#### 110TH CONGRESS 1ST SESSION

# S. 1408

To improve quality in health care by providing incentives for adoption of modern information technology.

### IN THE SENATE OF THE UNITED STATES

May 16, 2007

Ms. Stabenow (for herself and Ms. Snowe) introduced the following bill; which was read twice and referred to the Committee on Finance

## A BILL

To improve quality in health care by providing incentives for adoption of modern information technology.

- 1 Be it enacted by the Senate and House of Representa-
- 2 tives of the United States of America in Congress assembled,
- 3 SECTION 1. SHORT TITLE.
- 4 This Act may be cited as the "Health Information
- 5 Technology Act of 2007".
- 6 SEC. 2. INFORMATICS SYSTEMS GRANT PROGRAM.
- 7 (a) Grants.—
- 8 (1) IN GENERAL.—The Secretary of Health and
- 9 Human Services (in this section referred to as the
- 10 "Secretary") shall establish a program to award

1	grants to eligible entities that have submitted appli-
2	cations in accordance with subsection (b) for the
3	purpose of assisting such entities in offsetting the
4	costs incurred after December 31, 2006, that are re-
5	lated to clinical health care informatics systems and
6	services designed to improve quality in health care
7	and patient safety.
8	(2) Duration.—The authority of the Secretary
9	to make grants under this section shall terminate on
10	September 30, 2012.
11	(3) Costs defined.—For purposes of this sec-
12	tion, the term "costs" shall include total expendi-
13	tures incurred for—
14	(A) purchasing, leasing, and installing
15	computer software and hardware, including
16	handheld computer technologies, and related
17	services;
18	(B) making improvements to existing com-
19	puter software and hardware;
20	(C) purchasing or leasing communications
21	capabilities necessary for clinical data access,

storage, and exchange;

(D) services associated with acquiring, im-

plementing, operating, or optimizing the use of

new or existing computer software and hard-

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1	ware and clinical health care informatics sys-
2	tems;
3	(E) providing education and training to eli-
4	gible entity staff on information systems and
5	technology designed to improve patient safety
6	and quality of care; and
7	(F) purchasing, leasing, subscribing, inte-
8	grating, or servicing clinical decision support
9	tools that—
10	(i) integrate patient-specific clinical
11	data with well-established national treat-
12	ment guidelines; and
13	(ii) provide ongoing, continuous qual-
14	ity improvement functions that allow pro-
15	viders to assess improvement rates over
16	time and against averages for similar pro-
17	viders.
18	(4) Eligible entity defined.—For purposes
19	of this section, the term "eligible entity" means the
20	following entities:
21	(A) Hospital.—A hospital (as defined in
22	section 1861(e) of the Social Security Act (42
23	U.S.C. 1395x(e)).
24	(B) Critical access hospital.—A crit-
25	ical access hospital (as defined in section

1	1861(mm)(1) of such Act $(42  U.S.C.)$
2	1395x(mm)(1)).
3	(C) SKILLED NURSING FACILITY.—A
4	skilled nursing facility (as defined in section
5	1819(a) of such Act (42 U.S.C. 1395i-3(a))).
6	(D) Federally qualified health cen-
7	TER.—A Federally qualified health center (as
8	defined in section 1861(aa)(4) of such Act (42
9	U.S.C. $1395x(aa)(4))$ .
10	(E) Physician.—A physician (as defined
11	in section 1861(r) of such Act (42 U.S.C.
12	1395x(r))).
13	(F) Physician group practice.—A phy-
14	sician group practice.
15	(G) COMMUNITY MENTAL HEALTH CEN-
16	TER.—A community mental health center (as
17	defined in section 1861(ff)(3)(B) of such Act
18	(42  U.S.C.  1395x(ff)(3)(B))).
19	(b) Application.—
20	(1) In general.—An eligible entity seeking a
21	grant under this section shall submit an application
22	to the Secretary at such time, in such form and
23	manner, and containing the information described in
24	paragraph (2).

