

104<sup>TH</sup> CONGRESS  
1<sup>ST</sup> SESSION

# S. 1360

To ensure personal privacy with respect to medical records and health care-related information, and for other purposes.

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## IN THE SENATE OF THE UNITED STATES

OCTOBER 24, 1995

Mr. BENNETT (for himself, Mr. DOLE, Mr. LEAHY, Mrs. KASSEBAUM, Mr. KENNEDY, Mr. FRIST, Mr. SIMON, Mr. HATCH, Mr. GREGG, Mr. STEVENS, Mr. JEFFORDS, Mr. KOHL, Mr. DASCHLE, and Mr. FEINGOLD) introduced the following bill; which was read twice and referred to the Committee on Labor and Human Resources

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## A BILL

To ensure personal privacy with respect to medical records and health care-related information, and for other purposes.

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; TABLE OF CONTENTS.**

4       (a) SHORT TITLE.—This Act may be cited as the  
5       “Medical Records Confidentiality Act of 1995”.

6       (b) TABLE OF CONTENTS.—The table of contents for  
7       this Act is as follows:

- Sec. 1. Short title; table of contents.
- Sec. 2. Purpose.
- Sec. 3. Definitions.

TITLE I—INDIVIDUAL'S RIGHTS

Subtitle A—Review of Protected Health Information by Subjects of the Information

- Sec. 101. Inspection and copying of protected health information.
- Sec. 102. Correction or amendment of protected health information.
- Sec. 103. Notice of information practices.

Subtitle B—Establishment of Safeguards

- Sec. 111. Establishment of safeguards.
- Sec. 112. Accounting for disclosures.

TITLE II—RESTRICTIONS ON USE AND DISCLOSURE

- Sec. 201. General rules regarding use and disclosure.
- Sec. 202. Authorizations for disclosure of protected health information for treatment or payment.
- Sec. 203. Authorizations for disclosure of protected health information, other than for treatment or payment.
- Sec. 204. Health information services.
- Sec. 205. Next of kin and directory information.
- Sec. 206. Emergency circumstances.
- Sec. 207. Oversight.
- Sec. 208. Public health.
- Sec. 209. Health research.
- Sec. 210. Judicial and administrative purposes.
- Sec. 211. Non-law enforcement subpoenas.
- Sec. 212. Law enforcement.
- Sec. 213. Standards for electronic disclosures.

TITLE III—SANCTIONS

Subtitle A—Civil Sanctions

- Sec. 301. Civil penalty.
- Sec. 302. Civil action.

Subtitle B—Criminal Sanctions

- Sec. 311. Wrongful disclosure of protected health information.

TITLE IV—MISCELLANEOUS

- Sec. 401. Relationship to other laws.
- Sec. 402. No liability for permissible disclosures.
- Sec. 403. Effective date.

1 **SEC. 2. PURPOSE.**

2 The purpose of this Act is to—

3 (1) establish strong and effective mechanisms

4 to protect the privacy of persons with respect to per-

1 personally identifiable health care information that is  
2 created or maintained as part of health treatment,  
3 diagnosis, enrollment, payment, testing, or research  
4 processes;

5 (2) promote the efficiency and security of the  
6 health information infrastructure so that members  
7 of the health care community may more effectively  
8 exchange and transfer health information in a man-  
9 ner that will ensure the confidentiality of personally  
10 identifiable health information; and

11 (3) establish strong and effective remedies for  
12 violations of this Act.

13 **SEC. 3. DEFINITIONS.**

14 As used in this Act:

15 (1) CERTIFIED HEALTH INFORMATION SERV-  
16 ICE.—The term “certified health information serv-  
17 ice” means a health information service that receives  
18 personally identifiable health information for the  
19 purpose of creating nonidentifiable health informa-  
20 tion and has been certified by the Secretary pursu-  
21 ant to section 204(b).

22 (2) CERTIFIED INSTITUTIONAL REVIEW  
23 BOARD.—The term “certified institutional review  
24 board” means an institutional review board that has

1       been certified by the Secretary pursuant to section  
2       209(d).

3           (3) DISCLOSE.—The term “disclose” means to  
4       release, transfer, or otherwise divulge protected  
5       health information to any person other than the in-  
6       dividual who is the subject of such information.

