

AMENDMENT NO. \_\_\_\_\_ Calendar No. \_\_\_\_\_

Purpose: To provide for the privacy and security of protected health information.

**IN THE SENATE OF THE UNITED STATES—110th Cong., 1st Sess.**

**S. 1693**

To enhance the adoption of a nationwide interoperable health information technology system and to improve the quality and reduce the costs of health care in the United States.

Referred to the Committee on \_\_\_\_\_ and ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT intended to be proposed by \_\_\_\_\_

Viz:

1 On page 85, between lines 9 and 10, insert the following:  
2

3 “(9) PROTECTED HEALTH INFORMATION.—The  
4 term ‘protected health information’ means any information,  
5 including genetic information, biometric information,  
6 demographic information, and tissue samples collected from an individual, whether oral or recorded  
7 in any form or medium, that—  
8

1           “(A) is created or received by a health care  
2 provider, health researcher, health plan, health  
3 or life insurer, medical or health savings plan  
4 administrator, school or university, health care  
5 clearinghouse, health oversight agency, public  
6 health authority, employer, data broker, or  
7 other person or such person’s agent, officer, or  
8 employee;

9           “(B) relates to the past, present, or future  
10 physical or mental health or condition of an in-  
11 dividual (including individual cells and their  
12 components), the provision of health care to an  
13 individual, or the past, present, or future pay-  
14 ment for the provision of health care to an indi-  
15 vidual; and

16           “(C)(i) identifies an individual; or

17           “(ii) with respect to which there is a rea-  
18 sonable basis to believe that the information  
19 can be used to identify an individual.”.

20           On page 85, line 10, strike “(9)” and insert “(10)”.

21           On page 86, line 13, strike “(10)” and insert “(11)”.

1           On page 158, between line 17 and 18, insert the fol-  
2   lowing:

3   **SEC. 401. RIGHT OF SUBJECTS OF PROTECTED HEALTH IN-**  
4                                   **FORMATION.**

5           Title XXX of the Public Health Service Act, as  
6   amended by section 301, is further amended by adding  
7   at the end the following:

8   **“SEC. 3014. RIGHT TO PRIVACY AND SECURITY.**

9           “(a) IN GENERAL.—In addition to the rights de-  
10   scribed in section 3013, individuals who are the subject  
11   of protected health information shall have the right to—

12                   “(1) privacy and security with respect to the  
13   use and disclosure of such information;

14                   “(2) control and withhold protected health in-  
15   formation of which they are the subject; and

16                   “(3) exercise nondisclosure and nonuse rights  
17   (referred to in this title as the right to ‘opt-out’)  
18   with respect to their protected health information,  
19   including the right to opt out of any local, regional,  
20   or nationwide health information network or system  
21   that is used by the individual.

22           “(b) OBLIGATIONS.—A person that discloses, uses, or  
23   receives an individual’s protected health information shall  
24   expressly recognize the right to privacy and security of

1 such individual with respect to the use and disclosure of  
2 such information.

3 **“SEC. 3015. INSPECTION AND COPYING OF PROTECTED**  
4 **HEALTH INFORMATION.**

5 “(a) RIGHT OF THE INDIVIDUAL.—

6 “(1) IN GENERAL.—A person, including a  
7 health care provider, health researcher, health plan,  
8 health or life insurer, medical or health savings plan  
9 administrator, school or university, health care clear-  
10 inghouse, health oversight agency, public health au-  
11 thority, employer, or data broker, or such person’s  
12 agent, officer, employee, or affiliate, that accesses,  
13 maintains, retains, modifies, records, stores, or oth-  
14 erwise holds, uses, or discloses protected health in-  
15 formation, shall permit an individual who is the sub-  
16 ject of such protected health information, or the in-  
17 dividual’s designee, to inspect and copy the protected  
18 health information concerning the individual, includ-  
19 ing records created under this section and section  
20 3020.