1	(2) Information described.—The informa-
2	tion described in this paragraph is the following in-
3	formation:
4	(A) A description of—
5	(i) the clinical health care informatics
6	system and services that the eligible entity
7	intends to implement with the assistance
8	received under this section;
9	(ii) how the system will improve qual-
10	ity in health care and patient safety, in-
11	cluding estimates of the impact on the
12	health of, and the health costs associated
13	with the treatment of, patients with heart
14	disease, cancer, stroke, diabetes, chronic
15	obstructive pulmonary disease, asthma, or
16	any other disease or condition specified by
17	the Secretary; and
18	(iii) how the system will ensure the
19	privacy and security of individually identi-
20	fiable health information.
21	(B) Any additional information that the
22	Secretary may specify.
23	(c) Priority for Certain Eligible Entities.—
24	In awarding grants under this section, the Secretary shall
25	give priority—

1	(1) first, to eligible entities—
2	(A) that are exempt from tax under section
3	501(a) of the Internal Revenue Code of 1986
4	and
5	(B)(i) in which the total of individuals that
6	are eligible for benefits under the Medicare pro-
7	gram under title XVIII of the Social Security
8	Act, the Medicaid program under title XIX of
9	such Act, or under the State children's health
10	insurance program under title XXI of such Act
11	make up a high percentage (as determined ap-
12	propriate by the Secretary) of the total patient
13	population of the entity; or
14	(ii) that provide services to a large number
15	(as determined appropriate by the Secretary) of
16	such individuals;
17	(2) then, to eligible entities that meet the re-
18	quirement under clause (i) or (ii) of paragraph
19	(1)(B); and
20	(3) then, to other eligible entities.
21	(d) Reserve Funds for Entities in Health
22	Professional Shortage Areas or Rural Areas.—
23	(1) In general.—Subject to paragraph (2)
24	the Secretary shall ensure that at least 20 percent

1	of the funds available for making grants under this
2	section to—
3	(A) hospitals and critical access hospitals
4	are used for making grants to such hospitals
5	that are located exclusively in an applicable
6	area;
7	(B) skilled nursing facilities are used for
8	making grants to such facilities that are located
9	exclusively in an applicable area;
10	(C) Federally qualified health centers are
11	used for making grants to such centers that are
12	located exclusively in an applicable area;
13	(D) physicians and physician group prac-
14	tices are used for making grants to physicians
15	and such practices that are located exclusively
16	in an applicable area; and
17	(E) community mental health centers are
18	used for making grants to such centers that are
19	located exclusively in an applicable area.
20	(2) Availability of reserve funds if lim-
21	ITED NUMBER OF ENTITIES APPLY FOR RESERVED
22	GRANTS.—If the Secretary estimates that the
23	amount of funds reserved under subparagraph (A),
24	(B), (C), (D), or (E) of paragraph (1) for the type
25	of entity involved exceeds the maximum amount of

1	funds permitted for such entities under subsection
2	(e), the Secretary may reduce the amount reserved
3	for such entities by an amount equal to such excess
4	and use such funds for awarding grants to other eli-
5	gible entities.
6	(3) Applicable area defined.—For pur-
7	poses of paragraph (1), the term "applicable area"
8	means—
9	(A) an area that is designated as a health
10	professional shortage area under section
11	332(a)(1)(A) of the Public Health Service Act;
12	(B) a rural area (as such term is defined
13	for purposes of section 1886(d) of the Social
14	Security Act (42 U.S.C. 1395ww(d))); or
15	(C) a rural census tract of a metropolitan
16	statistical area (as determined under the most
17	recent modification of the Goldsmith Modifica-
18	tion, originally published in the Federal Reg-
19	ister on February 27, 1992 (57 Fed. Reg.
20	6725)).
21	(e) Amount of Grant.—
22	(1) Amount.—
23	(A) In General.—Subject to subpara-
24	graph (B) and paragraph (2), the Secretary

1	shall determine the amount of a grant awarded
2	under this section.
3	(B) Consideration.—In determining the
4	amount of a grant under this section, the Sec-
5	retary shall take into account the ability to take
6	an expense deduction for health care
7	informatics system expenses under section
8	179F of the Internal Revenue Code of 1986, as
9	added by section 5.
10	(2) Limitation.—
11	(A) IN GENERAL.—A grant awarded under
12	this section may not exceed the lesser of—
13	(i) an amount equal to the applicable
14	percentage of the costs incurred by the eli-
15	gible entity for the project for which the
16	entity is seeking assistance under this sec-
17	tion; or
18	(ii) in the case of a grant made to—
19	(I) a hospital or a critical access
20	hospital, \$1,000,000;
21	(II) a skilled nursing facility,
22	\$200,000;
23	(III) a Federally qualified health
24	center, \$150,000;
25	(IV) a physician, \$15,000;

