[DISCUSSION DRAFT]

1	SEC ENSURING INTEROPERABILITY OF QUALIFIED
2	ELECTRONIC HEALTH RECORDS.
3	(a) Development of and Recommendations for
4	METHODS TO MEASURE INTEROPERABILITY.—
5	(1) In general.—Subtitle A of title XXX of
6	the Public Health Service Act (42 U.S.C. 300jj-11
7	et seq.) is amended by adding at the end the fol-
8	lowing new section:
9	"SEC. 3010. ENSURING INTEROPERABILITY OF QUALIFIED
10	ELECTRONIC HEALTH RECORDS.
11	"(a) Interoperability.—In order for a qualified
12	electronic health record to be considered interoperable,
13	such record must satisfy the following criteria:
14	"(1) Open access.—The record allows author-
15	ized users access to the entirety of a patient's data
16	from any and all qualified electronic health records
17	without restriction.
18	"(2) Complete access to health data.—
19	The record allows authorized users access to the en-
20	tirety of a patient's data in one location, without the
21	need for multiple interfaces (such as sign on sys-
22	tems).

1	"(3) Does not block access to other
2	QUALIFIED ELECTRONIC HEALTH RECORDS.—The
3	record does not prevent end users from interfacing
4	with other qualified electronic health records.
5	"(4) [Other criteria?]
6	"(b) Determining Methods in Which to Meas-
7	URE IF QUALIFIED ELECTRONIC HEALTH RECORDS ARE
8	Interoperable.—
9	"(1) IN GENERAL.—The Secretary shall adopt,
10	in accordance with this section—
11	"(A) methods in which to measure if quali-
12	fied electronic health records satisfy the criteria
13	described in subsection (a); and
14	"(B) modifications (including additions) to
15	such methods, as appropriate.
16	"(2) Role of Charter Organization.—
17	"(A) IN GENERAL.—Except as provided in
18	subparagraph (B), any method adopted under
19	this subsection shall be a method that has been
20	recommended by the Charter Organization es-
21	tablished under subsection (c).
22	"(B) Special rules.—
23	"(i) DIFFERENT METHODS.—The
24	Secretary may adopt a method that is dif-

1	ferent from any method recommended by
2	the Charter Organization, if—
3	"(I) the different method will
4	substantially reduce administrative
5	costs to health care providers and
6	health plans compared to the alter-
7	natives; and
8	"(II) the method is promulgated
9	in accordance with the rulemaking
10	procedures of subchapter III of chap-
11	ter 5 of title 5, United States Code.
12	"(ii) No standard by charter or-
13	GANIZATION.—If the Charter Organization
14	under subsection (c) has not recommended
15	any method relating to a criteria described
16	in subsection (a)—
17	"(I) subparagraph (A) shall not
18	apply; and
19	"(II) paragraph (3) shall apply.
20	"(C) Consultation requirement.—
21	"(i) In General.—The Secretary, in
22	complying with paragraph (3), may not
23	adopt under this subsection a method that
24	has not been recommended by the Charter
25	Organization under subsection (c) unless

1	the Secretary consulted with each of the
2	organizations described in clause (ii) before
3	adopting the method.
4	"(ii) Organizations described.—
5	The organizations referred to in clause (i)
6	are the following: [Please review what or-
7	ganizations should be included.
8	"(3) Assistance to the secretary.—In
9	complying with the requirements of this subsection,
10	the Secretary shall rely on the recommendations of
11	the National Committee on Vital and Health Statis-
12	tics established under section 306(k) of the Public
13	Health Service Act (42 U.S.C. 242k(k)), and shall
14	consult with appropriate Federal and State agencies
15	and private organizations. The Secretary shall pub-
16	lish in the Federal Register any recommendation of
17	the National Committee on Vital and Health Statis-
18	tics regarding the adoption of a method under this
19	subsection.
20	"(4) Application to modification of meth-
21	ODS.—Paragraphs (2) and (3) shall apply to a modi-
22	fication to a method (including an addition to a
23	method) adopted under paragraph (1)(B) in the
24	same manner as such paragraphs apply to an initial
25	method adopted under paragraph (1)(A).

