Information Technology for Economic and Clinical Health Act. [Need conforming amendment to such 13201(a).]

“(f) Consistency.—The methods recommended under this section shall be consistent with the standards for information transactions and data elements adopted pursuant to section 1173 of the Social Security Act.”.

(2) Sunsetting HIT Policy Committee and HIT Standards Committee.—

(A) HIT Policy Committee.—Section 3002 of the Public Health Service Act (42 U.S.C. 300jj–12) is amended by adding at the end the following new subsection:

“(f) Termination.—The HIT Policy Committee shall terminate on the date of the enactment of the Act.”.

(B) HIT Standards Committee.—Section 3003 of the Public Health Service Act (42
U.S.C. 300jj–13) is amended by adding at the end the following new subsection:

“(f) TERMINATION.—The HIT Standards Committee shall terminate on the date that is 6 months after the date of the enactment of this section.”.

(b) ADOPTION.—Section 3004 of the Public Health Service Act (42 U.S.C. 300jj–14) is amended—

(1) in subsection (b), by adding at the end the following new paragraph:

“(4) TERMINATION.—The Secretary may not adopt any standards, implementation specifications, or certification criteria under this subsection or subsection (a) after the date that is 6 months after the date of the enactment of this section.”; and

(2) by adding at the end the following new subsection:

“(c) ADOPTION OF METHODS TO MEASURE INTEROPERABILITY.—For provisions relating to the adoption of methods to measure interoperability, see section 3010.”.

(c) REPORTS AND NOTIFICATIONS.—Section 3010 of the Public Health Service Act, as added by subsection (a), is amended by adding at the end the following new subsection:

“(g) DISSEMINATION OF INFORMATION.—
“(1) **INITIAL SUMMARY REPORT.**—Not later than July 1, 2016, the Secretary, after consultation with relevant stakeholders, shall submit to Congress and provide for publication in the Federal Register and the posting on the Internet website of the Office of the National Coordinator for Health Information Technology of a report on the following:

“(A) The initial set of methods adopted under this section.

“(B) The strategies for achieving widespread interoperability.

“(C) An overview of the extent to which qualified electronic health records offered as of such date satisfy such initial set.

“(D) Any barriers that are preventing widespread interoperability.

“(E) The plan and milestones, including specific steps, to achieve widespread interoperability.

“(2) **FOLLOW-UP DETERMINATION AND REPORT ON WIDESPREAD INTEROPERABILITY.**—Not later than December 31, 2017, the Secretary shall provide for publication in the Federal Register and the posting on the Internet website of the Office of the Na-
tional Coordinator for Health Information Technology of the following:

“(A) A determination by the Secretary whether the goal of widespread interoperability has been achieved.

“(B) A list identifying the vendors of, or other entities offering, qualified electronic health records, which categorizes such entities, with respect to such records, as in compliance or not in compliance with the certification criteria described in section 3001(c)(5)(B)(ii) and with the requirements under clause (i) of section 3001(c)(5)(C) (including with the terms of the attestation and other requirements under such clause).

“(C) Actions that may be taken by entities identified under subparagraph (B) as not being in compliance with such criteria and requirements in order for such entities to become in compliance with such criteria and requirements.

“(D) Penalties described in section 3010A(b) to which entities, with respect to such qualified electronic health records, beginning January 1, 2019, are subject if such technology and entities are not in compliance with the cer-
notification criteria described in section 3001(c)(5)(B)(ii) and with the requirements under clause (i) of section 3001(c)(5)(C), respectively.

“(3) ONGOING PUBLICATION OF RECOMMENDATIONS.—The Secretary shall provide for publication in the Federal Register and the posting on the Internet website of the Office of the National Coordinator for Health Information Technology of all recommendations made under this section.”.

(d) CERTIFICATION AND OTHER ENFORCEMENT PROVISIONS.—

(1) CERTIFICATION OF QUALIFIED ELECTRONIC HEALTH RECORD TECHNOLOGY.—

(A) IN GENERAL.—Section 3007(b) of the Public Health Service Act (42 U.S.C. 300jj–17(b)) is amended by striking “under section 3001(c)(3) to be in compliance with” and all that follows through the period at the end and inserting “under section 3001(c)(3)—

“(1) for certifications made before January 1, 2018, to be in compliance with applicable standards adopted under subsections (a) and (b) of section 3004; and
“(2) for certifications made on or after January 1, 2018, to be interoperable in accordance with section 3010, including as measured by the methods adopted under such section.”.