21 “(2) PROCEDURES AND FEES.—A person de-  
22 scribed in paragraph (1) may establish appropriate  
23 procedures to be followed for the inspection and  
24 copying of information under such paragraph and  
25 may require an individual to pay reasonable fees as-

1       sociated with such inspection and copying in an  
2       amount that does not exceed the actual costs of pro-  
3       viding such copying. Such fees may not be assessed  
4       where such an assessment would have the effect of  
5       inhibiting an individual from gaining access to the  
6       information described in paragraph (1).

7       “(b) DEADLINE.—A person described in subsection  
8 (a)(1) shall comply with a request for inspection or copy-  
9 ing of protected health information under this section by  
10 not later than—

11           “(1) 15 business days after the date on which  
12       the person receives the request, if such request re-  
13       quires the inspection, copying, or sending of printed  
14       materials; or

15           “(2) 5 business days after the date on which  
16       the person receives the request, or earlier if the Sec-  
17       retary determines appropriate, if such request re-  
18       quires only the inspection, copying, or sending of  
19       electronic or other digital materials.

20       “(c) RULES GOVERNING AGENTS.—A person that is  
21 the agent, officer, or employee of a person described in  
22 subsection (a) shall provide for the inspection and copying  
23 of protected health information if—

24           “(1) the protected health information is re-  
25       tained by the person; and

1           “(2) the person has been asked by the person  
2           described in subsection (a)(1) to fulfill the require-  
3           ments of this section.

4           “(d) SPECIAL RULE RELATING TO ONGOING CLIN-  
5           ICAL TRIALS.—With respect to protected health informa-  
6           tion that is created as part of an individual’s participation  
7           in an ongoing clinical trial, access to the information shall  
8           be provided consistent with the individual’s agreement to  
9           participate in the clinical trial.

10       **“SEC. 3016. MODIFICATIONS TO PROTECTED HEALTH IN-**  
11                               **FORMATION.**

12           “(a) IN GENERAL.—Not later than 15 business days,  
13           or earlier if the Secretary determines appropriate, after  
14           the date on which a person described in section 3015(a)(1)  
15           receives from an individual a request in writing to supple-  
16           ment, correct, amend, segregate, or remove protected  
17           health information concerning the individual, such person  
18           shall—

19                       “(1) subject to subsections (b) and (c), modify  
20           the information, by adding the requested supple-  
21           ment, correction, or amendment to the information,  
22           or by removing any information that has been re-  
23           quested to be destroyed;

24                       “(2) inform the individual that the modification  
25           has been made; and

1           “(3) make reasonable efforts to inform any per-  
2           son to which the portion of the unmodified informa-  
3           tion was previously disclosed, of any substantive  
4           modification that has been made.

5           “(b) REFUSAL TO MODIFY.—If a person described in  
6           subsection (a) declines to make the modification requested  
7           under such subsection within 15 business days after re-  
8           ceipt of such request, such person shall inform the indi-  
9           vidual involved in writing of—

10           “(1) the reasons for declining to make the  
11           modification;

12           “(2) any procedures for further review of the  
13           declining of such modification; and

14           “(3) the individual’s right to file with the per-  
15           son a concise statement setting forth the requested  
16           modification and the individual’s reasons for dis-  
17           agreeing with the declining person and the individ-  
18           ual’s right to include a copy of such refusal in the  
19           health record set concerning the individual.

20           “(c) STATEMENT OF DISAGREEMENT.—If an indi-  
21           vidual has filed with a person a statement of disagreement  
22           under subsection (b)(3), the person, in any subsequent dis-  
23           closure of the disputed portion of the information—

1           “(1) shall include, at the individual’s request, a  
2           copy of the individual’s statement in the individual’s  
3           health record set; and

4           “(2) may include a concise statement of the  
5           reasons for not making the requested modification.