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1	(V) a physician group practice
2	an amount equal to \$15,000 multi-
3	plied by the number of physicians in
4	the practice; or
5	(VI) a community mental health
6	center, \$75,000.
7	(B) Applicable percentage.—For pur-
8	poses of subparagraph (A)(i), the term "appli-
9	cable percentage" means, with respect to an eli-
10	gible entity for the period involved, the percent-
11	age of total revenues (excluding grants and
12	gifts from Federal, State, local government, and
13	private sources) for such period that consists of
14	total revenues from the Medicare program, the
15	Medicaid program, and the State children's
16	health insurance program under titles XVIII
17	XIX, and XXI, respectively, of the Social Secu-
18	rity Act.
19	(f) Requirements.—
20	(1) Compliant with standards.—A clinical
21	hasth agra information exetam funded under this

(1) Compliant with standards.—A clinical health care informatics system funded under this section and placed in service on or after the date the standards are adopted under section 4 shall be compliant with such standards.

1	(2) Notification.—An eligible entity receiving
2	a grant under this section shall notify patients if
3	their individually identifiable health information is
4	wrongfully disclosed.
5	(3) Furnishing the secretary with infor-
6	MATION.—
7	(A) In general.—An eligible entity re-
8	ceiving a grant under this section shall furnish
9	the Secretary with such information as the Sec-
10	retary may require to—
11	(i) evaluate the project for which the
12	grant is made; and
13	(ii) ensure that assistance provided
14	under the grant is expended for the pur-
15	poses for which it is made.
16	(B) COORDINATION.—The Secretary shall
17	ensure that the requirements for furnishing in-
18	formation under subparagraph (A) are coordi-
19	nated with other requirements for furnishing in-
20	formation to the Secretary that the eligible enti-
21	ty is subject to.
22	(g) Studies.—The Secretary shall conduct studies
23	to—
24	(1) evaluate the use of clinical health care
25	informatics systems and services implemented with

1	assistance under this section to measure and report
2	quality data based on accepted clinical performance
3	measures; and
4	(2) assess the impact of such systems and serv-
5	ices on improving patient care, reducing costs, and
6	increasing efficiencies.
7	(h) Reports.—
8	(1) Interim reports.—
9	(A) In General.—The Secretary shall
10	submit, at least annually, a report to the appro-
11	priate committees of Congress on the grant pro-
12	gram established under this section.
13	(B) Contents.—A report submitted pur-
14	suant to subparagraph (A) shall include infor-
15	mation on—
16	(i) the number of grants made;
17	(ii) the nature of the projects for
18	which assistance is provided under the
19	grant program;
20	(iii) the geographic distribution of
21	grant recipients;
22	(iv) the impact of the projects on the
23	health of, and the health costs associated
24	with the treatment of, patients with heart
25	disease, cancer, stroke, diabetes, chronic

1	obstructive pulmonary disease, asthma, or
2	any other disease or conditions specified by
3	the Secretary;
4	(v) the results of the studies con-
5	ducted under subsection (g); and
6	(vi) such other matters as the Sec-
7	retary determines appropriate.
8	(2) Final Report.—Not later than 180 days
9	after the completion of all of the projects for which
10	assistance is provided under this section, the Sec-
11	retary shall submit a final report to the appropriate
12	committees of Congress on the grant program estab-
13	lished under this section, together with such rec-
14	ommendations for legislation and administrative ac-
15	tion as the Secretary determines appropriate.
16	(i) Funding.—
17	(1) Hospitals.—There are appropriated from
18	the Federal Hospital Insurance Trust Fund under
19	section 1817 of the Social Security Act (42 U.S.C.
20	1395i) \$250,000,000, for each of the fiscal years
21	2008 through 2012, for the purpose of making
22	grants under this section to eligible entities that are
23	hospitals or critical access hospitals.
24	(2) Skilled nursing facilities.—There are
25	appropriated from the Federal Hospital Insurance