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

(i) by amending subparagraph (B) of such section to read as follows:

“(B) CERTIFICATION CRITERIA DESCRIBED.—In this title, the term ‘certification criteria’ means, with respect to qualified electronic health records—

“(i) for certifications made before January 1, 2018, criteria to establish that the technology meets standards and implementation specifications adopted under subsections (a) and (b) of section 3004 for qualified electronic health records; and

“(ii) for certifications made on or after January 1, 2018, criteria to establish that the technology is interoperable, in accordance with section 3010, including as measured by the methods adopted under such section.”; and
(ii) by adding at the end the following new subparagraph:

```
(C) Enforcement;
```

DECERTIFICATIONS.—

```
(i) Requirements.—Under any program kept or recognized under subparagraph (A), the Secretary shall ensure that any vendor of or other entity offering qualified electronic health records seeking a certification of such records under such program on or after January 1, 2018, shall, as a condition of certification (and maintenance of certification) of such records under such program—

```
(I) provide to the Secretary an attestation that the entity, unless for a legitimate purpose specified by the Secretary, has not knowingly and willfully taken any action, including through any financial, administrative, or technological barrier, to limit or restrict the exchange of information or to prevent or dis incentivize widespread interoperability between any providers using such records or other qualified
electronic health records in connection
with such records;

“(II) publish application pro-
gramming interfaces, with respect to
such records, for medical records
data, search and indexing, semantic
harmonization and vocabulary trans-
lation, and user interface applications;
and

“(III) demonstrate to the satis-
faction of the Secretary that data
from such records is able to be ex-
changed through the use of applica-
tion programming interfaces and used
in a manner that allows for exchange
and everyday use of such records by
authorized users.

“(ii) DECERTIFICATION.—Under any
program kept or recognized under subpara-
graph (A), the Secretary shall ensure that
beginning January 1, 2019, any qualified
electronic health record that does not sat-
ify the certification criteria described in
section 3001(c)(5)(B)(ii) or with respect to
which the vendor or other entity described
in clause (i) does not satisfy the requirements under such clause (or is determined to be in violation of the terms of the attestation or other requirements under such clause) shall no longer be considered as certified under such program.

“(iii) ANNUAL PUBLICATION.—For 2019 and each subsequent year, the Secretary shall post on the public Internet website of the Department of Health and Human Services a list of any vendors of or other entities offering qualified electronic health records with respect to which certification has been withdrawn under clause (ii) during such year.”.

(2) ADDITIONAL ENFORCEMENT PROVISIONS UNDER THE PUBLIC HEALTH SERVICE ACT.—Subtitle A of title XXX of the Public Health Service Act (42 U.S.C. 300jj–11 et seq.), as amended by subsection (a)(1), is further amended by adding at the end the following new section:

“SEC. 3010A. ENFORCEMENT MECHANISMS.

“(a) INSPECTOR GENERAL AUTHORITY.—The Inspector General of the Department of Health and Human Services shall have the authority to investigate claims of—
“(1) vendors of, or other entities offering, qualified electronic health records being in violation of an attestation made under section 3001(c)(5)(C)(i)(I), with respect to the use of such records by a health care provider under a specified Medicare incentive program; and

“(2) health care providers, with respect to the use of such records under a specified Medicare incentive program, having, unless for a legitimate purpose specified by the Secretary, knowingly and willfully taken any action, including through any financial, administrative, or technical barrier, to limit or restrict the exchange of information or to prevent or disincentivize widespread interoperability between any providers using such records or other qualified electronic health records in connection with such records.

“(b) Penalty.—[Review what the penalties should be. ] Any person or entity determined to have committed an act described in subsection (a), in connection with a specified Medicare incentive program, shall be subject to the provisions of sections 1128, 1128A, and 1128B in the same manner as a person or entity determined to have committed an act described in such respective section. The provisions of section 1128A (other than subsections (a)
and (b)) shall apply to a civil money penalty applied under this subsection in the same manner as they apply to a civil money penalty or proceeding under section 1128A(a).

“(c) SPECIFIED MEDICARE INCENTIVE PROGRAM.—
For purposes of this section, the term ‘specified Medicare incentive program’ includes the following:

“(1) The incentive payments under subsection (o) of section 1848 of the Social Security Act (42 U.S.C. 1395w–4) and adjustments under subsection (a)(7) of such section.

“(2) The incentive payments under subsection (n) of section 1848 of such Act (42 U.S.C. 1395ww) and adjustments under subsection (b)(3)(B) of such section.

“(3) The incentive payments and adjustments made under subsections (l) and (m) of section 1853 of such Act (42 U.S.C. 1395w–23).

“(4) The incentive payment under paragraph (3) of section 1814(l) of such Act (42 U.S.C. 1395f(l)) and adjustment under paragraph (4) of such section.

“(5) The shared savings program under section 1899 of the Social Security Act (42 U.S.C. 1395jjj).”
(3) Demonstration required for meaningful EHR use incentives under Medicare.—

(A) Incentives for Professionals.—Section 1848(o)(2)(C) of the Social Security Act (42 U.S.C. 1395w–4(o)(2)(C)) is amended by adding at the end the following new clause:”.