1	"(5) Methods.—[Definition?]
2	"(c) Charter Organization.—
3	"(1) Establishment.—Not later than 180
4	days after the date of the enactment of this section,
5	the Secretary shall establish a committee to be
6	known as the 'Charter Organization' to provide to
7	the Secretary recommendations for methods in
8	which to measure if qualified electronic health
9	records satisfy the criteria described in subsection
10	(a).
11	"(2) Recommendations.—
12	"(A) Initial methods.—Not later than
13	one year after the date of the enactment of this
14	section, the Charter Organization shall submit
15	to the Secretary recommendations for an initial
16	set of methods described in paragraph (1).
17	"(B) Modifications and additions.—
18	"(i) Evaluations and reports.—
19	"(I) Hearings.—Not later than
20	three years after the date of the en-
21	actment of this section, and not less
22	than biennially thereafter, the Sec-
23	retary, acting through the Charter Or-
24	ganization, shall conduct hearings to

1	evaluate and review the adopted meth-
2	ods under this section.
3	"(II) Report.—Not later than
4	five years after the date of the enact-
5	ment of this section, and not less than
6	biennially thereafter, the Charter Or-
7	ganization shall provide recommenda-
8	tions for updating and improving such
9	methods.
10	"(ii) Interim final rulemaking.—
11	"(I) In general.—[Subject to
12	subclause (III) and subsection
13	(b)(2)(B), any recommendations to
14	amend adopted methods that have
15	been approved by the Charter Organi-
16	zation and submitted to the Secretary
17	under clause (i)(II) shall be adopted
18	by the Secretary through promulga-
19	tion of an interim final rule not later
20	than 90 days after receipt of the orga-
21	nization's submission.
22	"(II) Public comment.—The
23	Secretary shall accept and consider
24	public comments on any interim final
25	rule published under this clause for

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1	60 days after the date of such publi-
2	cation.
3	["(III) Authority not to
4	ADOPT.—The Secretary, after the pe-
5	riod of public comment described in
6	subclause (II), may determine not to
7	adopt a recommendation to amend an
8	adopted method if []. [Not
9	later than [days] after the date
10	of such determination, the Secretary
11	shall publish in the Federal Register
12	the reason for such determination not
13	to adopt such recommendation.]]
14	"(IV) EFFECTIVE DATE.—The
15	effective date of any amendment to
16	existing methods that is adopted
17	through an interim final rule pub-
18	lished under this paragraph shall be
19	25 months following the close of the
20	public comment period described in
21	subclause (II).
22	"(3) Membership.—The Charter Organization
23	shall consist of the following members:
24	"(A) STANDARDS DEVELOPMENT ORGANI-
25	ZATIONS.—One representative from each of the

1	standards development organizations accredited
2	by the American National Standards Institute,
3	appointed by the Committee on Energy and
4	Commerce of the House of Representatives and
5	the Committee on Health, Education, Labor,
6	and Pensions of the Senate.
7	"(B) Stakeholders.—Twelve representa-
8	tives of health care providers, qualified elec-
9	tronic health records developers, health insur-
10	ance issuers and group health plans, and other
11	appropriate stakeholders—
12	"(i) six of whom shall be appointed by
13	the Speaker and minority leader of the
14	House of Representatives; and
15	"(ii) six of whom shall be appointed
16	by the majority leader and minority leader
17	of the Senate.
18	"(4) APPLICATION OF FACA.—The Federal Ad-
19	visory Committee Act (5 U.S.C. App.), other than
20	section 14, shall apply to the Charter Organization.
21	"(d) Harmonization.—In carrying out this section,
22	the Secretary shall recognize methods, with respect to
23	interoperability of qualified electronic health records, from
24	an entity or entities for the purpose of harmonizing or