- Trust Fund under section 1817 of the Social Security Act (42 U.S.C. 1395i) \$100,000,000, for each of the fiscal years 2008 through 2012, for the purpose of making grants under this section to eligible entities that are skilled nursing facilities.
  - (3) FEDERALLY QUALIFIED HEALTH CENTERS.—There are appropriated from the Federal Supplementary Medical Insurance Trust Fund under section 1841 of the Social Security Act (42 U.S.C. 1395t) \$40,000,000, for each of the fiscal years 2008 through 2012, for the purpose of making grants under this section to eligible entities that are Federally qualified health centers.
  - (4) Physicians.—There are appropriated from the Federal Supplementary Medical Insurance Trust Fund under section 1841 of the Social Security Act (42 U.S.C. 1395t) \$400,000,000, for each of the fiscal years 2008 through 2012, for the purpose of making grants under this section to eligible entities that are physicians or physician group practices.
  - (5) COMMUNITY MENTAL HEALTH CENTERS.—
    There are appropriated from the Federal Supplementary Medical Insurance Trust Fund under section 1841 of the Social Security Act (42 U.S.C. 1395t) \$20,000,000, for each of the fiscal years

1	2008 through 2012, for the purpose of making
2	grants under this section to eligible entities that are
3	community mental health centers.
4	SEC. 3. ADJUSTMENTS TO MEDICARE PAYMENTS FOR
5	HEALTH INFORMATION TECHNOLOGY EN-
6	ABLED QUALITY SERVICES.
7	(a) Adjustments.—The Secretary of Health and
8	Human Services (in this section referred to as the "Sec-
9	retary") shall establish a methodology for making adjust-
10	ments in payment amounts under title XVIII of the Social
11	Security Act (42 U.S.C. 1395 et seq.) made to providers
12	of services and suppliers who—
13	(1) furnish items or services for which payment
14	is made under such title; and
15	(2) in the course of furnishing such items and
16	services, use health information technology and tech-
17	nology services with patient-specific applications that
18	the Secretary determines improves the quality and
19	accuracy of clinical decision-making, compliance,
20	health care delivery, and efficiency, such as elec-
21	tronic medical records, electronic prescribing, clinical
22	decision support tools integrating well-established
23	national treatment guidelines with continuous qual-

ity improvement functions, and computerized physi-

- 1 cian order entry with clinical decision-support capa-
- 2 bilities.
- 3 (b) REQUIREMENTS.—The methodology established
- 4 under subsection (a) shall—
- 5 (1) include the establishment of new codes,
- 6 modification of existing codes, and adjustment of
- 7 evaluation and management modifiers to such codes,
- 8 that take into account the costs of acquiring, using,
- 9 and maintaining health information technology and
- services with patient-specific applications;
- 11 (2) first address adjustments for payments for
- items and services related to the diagnosis or treat-
- ment of heart disease, cancer, stroke, diabetes,
- chronic obstructive pulmonary disease (COPD), and
- other diseases and conditions that result in high ex-
- penditures under the Medicare program and for
- which effective health information technology exists;
- 18 and
- 19 (3) take into account estimated aggregate an-
- 20 nual savings in overall payments under such title
- 21 XVIII attributable to the use of health information
- technology and services with patient-specific applica-
- tions.
- (c) Duration.—The Secretary may reduce or elimi-
- 25 nate adjustments made to payments pursuant to sub-

- 1 section (a) as payment methodologies under title XVIII
- 2 of the Social Security Act (42 U.S.C. 1395 et seq.) are
- 3 adjusted to reflect provider quality and efficiency.
- 4 (d) Rule of Construction.—In making national
- 5 coverage determinations under section 1862(a) of the So-
- 6 cial Security Act (42 U.S.C. 1395y(a)) with respect to
- 7 maintaining health information technology and services
- 8 with patient-specific applications, in determining whether
- 9 the health information technology and services are reason-
- 10 able and necessary for the diagnosis or treatment of illness
- 11 or injury or to improve the functioning of a malformed
- 12 body member, the Secretary shall consider whether the
- 13 health information technology and services improve the
- 14 health of Medicare beneficiaries, including the improve-
- 15 ment of clinical outcomes or cost-effectiveness of treat-
- 16 ment.
- 17 (e) Definitions.—In this section:
- 18 (1) Provider of Services.—The term "pro-
- vider of services" has the meaning given that term
- under section 1861(u) of the Social Security Act (42
- 21 U.S.C. 1395x(u)).
- 22 (2) SUPPLIER.—The term "supplier" has the
- meaning given that term under section 1861(d) of
- 24 such Act (42 U.S.C. 1395x(d)).