6           “(d) RULES GOVERNING AGENTS.—A person that is  
7           the agent of a person described in subsection (a) shall only  
8           be required to make a modification to protected health in-  
9           formation where—

10           “(1) the protected health information is re-  
11           tained, distributed, used, or maintained by the  
12           agent; and

13           “(2) the agent has been asked by such person  
14           to fulfill the requirements of this section.

15           “(e) NOTIFICATION OF LOSS OR CORRUPTION.—Not  
16           later than 15 business days, or earlier if the Secretary de-  
17           termines appropriate, after the date on which a person de-  
18           scribed in subsection (a) discovers the loss or corruption  
19           of health record sets or protected health information under  
20           its management, or if such person has reason to believe  
21           that its database has been compromised, such person  
22           shall—

23           “(1) notify individuals whose records have been  
24           affected;

1           “(2) notify persons and the agents of persons  
2           that receive, access, maintain, retain, modify, record,  
3           store, destroy, or otherwise use or disclose such  
4           data; and

5           “(3) repair or restore corrupted data to the ex-  
6           tent practicable.

7   **“SEC. 3017. NOTICE OF PRIVACY PRACTICES.**

8           “(a) PREPARATION OF WRITTEN NOTICE.—A person  
9           described in section 3015(a)(1) shall prepare a written no-  
10          tice of the privacy practices of such person, including in-  
11          formation with respect to the following:

12           “(1) The express right of an individual to pri-  
13           vacy, security, and confidentiality with respect to the  
14           electronic disclosure of such individual’s protected  
15           health information.

16           “(2) The procedures for an individual to au-  
17           thorize disclosures of protected health information,  
18           and to object to, modify, and revoke such authoriza-  
19           tions.

20           “(3) The right of an individual to inspect, copy,  
21           and modify that individual’s protected health infor-  
22           mation.

23           “(4) The right of an individual not to have em-  
24           ployment or the receipt of services or choice of

1 health plan conditioned upon the execution by the  
2 individual of an authorization for disclosure.

3 “(5) A description of the categories or types of  
4 employees, by general category or by general job de-  
5 scription, who have access to or use of protected  
6 health information regarding the individual.

7 “(6) A simple, concise description of any infor-  
8 mation systems used to store or transmit protected  
9 health information, including a description of any  
10 linkages made with other networks, systems, or  
11 databases outside the person’s direct control.

12 “(7) The right of and procedures for an indi-  
13 vidual to request segregation of protected health in-  
14 formation, and to restrict the use of such informa-  
15 tion by employees, agents, and contractors of a per-  
16 son.

17 “(8) The circumstances under which the infor-  
18 mation will be, lawfully and actually, used or dis-  
19 closed without an authorization executed by the indi-  
20 vidual.

21 “(9) A statement that, if an individual elects to  
22 pay for health care from the individual’s own funds,  
23 that individual may elect for identifying information  
24 not to be disclosed to anyone other than designated  
25 health care providers, unless such disclosure is re-

1       quired by mandatory reporting requirements or  
2       other similar information collection duties required  
3       by law.

4               “(10) The right of the individual to have con-  
5       tinued maintenance, distribution, or storage of that  
6       individual’s personal health information not condi-  
7       tioned upon whether that individual amends or re-  
8       vokes an authorization for disclosure, or requests a  
9       modification of protected health information.

10              “(11) The right of and procedures for an indi-  
11       vidual to request that protected health information  
12       be transferred to a third party person without un-  
13       reasonable delay.

14              “(12) The right to prompt notification of an ac-  
15       tual or suspected security breach of protected health  
16       information, and how such breaches will be remedied  
17       by the person.

18              “(13) The right of an individual to inspect and  
19       obtain a copy of records of authorized and unauthor-  
20       ized disclosures as well as attempted and actual ac-  
21       cess and use by an authorized or unauthorized per-  
22       son.

23              “(14) The right of an individual to exercise  
24       nondisclosure and nonuse rights (referred to in this  
25       title as the right to ‘opt-out’) with respect to their

1       protected health information, including the right to  
2       opt out of any local, regional, or nationwide health  
3       information network or system that is used by the  
4       person.