1	updating methods in order to achieve uniform and con-
2	sistent implementation of the methods.
3	"(e) Pilot Testing of Methods.—In the develop-
4	ment, harmonization, or recognition of methods under this
5	section, the Secretary shall, as appropriate, provide for the
6	testing of such methods by the National Institute for
7	Standards and Technology under section 13201(a) of the
8	Health Information Technology for Economic and Clinical
9	Health Act. [Need conforming amendment to such
10	13201(a).]
11	"(f) Consistency.—The methods recommended
12	under this section shall be consistent with the standards
13	for information transactions and data elements adopted
14	pursuant to section 1173 of the Social Security Act.".
15	(2) Sunsetting hit policy committee and
16	HIT STANDARDS COMMITTEE.—
17	(A) HIT POLICY COMMITTEE.—Section
18	3002 of the Public Health Service Act (42
19	U.S.C. 300jj-12) is amended by adding at the
20	end the following new subsection:
21	"(f) TERMINATION.—The HIT Policy Committee
22	shall terminate on the date of the enactment of the
23	[] Act.''.
24	(B) HIT STANDARDS COMMITTEE.—Sec-
25	tion 3003 of the Public Health Service Act (42

1	U.S.C. 300jj-13) is amended by adding at the
2	end the following new subsection:
3	"(f) Termination.—The HIT Standards Committee
4	shall terminate on the date that is 6 months after the date
5	of the enactment of this section.".
6	(b) Adoption.—Section 3004 of the Public Health
7	Service Act (42 U.S.C. 300jj-14) is amended—
8	(1) in subsection (b), by adding at the end the
9	following new paragraph:
10	"(4) Termination.—The Secretary may not
11	adopt any standards, implementation specifications,
12	or certification criteria under this subsection or sub-
13	section (a) after the date that is 6 months after the
14	date of the enactment of this section."; and
15	(2) by adding at the end the following new sub-
16	section:
17	"(c) Adoption of Methods to Measure Inter-
18	OPERABILITY.—For provisions relating to the adoption of
19	methods to measure interoperability, see section 3010.".
20	(c) Reports and Notifications.—Section 3010 of
21	the Public Health Service Act, as added by subsection (a),
22	is amended by adding at the end the following new sub-
23	section:
24	"(g) Dissemination of Information.—

1	"(1) Initial summary report.—Not later
2	than July 1, 2016, the Secretary, after consultation
3	with relevant stakeholders, shall submit to Congress
4	and provide for publication in the Federal Register
5	and the posting on the Internet website of the Office
6	of the National Coordinator for Health Information
7	Technology of a report on the following:
8	"(A) The initial set of methods adopted
9	under this section.
10	"(B) The strategies for achieving wide-
11	spread interoperability.
12	"(C) An overview of the extent to which
13	qualified electronic health records offered as of
14	such date satisfy such initial set.
15	"(D) Any barriers that are preventing
16	widespread interoperability.
17	"(E) The plan and milestones, including
18	specific steps, to achieve widespread interoper-
19	ability.
20	"(2) Follow-up determination and report
21	ON WIDESPREAD INTEROPERABILITY.—Not later
22	than December 31, 2017, the Secretary shall provide
23	for publication in the Federal Register and the post-
24	ing on the Internet website of the Office of the Na-

1	tional Coordinator for Health Information Tech-
2	nology of the following:
3	"(A) A determination by the Secretary
4	whether the goal of widespread interoperability
5	has been achieved.
6	"(B) A list identifying the vendors of, or
7	other entities offering, qualified electronic
8	health records, which categorizes such entities,
9	with respect to such records, as in compliance
10	or not in compliance with the certification cri-
11	teria described in section 3001(c)(5)(B)(ii) and
12	with the requirements under clause (i) of sec-
13	tion $3001(c)(5)(C)$ (including with the terms of
14	the attestation and other requirements under
15	such clause).
16	"(C) Actions that may be taken by entities
17	identified under subparagraph (B) as not being
18	in compliance with such criteria and require-
19	ments in order for such entities to become in
20	compliance with such criteria and requirements.
21	"(D) Penalties described in section
22	3010A(b) to which entities, with respect to such
23	qualified electronic health records, beginning
24	January 1, 2019, are subject if such technology
25	and entities are not in compliance with the cer-