### 1 SEC. 4. INTEROPERABILITY.

2	(a) Development and Adoption of Stand-
3	ARDS.—
4	(1) IN GENERAL.—Not later than 2 years after
5	the date of enactment of this Act, the Secretary of
6	Health and Human Services (in this section referred
7	to as the "Secretary") shall provide for the develop-
8	ment and adoption under programs administered by
9	the Secretary of national data and communication
10	health information technology standards that pro-
11	mote the efficient exchange of data between varieties
12	of provider health information technology systems.
13	In carrying out the preceding sentence, the Sec-
14	retary may adopt existing standards consistent with
15	standards established under subsections $(b)(2)(B)(i)$
16	and (e)(4) of section 1860D-4 of the Social Security
17	Act (42 U.S.C. 1395w-104).
18	(2) Requirements.—The standards developed
19	and adopted under paragraph (1) shall be designed
20	to—
21	(A) enable health information technology
22	to be used for the collection and use of clinically
23	specific data;
24	(B) promote the interoperability of health
25	care information across health care settings, in-

1	cluding reporting to the Secretary and other
2	Federal agencies; and
3	(C) facilitate clinical decision support
4	through the use of health information tech-
5	nology.
6	(b) Implementation of Procedures for the
7	SECRETARY TO ACCEPT DATA USING STANDARDS.—
8	(1) Data from New Health care reporting
9	REQUIREMENTS.—Not later than January 1, 2010,
10	the Secretary shall implement procedures to enable
11	the Department of Health and Human Services to
12	accept the optional submission of data derived from
13	health care reporting requirements established after
14	the date of enactment of this Act using data stand-
15	ards adopted under this section.
16	(2) Data from all requirements.—
17	(A) IN GENERAL.—Not later than January
18	1, 2012, the Secretary shall implement proce-
19	dures to enable the Department of Health and
20	Human Services to accept the optional submis-
21	sion of data derived from all health care report-
22	ing requirements using data standards adopted
23	under this section.
24	(B) Limitation.—

1	(i) In general.—On and after Janu-
2	ary 1, 2012, if an entity or individual
3	elects to submit data to the Secretary
4	using data standards adopted under this
5	section, the Secretary, subject to clause
6	(ii), may not require such entity or indi-
7	vidual to also submit such data in an addi-
8	tional format.
9	(ii) Exception.—The Secretary may
10	provide for an exception, not to exceed 2
11	years, to the limitation under clause (i)
12	with respect to certain types of data if the
13	Secretary determines that such an excep-
14	tion is appropriate.
15	SEC. 5. ELECTION TO EXPENSE HEALTH CARE
16	INFORMATICS SYSTEMS.
17	(a) In General.—Part VI of subchapter B of chap-
18	ter 1 of the Internal Revenue Code of 1986 (relating to
19	itemized deductions for individuals and corporations) is
20	amended by inserting after section 179E the following new
21	section:
22	"SEC. 179F. HEALTH CARE INFORMATICS SYSTEM EXPENDI-
23	TURES.
24	"(a) Treatment of Expenditures.—

- "(1) In General.—An eligible entity may elect to treat any qualified health care informatics system expenditure which is paid or incurred by the taxpayer as an expense which is not chargeable to capital account. Any expenditure which is so treated shall be allowed as a deduction.
- 7 "(2) ELECTION.—An election under paragraph 8 (1) shall be made under rules similar to the rules of 9 section 179(c).

### 10 "(b) Limitations.—

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- "(1) Dollar Limitation.—With respect to any eligible entity, the aggregate cost which may be taken into account under subsection (a)(1) for any taxable year shall not exceed, when added to any cost taken into account under this section in any preceding taxable year, the dollar amount specified under section 2(e)(2)(A)(ii) of the Health Information Technology Act of 2007.
- "(2) APPLICABLE RULES.—For purposes of this subsection, rules similar to the rules of paragraphs (3) and (4) of subsection (b) and paragraphs (6),
- 22 (7), and (8) of subsection (d) of section 179 shall apply.
- 24 "(c) Definitions and Special Rules.—For pur-
- 25 poses of this section—