5       “(b) PROVISION AND POSTING OF WRITTEN NO-  
6       TICE.—

7               “(1) PROVISION.—A person described in sub-  
8       section (a) shall provide a copy of the written notice  
9       of privacy practices required under such sub-  
10      section—

11               “(A) at the time an authorization is sought  
12      for the disclosure of protected health informa-  
13      tion; and

14               “(B) upon the request of an individual.

15               “(2) POSTING.—A person described in sub-  
16      section (a) shall post, in a clear and conspicuous  
17      manner, a brief summary of the privacy practices of  
18      the person.

19       “(c) MODEL NOTICE.—The Secretary, after notice  
20      and opportunity for public comment, shall develop and dis-  
21      seminate model notices of privacy practices, and model  
22      summary notices for posting for use under this section.  
23      Use of such model notice shall be deemed to satisfy the  
24      requirements of this section.

1           “(d) **REQUIREMENT FOR OPT-OUT.**—A person shall  
2 not access, maintain, retain, modify, record, store, destroy,  
3 or otherwise use or disclose an individual’s protected  
4 health information for other than treatment or payment  
5 purposes until that individual has been given an oppor-  
6 tunity, before the time that such information is initially  
7 used or disclosed, to direct that such information not be  
8 used or disclosed. The individual must be given adequate  
9 time to exercise the nondisclosure and nonuse option (the  
10 right to opt-out) through the method that is most conven-  
11 ient to the individual, along with an explanation of how  
12 the individual can exercise such option.

13 **“SEC. 3018. DEMONSTRATION GRANT.**

14           “(a) **IN GENERAL.**—The Secretary shall award con-  
15 tracts or competitive grants to eligible entities to support  
16 demonstration projects that are designed to improve the  
17 communication of information pertaining to health privacy  
18 rights with individuals with limited English language pro-  
19 ficiency and limited health literacy.

20           “(b) **PURPOSE.**—It is the purpose of this section, to  
21 promote the cultural competency of persons that access,  
22 maintain, retain, modify, record, store, destroy, or other-  
23 wise use or disclose protected health information, and to  
24 enable such persons to better communicate privacy proce-

1 dures to non-English speakers, those with limited English  
2 proficiency, and those with limited health literacy.

3 “(c) ELIGIBLE ENTITIES.—In this section, the term  
4 ‘eligible entity’ means an organization or community-  
5 based consortium that includes—

6 “(1) individuals who are representatives of or-  
7 ganizations serving or advocating for ethnic and ra-  
8 cial minorities, low income immigrant populations,  
9 and others with limited English language proficiency  
10 and limited health literacy;

11 “(2) health care providers that provide care for  
12 ethnic and racial minorities, low income immigrant  
13 populations, and others with limited English lan-  
14 guage proficiency and limited health literacy;

15 “(3) community leaders and leaders of commu-  
16 nity-based organizations; and

17 “(4) experts and researchers in the areas of so-  
18 cial and behavioral sciences, who have knowledge,  
19 training, or practical experience in health policy, ad-  
20 vocacy, cultural and linguistic competency, or other  
21 relevant areas as determined by the Secretary.

22 “(d) APPLICATION.—An eligible entity seeking a con-  
23 tract or grant under this section shall submit an applica-  
24 tion to the Secretary at such time, in such manner, and  
25 containing such information as the Secretary may require.

1           “(e) USE OF FUNDS.—An eligible entity shall use  
2 amounts received under this section to carry out programs  
3 and studies designed to help identify best practices in the  
4 communication of privacy rights and procedures to ensure  
5 comprehension by individuals with limited English pro-  
6 ficiency and limited health literacy.