1	tification criteria described in section
2	3001(e)(5)(B)(ii) and with the requirements
3	under clause (i) of section $3001(c)(5)(C)$, re-
4	spectively.
5	"(3) Ongoing publication of recommenda-
6	TIONS.—The Secretary shall provide for publication
7	in the Federal Register and the posting on the
8	Internet website of the Office of the National Coor-
9	dinator for Health Information Technology of all
10	recommendations made under this section.".
11	(d) CERTIFICATION AND OTHER ENFORCEMENT
12	Provisions.—
13	(1) CERTIFICATION OF QUALIFIED ELECTRONIC
14	HEALTH RECORD TECHNOLOGY.—
15	(A) IN GENERAL.—Section 3007(b) of the
16	Public Health Service Act (42 U.S.C. 300jj-
17	17(b)) is amended by striking "under section
18	3001(e)(3) to be in compliance with" and all
19	that follows through the period at the end and
20	inserting "under section $3001(c)(3)$ —
21	"(1) for certifications made before January 1,
22	2018, to be in compliance with applicable standards
23	adopted under subsections (a) and (b) of section
24	3004; and

1	"(2) for certifications made on or after January
2	1, 2018, to be interoperable in accordance with sec-
3	tion 3010, including as measured by the methods
4	adopted under such section.".
5	(B) REQUIREMENTS OF SECRETARY.—Sec-
6	tion 3001(c)(5) of the Public Health Service
7	Act (42 U.S.C. 300jj-11(c)(5)) is amended—
8	(i) by amending subparagraph (B) of
9	such section to read as follows:
10	"(B) CERTIFICATION CRITERIA DE-
11	SCRIBED.—In this title, the term 'certification
12	criteria' means, with respect to qualified elec-
13	tronic health records—
14	"(i) for certifications made before
15	January 1, 2018, criteria to establish that
16	the technology meets standards and imple-
17	mentation specifications adopted under
18	subsections (a) and (b) of section 3004 for
19	qualified electronic health records; and
20	"(ii) for certifications made on or
21	after January 1, 2018, criteria to establish
22	that the technology is interoperable, in ac-
23	cordance with section 3010, including as
24	measured by the methods adopted under
25	such section."; and

15

(ii) by adding at the end the following	ng
new subparagraph:	
"(C) Enforcemen	JТ;
DECERTIFICATIONS.—	
"(i) Requirements.—Under a	ny
program kept or recognized under subpar	·a-
graph (A), the Secretary shall ensure the	ıat
any vendor of or other entity offeri	ng
qualified electronic health records seeki	ng
a certification of such records under su	.ch
program on or after January 1, 201	18,
shall, as a condition of certification (a	nd
maintenance of certification) of su	.ch
records under such program—	
"(I) provide to the Secretary	an
attestation that the entity, unless t	or
a legitimate purpose specified by t	he
Secretary, has not knowingly and w	ill-
fully taken any action, includi	ng
through any financial, administrati	ve,
or technological barrier, to limit or	re-
strict the exchange of information	or
to prevent or disincentivize widespre	ad
interoperability between any provide	ers
using such records or other qualifi	ed

1	electronic health records in connection
2	with such records;
3	"(II) publish application pro-
4	gramming interfaces, with respect to
5	such records, for medical records
6	data, search and indexing, semantic
7	harmonization and vocabulary trans-
8	lation, and user interface applications;
9	and
10	"(III) demonstrate to the satis-
11	faction of the Secretary that data
12	from such records is able to be ex-
13	changed through the use of applica-
14	tion programming interfaces and used
15	in a manner that allows for exchange
16	and everyday use of such records by
17	authorized users.
18	"(ii) Decertification.—Under any
19	program kept or recognized under subpara-
20	graph (A), the Secretary shall ensure that
21	beginning January 1, 2019, any qualified
22	electronic health record that does not sat-
23	isfy the certification criteria described in
24	section 3001(c)(5)(B)(ii) or with respect to
25	which the vendor or other entity described

1	in clause (i) does not satisfy the require-
2	ments under such clause (or is determined
3	to be in violation of the terms of the attes-
4	tation or other requirements under such
5	clause) shall no longer be considered as
6	certified under such program.
7	"(iii) Annual publication.—For
8	2019 and each subsequent year, the Sec-
9	retary shall post on the public Internet
10	website of the Department of Health and
11	Human Services a list of any vendors of or
12	other entities offering qualified electronic
13	health records with respect to which cer-
14	tification has been withdrawn under clause
15	(ii) during such year.".
16	(2) Additional enforcement provisions
17	UNDER THE PUBLIC HEALTH SERVICE ACT.—Sub-
18	title A of title XXX of the Public Health Service Act
19	(42 U.S.C. 300jj-11 et seq.), as amended by sub-
20	section (a)(1), is further amended by adding at the
21	end the following new section:
22	"SEC. 3010A. ENFORCEMENT MECHANISMS.
23	"(a) Inspector General Authority.—The In-
24	spector General of the Department of Health and Human
25	Services shall have the authority to investigate claims of—