7           (4) HEALTH CARE.—The term “health care”  
8       means—

9           (A)(i) preventive, diagnostic, therapeutic,  
10       rehabilitative, maintenance, or palliative care,  
11       counseling, service, or procedure—

12           (I) with respect to the physical or  
13       mental condition of an individual; or

14           (II) affecting the structure or function  
15       of the human body or any part of the  
16       human body; or

17           (ii) any sale or dispensing of a drug, de-  
18       vice, equipment, or other item to an individual,  
19       or for the use of an individual, pursuant to a  
20       prescription.

21           (5) HEALTH CARE PROVIDER.—The term  
22       “health care provider” means a person who, with re-  
23       spect to a specific item of protected health informa-  
24       tion, receives, creates, uses, maintains, or discloses

1 the information while acting in whole or in part in  
2 the capacity of—

3 (A) a person who is licensed, certified, reg-  
4 istered, or otherwise authorized by law to pro-  
5 vide an item or service that constitutes health  
6 care, in the ordinary course of business or prac-  
7 tice of a profession;

8 (B) a Federal or State program that di-  
9 rectly provides items or services that constitute  
10 health care to beneficiaries; or

11 (C) an officer or employee of a person de-  
12 scribed in subparagraph (A) or (B).

13 (6) HEALTH INFORMATION SERVICE.—The  
14 term “health information service” means a person  
15 that—

16 (A) uses protected health information to  
17 provide services to health information trustees  
18 for purposes authorized under the Act;

19 (B) facilitates the transfer and exchange of  
20 protected health information between health in-  
21 formation trustees;

22 (C) processes protected health information  
23 into standard format for transfer and ex-  
24 changes between health information trustees;

1 (D) facilitates authorized access to pro-  
2 tected health information; or

3 (E) transforms protected health informa-  
4 tion into nonidentifiable health information.

5 (7) HEALTH INFORMATION TRUSTEE.—

6 (A) IN GENERAL.—The term “health infor-  
7 mation trustee” means—

8 (i) a health care provider, health plan,  
9 health oversight agency, health researcher,  
10 public health authority, employer, insurer,  
11 school or university, or health information  
12 service insofar as it creates, receives, ob-  
13 tains, maintains, uses, or transmits pro-  
14 tected health information;

15 (ii) any person who obtains protected  
16 health information under sections 206,  
17 207, 208, 209, 210, 211, or 212; or

18 (iii) any employee, agent, or contrac-  
19 tor of a person covered under clause (i) or  
20 (ii) insofar as such employee, agent, or  
21 contractor creates, receives, obtains, main-  
22 tains, uses, or transmits protected health  
23 information.

24 (B) DUTIES AND RESPONSIBILITIES.—The  
25 duties and responsibilities of a health informa-

1           tion trustee shall be negotiated between the  
2           trustee and any agent or contractor of the  
3           trustee.

4           (8) HEALTH OVERSIGHT AGENCY.—The term  
5           “health oversight agency” means a person who—

6                   (A) performs or oversees the performance  
7                   of an assessment, evaluation, determination, or  
8                   investigation relating to the licensing, accredita-  
9                   tion, or certification of health care providers; or

10                   (B)(i) performs or oversees the perform-  
11                   ance of an assessment, evaluation, determina-  
12                   tion, investigation, or prosecution relating to  
13                   compliance with legal, fiscal, medical, or sci-  
14                   entific standards relating to—

15                           (I) the delivery of or payment for,  
16                           health care, health services or equipment,  
17                           or health research; or

18                           (II) health care fraud or fraudulent  
19                           claims regarding health care, health serv-  
20                           ices or equipment, or related activities and  
21                           items; and

22                           (ii) is a public agency, acting on behalf of  
23                           a public agency, acting pursuant to a require-  
24                           ment of a public agency, or carrying out activi-  
25                           ties under a Federal or State law governing the

1 assessment, evaluation, determination, inves-  
2 tigation, or prosecution described in clause (i).

3 (9) HEALTH PLAN.—The term “health plan”  
4 means any health insurance plan, including any hos-  
5 pital or medical service plan, dental or other health  
6 service plan or health maintenance organization  
7 plan, or other program providing health benefits,  
8 whether or not funded through the purchase of in-  
9 surance.