7           **“SEC. 3019. ESTABLISHMENT OF SAFEGUARDS.**

8           “(a) IN GENERAL.—A person described in section  
9 3015(a)(1) shall establish and maintain appropriate ad-  
10 ministrative, organizational, technical, and physical safe-  
11 guards and procedures to ensure the privacy, confiden-  
12 tiality, security, accuracy, and integrity of protected health  
13 information that is accessed, maintained, retained, modi-  
14 fied, recorded, stored, destroyed, or otherwise used or dis-  
15 closed by such person.

16           “(b) FACTORS TO BE CONSIDERED.—The safeguards  
17 and procedures established under subsection (a) shall en-  
18 sure that—

19                   “(1) protected health information is used or  
20 disclosed only with informed consent;

21                   “(2) the categories of personnel who will have  
22 access to protected health information are identified;

23                   “(3) the feasibility of limiting access to pro-  
24 tected health information is considered;

1           “(4) the privacy, security and confidentiality of  
2           protected health information is maintained;

3           “(5) protected health information is protected  
4           against any anticipated vulnerabilities to the privacy,  
5           security, or integrity of such information; and

6           “(6) protected health information is protected  
7           against unauthorized access, use, or misuse of such  
8           information.

9           “(c) MODEL GUIDELINES.—The Secretary, after no-  
10          tice and opportunity for public comment, shall develop and  
11          disseminate model guidelines for the establishment of safe-  
12          guards and procedures for use under this section, such  
13          as, where appropriate, individual authentication of uses of  
14          computer systems, access controls, audit trails, encryption,  
15          physical security, protection of remote access points and  
16          protection of external electronic communications, periodic  
17          security assessments, incident reports, and sanctions. The  
18          Secretary, or his or her designee, shall update and dis-  
19          seminate the guidelines, as appropriate, to take advantage  
20          of new technologies.

21          “(d) REVIEW AND UPDATING OF SAFEGUARDS.—  
22          Persons subject to this title shall monitor, evaluate, and  
23          adjust, as appropriate, all safeguards and procedures, con-  
24          comitant with relevant changes in technology, the sensi-  
25          tivity of personally identifiable information, internal or ex-

1 ternal threats to personally identifiable information, and  
2 any changes in the contracts or business of the person.  
3 For the purpose of reviewing and updating safeguards, the  
4 Secretary may provide technical assistance to persons de-  
5 scribed in subsection (a), as appropriate.

6 **“SEC. 3020. TRANSPARENCY.**

7       “(a) PUBLIC LIST OF DATA BROKERS.—A person de-  
8 scribed in section 3015(a)(1) shall establish a list of data  
9 brokers with which such person has entered into a con-  
10 tract or relationship for the purposes of providing services  
11 involving any protected health information. Such list and  
12 the contact information for each broker shall be made pub-  
13 licly accessible on the Internet.

14       “(b) SUBCONTRACTING AND OUTSOURCING OVER-  
15 SEAS.—In the event a person subject to this title contracts  
16 with service providers not subject to this title, including  
17 service providers operating in a foreign country, such per-  
18 son shall—

19               “(1) take reasonable steps to select and retain  
20 third party service providers capable of maintaining  
21 appropriate safeguards for the security, privacy, and  
22 integrity of protected health information;

23               “(2) require by contract that such service pro-  
24 viders implement and maintain appropriate meas-

1 ures designed to meet the requirements of persons  
2 subject to this title;

3 “(3) be held liable for any violation of this title  
4 by an overseas service provider or other provider not  
5 subject to this title; and

6 “(4) in the case of a service provider operating  
7 in a foreign country, obtain the informed consent of  
8 the individual involved prior to outsourcing such in-  
9 dividual’s protected health information to such pro-  
10 vider.

11 “(c) LIST OF PERSONS.—The Secretary shall main-  
12 tain a public list identifying persons described in [section  
13 102(a)(1)??] that have lost, stolen, disclosed, or used in  
14 an unauthorized manner or for an unauthorized purpose  
15 the protected health information of a significant number  
16 of individuals. The list shall include how many individuals  
17 were affected by such action.