1	"(1) vendors of, or other entities offering, quali-
2	fied electronic health records being in violation of an
3	attestation made under section $3001(e)(5)(C)(i)(I)$,
4	with respect to the use of such records by a health
5	care provider under a specified Medicare incentive
6	program; and
7	"(2) health care providers, with respect to the
8	use of such records under a specified Medicare in-
9	centive program, having, unless for a legitimate pur-
10	pose specified by the Secretary, knowingly and will-
11	fully taken any action, including through any finan-
12	cial, administrative, or technical barrier, to limit or
13	restrict the exchange of information or to prevent or
14	disincentivize widespread interoperability between
15	any providers using such records or other qualified
16	electronic health records in connection with such
17	records.
18	"(b) Penalty.—[Review what the penalties should
19	be.] Any person or entity determined to have committed
20	an act described in subsection (a), in connection with a
21	specified Medicare incentive program, shall be subject to
22	[the provisions of sections 1128, 1128A, and 1128B] in
23	the same manner as a person or entity determined to have
24	committed an act described in such respective section. The
25	provisions of section 1128A (other than subsections (a)

1	and (b)) shall apply to a civil money penalty applied under
2	this subsection in the same manner as they apply to a
3	civil money penalty or proceeding under section 1128A(a).
4	"(c) Specified Medicare Incentive Program.—
5	For purposes of this section, the term 'specified Medicare
6	incentive program' includes the following:
7	"(1) The incentive payments under subsection
8	(o) of section 1848 of the Social Security Act (42
9	U.S.C. 1395w-4) and adjustments under subsection
10	(a)(7) of such section.
11	"(2) The incentive payments under subsection
12	(n) of section 1848 of such Act (42 U.S.C. 1395ww)
13	and adjustments under subsection (b)(3)(B) of such
14	section.
15	"(3) The incentive payments and adjustments
16	made under subsections (l) and (m) of section 1853
17	of such Act (42 U.S.C. 1395w–23).
18	"(4) The incentive payment under paragraph
19	(3) of section 1814(l) of such Act (42 U.S.C.
20	1395f(l)) and adjustment under paragraph (4) of
21	such section.
22	"(5) The shared savings program under section
23	1899 of the Social Security Act (42 U.S.C.
24	1395jjj).".

1	(3) Demonstration required for meaning-
2	FUL EHR USE INCENTIVES UNDER MEDICARE.—
3	(A) Incentives for professionals.—
4	Section 1848(o)(2)(C) of the Social Security
5	Act (42 U.S.C. 1395w-4(o)(2)(C)) is amended
6	by adding at the end the following new clause:".
7	"(iii) Interoperability.—With re-
8	spect to EHR reporting periods for pay-
9	ment years beginning with 2018, the
10	means described in clause (i) specified by
11	the Secretary shall include a demonstra-
12	tion, through means such as an attesta-
13	tion, that the professional has not know-
14	ingly and willfully taken any action de-
15	scribed in section 3010A(a)(2) of the Pub-
16	lic Health Service Act, with respect to the
17	use of any certified EHR technology.".
18	(B) Incentives for hospitals.—Section
19	1886(0)(1) of the Social Security Act (42)
20	U.S.C. 1395ww(o)(1)) is amended—
21	(i) in subparagraph (A), by inserting
22	before the period at the end the following:
23	"and, for performance periods for fiscal
24	year 2018 or a subsequent fiscal year, that