10 (10) HEALTH RESEARCHER.—The term “health  
11 researcher” means a person who, with respect to a  
12 specific item of protected health information, re-  
13 ceives the information—

14 (A) pursuant to section 209 (relating to  
15 health research); or

16 (B) while acting in whole or in part in the  
17 capacity of an officer or employee of a person  
18 described in subparagraph (A).

19 (11) INDIVIDUAL REPRESENTATIVE.—The term  
20 “individual representative” means any individual le-  
21 gally empowered to make decisions concerning the  
22 provision of health care to an individual (where the  
23 individual lacks the legal capacity under State law to  
24 make such decisions) or the administrator or execu-  
25 tor of the estate of a deceased individual.

1           (12) LAW ENFORCEMENT INQUIRY.—The term  
2           “law enforcement inquiry” means a lawful investiga-  
3           tion or official proceeding inquiring into a violation  
4           of, or failure to comply with, any criminal or civil  
5           statute or any regulation, rule, or order issued pur-  
6           suant to such a statute.

7           (13) PERSON.—The term “person” means a  
8           government, governmental subdivision, agency or au-  
9           thority; corporation; company; association; firm;  
10          partnership; society; estate; trust; joint venture; indi-  
11          vidual; individual representative; and any other legal  
12          entity.

13          (14) PROTECTED HEALTH INFORMATION.—The  
14          term “protected health information” means any in-  
15          formation, including demographic information col-  
16          lected from an individual, whether oral or recorded  
17          in any form or medium, that—

18                 (A) is created or received by a health infor-  
19                 mation trustee; and

20                 (B)(i) relates to the past, present, or fu-  
21                 ture physical or mental health or condition of  
22                 an individual, the provision of health care to an  
23                 individual, or the past, present, or future pay-  
24                 ment for the provision of health care to an indi-  
25                 vidual; and

1 (ii)(I) identifies an individual; or  
2 (II) with respect to which there is a rea-  
3 sonable basis to believe that the information  
4 can be used to identify an individual.

5 (15) PUBLIC HEALTH AUTHORITY.—The term  
6 “public health authority” means an authority or in-  
7 strumentality of the United States, a State, or a po-  
8 litical subdivision of a State that is—

9 (A) responsible for public health matters;  
10 and

11 (B) engaged in such activities as injury re-  
12 porting, public health, surveillance, and public  
13 health investigation or intervention.

14 (16) SECRETARY.—The term “Secretary”  
15 means the Secretary of Health and Human Services.

16 (17) STATE.—The term “State” includes the  
17 District of Columbia, Puerto Rico, the Virgin Is-  
18 lands, Guam, American Samoa, and the Northern  
19 Mariana Islands.

20 (18) WRITING.—The term “writing” means  
21 writing in either a paper-based or computer-based  
22 form, including electronic signatures.

1 **TITLE I—INDIVIDUAL’S RIGHTS**  
2 **Subtitle A—Review of Protected**  
3 **Health Information by Subjects**  
4 **of the Information**

5 **SEC. 101. INSPECTION AND COPYING OF PROTECTED**  
6 **HEALTH INFORMATION.**

7 (a) IN GENERAL.—Except as provided in subsection  
8 (b), a health information trustee shall permit an individual  
9 who is the subject of protected health information or the  
10 individual’s designee, to inspect and copy protected health  
11 information concerning the individual, including records  
12 created under section 102 that the trustee maintains. A  
13 health information trustee may require an individual to  
14 reimburse the trustee for the cost of such inspection and  
15 copying.

16 (b) EXCEPTIONS.—A health information trustee is  
17 not required by this section to permit inspection or copy-  
18 ing of protected health information if any of the following  
19 conditions are met:

20 (1) ENDANGERMENT TO LIFE OR SAFETY.—  
21 The trustee determines that disclosure of the infor-  
22 mation could reasonably be expected to endanger the  
23 life or physical safety of any individual.

24 (2) CONFIDENTIAL SOURCE.—The information  
25 identifies or could reasonably lead to the identifica-

1       tion of a person who provided information under a  
2       promise of confidentiality to a health care provider  
3       concerning the individual who is the subject of the  
4       information.