18 **“SEC. 3021. RISK MANAGEMENT.**

19 “(a) IN GENERAL.—Persons described in section  
20 3015(a)(1) that have access to protected health informa-  
21 tion shall establish risk management and control processes  
22 to protect against anticipated vulnerabilities to the pri-  
23 vacy, security, and integrity of protected health informa-  
24 tion.

1           “(b) RISK ASSESSMENT.—A person described in sub-  
2 section (a) shall perform annual risk assessments of proce-  
3 dures, systems, or networks involved in the creation, ac-  
4 cessing, maintenance, retention, modification, recording,  
5 storage, distribution, destruction, or other use or disclo-  
6 sure of personal health information. Such risk assessment  
7 may include—

8           “(1) identifying reasonably foreseeable internal  
9 and external vulnerabilities that could result in inac-  
10 curacy or in unauthorized access, disclosure, use, or  
11 modification of protected health information, or of  
12 systems containing protected health information;

13           “(2) assessing the likelihood of and potential  
14 damage from inaccuracy or from unauthorized ac-  
15 cess, disclosure, use, or modification of protected  
16 health information;

17           “(3) assessing the sufficiency of policies, tech-  
18 nologies, and safeguards in place to minimize and  
19 control risks from unauthorized access, disclosure,  
20 use, or modification of protected health information;  
21 and

22           “(4) assessing the vulnerability of protected  
23 health information during destruction and disposal  
24 of such information, including through the disposal  
25 or retirement of hardware.

1       “(c) RISK MANAGEMENT.—A person described in  
2 subsection (a) shall establish risk management and control  
3 procedures designed to control risks such as those identi-  
4 fied in subsection (b). Such procedures shall include—

5           “(1) a means for the detection and recording of  
6 actual or attempted, unauthorized, fraudulent, or  
7 otherwise unlawful access, disclosure, transmission,  
8 modification, use, or loss of personal health informa-  
9 tion;

10          “(2) procedures for ensuring the secure disposal  
11 of personal health information;

12          “(3) a means for limiting physical access to  
13 hardware, software, data storage technology, servers,  
14 systems, or networks by unauthorized persons in  
15 order to minimize the risk of information disclosure,  
16 modification, transmission, access, use, or loss;

17          “(4) providing appropriate risk management  
18 and control training for employees; and

19          “(5) carrying out annual testing of such risk  
20 management and control procedures.

21 **“SEC. 3022. ACCOUNTING FOR DISCLOSURES AND USE.**

22       “(a) IN GENERAL.—A person described in section  
23 3015(a)(1) shall establish and maintain, with respect to  
24 any protected health information disclosure, a record of  
25 each disclosure in accordance with regulations promul-

1 gated by the Secretary. Such record shall include the pur-  
2 pose of any disclosure and the identity of the specific indi-  
3 vidual executing the disclosure, as well as the person to  
4 which such information is disclosed.

5 “(b) MAINTENANCE OF RECORD.—A record estab-  
6 lished under subsection (a) shall be maintained for not less  
7 than 7 years.

8 “(c) ELECTRONIC RECORDS.—A person described in  
9 subsection (a) shall, to the maximum extent practicable,  
10 maintain an accessible electronic record concerning each  
11 access, use, or disclosure, whether authorized or unauthor-  
12 ized and whether successful or unsuccessful, of protected  
13 health information maintained by such person in electronic  
14 form. The record shall include the identities of the specific  
15 individuals (or a way to identify such individuals, or infor-  
16 mation helpful in determining the identities of such indi-  
17 viduals) who access or seek to gain access to, use or seek  
18 to use, or disclose or seek to disclose, information suffi-  
19 cient to identify the protected health information sought  
20 or accessed, and other appropriate information.

21 “(d) ACCESS TO RECORDS.—A person described in  
22 subsection (a) shall permit an individual who is the subject  
23 of protected health information, or the individual’s des-  
24 ignee, to inspect and copy the records created under sub-  
25 section (a) and (c).”.