1	provide a demonstration described in sub-
2	paragraph (D) to the Secretary"; and
3	(ii) by adding at the end the following
4	new subparagraph:
5	"(D) DEMONSTRATION DESCRIBED.—The
6	demonstration described in this subparagraph is
7	a demonstration, through means such as an at-
8	testation, that the hospital has not knowingly
9	and willfully taken any action described in sec-
10	tion 3010A(a)(2) of the Public Health Service
11	Act, with respect to the use of any certified
12	EHR technology.".
13	(4) Demonstration required for meaning-
14	FUL EHR USE INCENTIVES UNDER MEDICAID.—Sec-
15	tion $1903(t)(2)$ of the Social Security Act (42)
16	U.S.C. $1396b(t)(2)$) is amended by adding at the
17	end the following: "An eligible professional shall not
18	qualify as a Medicaid provider under this subsection,
19	with respect to a year beginning with 2018, unless
20	such professional demonstrates to the Secretary,
21	through means such as an attestation, that the pro-
22	fessional has not knowingly and willfully taken any
23	action described in section 3010A(a)(2) of the Public
24	Health Service Act, with respect to the use of any
25	certified EHR technology.".

1	(e) Definitions.—
2	(1) CERTIFIED EHR TECHNOLOGY.—Paragraph
3	(1) of section 3000 of the Public Health Service Act
4	(42 U.S.C. 300jj) is amended to read as follows:
5	"(1) CERTIFIED EHR TECHNOLOGY.—The term
6	'certified EHR technology' means a qualified elec-
7	tronic health record that is certified pursuant to sec-
8	tion 3001(c)(5) as meeting the certification criteria
9	defined in subparagraph (B) of such section that are
10	applicable to the type of record involved (as deter-
11	mined by the Secretary, such as an ambulatory elec-
12	tronic health record for office-based physicians or an
13	inpatient hospital electronic health record for hos-
14	pitals) and, beginning January 1, 2018, with respect
15	to which the vendor or other entity offering such
16	technology is in compliance with the requirements
17	under section $3001(c)(5)(C)(i)$.".
18	(2) Widespread interoperability.—Section
19	3000 of the Public Health Service Act (42 U.S.C.
20	300jj) is amended by adding at the end the following
21	new paragraph:
22	"(15) Widespread interoperability.—The
23	term 'widespread interoperability' means that, on a
24	nationwide basis—

1	"(A) qualified electronic health records are
2	interoperable, in accordance with section 3010,
3	including as measured by the methods adopted
4	under such section; and
5	"(B) such records are employed by mean-
6	ingful EHR users under the specified Medicare
7	incentive programs (as defined in section
8	3010A(c)) and other clinicians and health care
9	providers.".
10	(f) Conforming Amendments.—
11	(1) Voluntary use of standards.—Section
12	3006 of the Public Health Service Act (42 U.S.C.
13	300jj-16) is amended—
14	(A) in subsection (a)—
15	(i) in paragraph (1), by inserting "or
16	a method adopted under section 3010"
17	after "section 3004"; and
18	(ii) in paragraph (2), by striking "or
19	implementation specification" and insert-
20	ing "implementation specification, or meth-
21	od''; and
22	(B) in subsection (b), by inserting "or the
23	methods adopted under section 3010" after
24	"section 3004".

1	(2) HIPAA PRIVACY AND SECURITY LAW DEFI-
2	NITION CORRECTION.—Section 3009(a)(2)(A) of the
3	Public Health Service Act (42 U.S.C. 300jj-
4	19(a)(2)(A)) is amended by striking "title IV" and
5	inserting "title XIII".
6	(3) Coordination of Federal activities.—
7	Section 13111 of the HITECH Act is amended—
8	(A) in subsection (a), by inserting before
9	the period at the end the following: "(or begin-
10	ning on January 1, 2018, that are interoperable
11	under section 3010 of such Act, including as
12	measured by the methods adopted under such
13	section)"; and
14	(B) in subsection (b)—
15	(i) by inserting (or beginning on Jan-
16	uary 1, 2018, a method adopted under sec-
17	tion 3010 of such Act) before "the Presi-
18	dent"; and
19	(ii) by inserting "(or method)" before
20	", respectively".
21	(4) Application to private entities.—Sec-
22	tion 13112 of the HITECH Act is amended by in-
23	serting before the period at the end the following
24	"(or beginning on January 1, 2018, that are inter-
25	operable under section 3010 of such Act, including

25

- as measured by the methods adopted under such 1
- 2 section)".
- [(5) OTHERS.—] 3