“(iii) Interoperability.—With respect to EHR reporting periods for payment years beginning with 2018, the means described in clause (i) specified by the Secretary shall include a demonstration, through means such as an attestation, that the professional has not knowingly and willfully taken any action described in section 3010A(a)(2) of the Public Health Service Act, with respect to the use of any certified EHR technology.”.

(B) Incentives for Hospitals.—Section 1886(o)(1) of the Social Security Act (42 U.S.C. 1395ww(o)(1)) is amended—

(i) in subparagraph (A), by inserting before the period at the end the following: “and, for performance periods for fiscal year 2018 or a subsequent fiscal year, that
provide a demonstration described in sub-
paragraph (D) to the Secretary”; and

(ii) by adding at the end the following
new subparagraph:

“(D) DEMONSTRATION DESCRIBED.—The
demonstration described in this subparagraph is
a demonstration, through means such as an at-
testation, that the hospital has not knowingly
and willfully taken any action described in sec-
tion 3010A(a)(2) of the Public Health Service
Act, with respect to the use of any certified
EHR technology.”.

(4) DEMONSTRATION REQUIRED FOR MEANING-
FUL EHR USE INCENTIVES UNDER MEDICAID.—Sec-
tion 1903(t)(2) of the Social Security Act (42
U.S.C. 1396b(t)(2)) is amended by adding at the
end the following: “An eligible professional shall not
qualify as a Medicaid provider under this subsection,
with respect to a year beginning with 2018, unless
such professional demonstrates to the Secretary,
through means such as an attestation, that the pro-
fessional has not knowingly and willfully taken any
action described in section 3010A(a)(2) of the Public
Health Service Act, with respect to the use of any
certified EHR technology.”.
(c) DEFINITIONS.—

(1) CERTIFIED EHR TECHNOLOGY.—Paragraph (1) of section 3000 of the Public Health Service Act (42 U.S.C. 300jj) is amended to read as follows:

“(1) CERTIFIED EHR TECHNOLOGY.—The term ‘certified EHR technology’ means a qualified electronic health record that is certified pursuant to section 3001(c)(5) as meeting the certification criteria defined in subparagraph (B) of such section that are applicable to the type of record involved (as determined by the Secretary, such as an ambulatory electronic health record for office-based physicians or an inpatient hospital electronic health record for hospitals) and, beginning January 1, 2018, with respect to which the vendor or other entity offering such technology is in compliance with the requirements under section 3001(c)(5)(C)(i).”.

(2) WIDESPREAD INTEROPERABILITY.—Section 3000 of the Public Health Service Act (42 U.S.C. 300jj) is amended by adding at the end the following new paragraph:

“(15) WIDESPREAD INTEROPERABILITY.—The term ‘widespread interoperability’ means that, on a nationwide basis—
“(A) qualified electronic health records are interoperable, in accordance with section 3010, including as measured by the methods adopted under such section; and

“(B) such records are employed by meaningful EHR users under the specified Medicare incentive programs (as defined in section 3010A(c)) and other clinicians and health care providers.”.

(f) CONFORMING AMENDMENTS.—

(1) V OLUNTARY USE OF STANDARDS.—Section 3006 of the Public Health Service Act (42 U.S.C. 300jj–16) is amended—

(A) in subsection (a)—

(i) in paragraph (1), by inserting “or a method adopted under section 3010” after “section 3004”; and

(ii) in paragraph (2), by striking “or implementation specification” and inserting “implementation specification, or method”; and

(B) in subsection (b), by inserting “or the methods adopted under section 3010” after “section 3004”.
(2) HIPAA PRIVACY AND SECURITY LAW DEFINITION CORRECTION.—Section 3009(a)(2)(A) of the Public Health Service Act (42 U.S.C. 300jj–19(a)(2)(A)) is amended by striking “title IV” and inserting “title XIII”.

(3) COORDINATION OF FEDERAL ACTIVITIES.—Section 13111 of the HITECH Act is amended—

(A) in subsection (a), by inserting before the period at the end the following: “(or beginning on January 1, 2018, that are interoperable under section 3010 of such Act, including as measured by the methods adopted under such section)”; and

(B) in subsection (b)—

(i) by inserting (or beginning on January 1, 2018, a method adopted under section 3010 of such Act) before “the President”; and

(ii) by inserting “(or method)” before “, respectively”.

(4) APPLICATION TO PRIVATE ENTITIES.—Section 13112 of the HITECH Act is amended by inserting before the period at the end the following “(or beginning on January 1, 2018, that are interoperable under section 3010 of such Act, including
as measured by the methods adopted under such section”).

\[(5)\] OTHERS.—