1	"(1) QUALIFIED HEALTH CARE INFORMATICS
2	SYSTEM EXPENDITURES.—
3	"(A) IN GENERAL.—The term 'qualified
4	health care informatics system expenditure'
5	means, with respect to any taxable year, any di-
6	rect or indirect costs incurred and properly
7	taken into account with respect to the purchase
8	or installation of equipment and facilities relat-
9	ing to any qualified health care informatics sys-
10	tem. Such term shall include so much of the
11	purchase price paid by the lessor of equipment
12	and facilities subject to a lease described in
13	subparagraph (B)(ii) as is attributable to ex-
14	penditures incurred by the lessee which would
15	otherwise be described in the preceding sen-
16	tence.
17	"(B) When expenditures taken into
18	ACCOUNT.—
19	"(i) In general.—Qualified health
20	care informatics system expenditures shall
21	be taken into account under this section
22	only with respect to equipment and facili-
23	ties—
24	"(I) the original use of which
25	commences with the taxpayer, and

1	"(II) which are placed in service
2	after December 31, 2006, and before
3	October 1, 2012.
4	"(ii) Sale-leasebacks.—For pur-
5	poses of clause (i), if property—
6	"(I) is originally placed in service
7	after December 31, 2006, and before
8	October 1, 2012, by any person, and
9	"(II) sold and leased back by
10	such person within 3 months after the
11	date such property was originally
12	placed in service,
13	such property shall be treated as originally
14	placed in service not earlier than the date
15	on which such property is used under the
16	leaseback referred to in subclause (II).
17	"(C) Grants, etc. excluded.—The term
18	'qualified health care informatics system ex-
19	penditure' shall not include any amount to the
20	extent such amount is funded by any grant,
21	contract, or otherwise by another person (or
22	any governmental entity).
23	"(2) Qualified health care informatics
24	SYSTEM.—The term 'qualified health care
25	informatics system' means a system which—

1	"(A) has been individually approved by the
2	Secretary of Health and Human Services for
3	purposes of this section,
4	"(B) consists of electronic health record
5	systems and other health information tech-
6	nologies, and
7	"(C) meets the standards adopted by the
8	Secretary of Health and Human Services under
9	section 4 of the Health Information Technology
10	Act of 2007 by not later than the date which
11	is 60 days after the date of the adoption of
12	such standards.
13	"(3) ELIGIBLE ENTITY.—The term 'eligible en-
14	tity' has the meaning given such term by section
15	2(a)(4) of the Health Information Technology Act of
16	2007.
17	"(4) Property used outside the united
18	STATES, ETC., NOT QUALIFIED.—No expenditures
19	shall be taken into account under subsection $(a)(1)$
20	with respect to the portion of the cost of any prop-
21	erty referred to in section 50(b) or with respect to
22	the portion of the cost of any property specified in
23	an election under section 179.
24	"(5) Ordinary income recapture.—For
25	purposes of section 1245, the amount of the deduc-

- 1 tion allowable under subsection (a)(1) with respect
- 2 to any property which is of a character subject to
- 3 the allowance for depreciation shall be treated as a
- 4 deduction allowed for depreciation under section
- 5 167.".
- 6 (b) Conforming Amendments.—
- 7 (1) Section 263(a)(1) of the Internal Revenue
- 8 Code of 1986 (relating to capital expenditures) is
- 9 amended by striking "or" at the end of subpara-
- graph (K), by striking the period at the end of sub-
- paragraph (L) and inserting ", or", and by adding
- at the end the following new subparagraph:
- 13 "(M) expenditures for which a deduction is
- allowed under section 179F.".
- 15 (2) The table of sections for part VI of sub-
- 16 chapter A of chapter 1 of such Code is amended by
- inserting after the item relating to section 179E the
- 18 following new item:
  - "Sec. 179F. Health care informatics system expenditures.".
- (c) Effective Date.—The amendments made by
- 20 this section shall apply to property placed in service after
- 21 December 31, 2006.
- 22 SEC. 6. ENSURING PRIVACY AND SECURITY.
- Nothing in this Act (or the amendments made by this
- 24 Act) shall be construed to affect the scope, substance, or
- 25 applicability of—

1	(1) section 264 of the Health Insurance Port-
2	ability and Accountability Act of 1996 (42 U.S.C.
3	1320d–2 note);
4	(2) the provisions of part C of title XI of the
5	Social Security Act (42 U.S.C. 1320d et seq.); and
6	(3) any regulation issued pursuant to any such
7	section.

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