5               (3) ADMINISTRATIVE PURPOSES.—The informa-  
6       tion—

7                       (A) is used by the trustee solely for admin-  
8                       istrative purposes and not in the provision of  
9                       health care or the administration of benefits to  
10                      the individual who is the subject of the informa-  
11                     tion; and

12                     (B) has not been disclosed by the health  
13                     information trustee to any other person.

14       (c) INSPECTION AND COPYING OF SEGREGABLE POR-  
15       TION.—A health information trustee shall permit inspec-  
16       tion and copying under subsection (a) of any reasonably  
17       segregable portion of a record after deletion of any portion  
18       that is exempt under subsection (b).

19       (d) DEADLINE.—A health information trustee shall  
20       comply with or deny (with a statement of the reasons for  
21       such denial) a request for inspection or copying of pro-  
22       tected health information under this section within the 30-  
23       day period beginning on the date on which the trustee re-  
24       ceives the request.

1 **SEC. 102. CORRECTION OR AMENDMENT OF PROTECTED**  
2 **HEALTH INFORMATION.**

3 (a) IN GENERAL.—A health information trustee shall  
4 within the 45-day period beginning on the date on which  
5 the trustee receives from an individual a written request  
6 to correct or amend information—

7 (1) make the correction or amendment re-  
8 quested;

9 (2) inform the individual of the correction or  
10 amendment that has been made; and

11 (3) make reasonable efforts to inform any per-  
12 son who is identified by the individual, who is not  
13 an officer, employer, or agent of the trustee, and to  
14 whom the uncorrected or unamended portion of the  
15 information was previously disclosed, of the correc-  
16 tion or amendment that has been made.

17 (b) REFUSAL TO CORRECT OR AMEND.—If the  
18 health information trustee refuses to make the correction  
19 or amendment, the trustee shall inform the individual of—

20 (1) the reasons for the refusal to make the cor-  
21 rection or amendment;

22 (2) any procedures for further review of the re-  
23 fusal; and

24 (3) the individual's right to file with the trustee  
25 a concise statement setting forth the requested cor-

1 rection or amendment and the individual's reasons  
2 for disagreeing with the refusal.

3 (c) STATEMENT OF DISAGREEMENT.—After an indi-  
4 vidual has filed a statement of disagreement under sub-  
5 section (b)(3), the health information trustee in any subse-  
6 quent disclosure of the disputed portion of the informa-  
7 tion—

8 (1) shall include a copy of the individual's  
9 statement; and

10 (2) may include a concise statement of the rea-  
11 sons for not making the requested correction or  
12 amendment.

13 (d) RULE OF CONSTRUCTION.—This section shall not  
14 be construed to require a health information trustee to  
15 conduct a formal, informal, or other hearing or proceeding  
16 concerning a request for a correction or amendment to  
17 protected health information.

18 (e) CORRECTION.—For purposes of subsection (a), a  
19 correction is deemed to have been made to protected  
20 health information when information that has been dis-  
21 puted by an individual has been corrected, clearly marked  
22 as incorrect, or supplemented by correct information.

23 **SEC. 103. NOTICE OF INFORMATION PRACTICES.**

24 (a) PREPARATION OF WRITTEN NOTICE.—A health  
25 information trustee other than a health information serv-

1 ice shall provide, in a clear and conspicuous manner, writ-  
2 ten notice of the trustee's information practices, including  
3 a description of the trustee's health information practices,  
4 including notice of individual rights with respect to pro-  
5 tected health information.

6 (b) MODEL NOTICE.—The Secretary, after notice  
7 and opportunity for public comment, shall develop and dis-  
8 seminate model notices of information practices for use  
9 under this section.

## 10 **Subtitle B—Establishment of** 11 **Safeguards**

### 12 **SEC. 111. ESTABLISHMENT OF SAFEGUARDS.**

13 (a) IN GENERAL.—A health information trustee shall  
14 establish and maintain appropriate administrative, tech-  
15 nical, and physical safeguards to ensure the confidential-  
16 ity, security, accuracy, and integrity of protected health  
17 information created, received, obtained, maintained, used  
18 or transmitted by the trustee.

19 (b) REGULATIONS.—

20 (1) PROMULGATION.—

21 (A) IN GENERAL.—In promulgating regu-  
22 lations under this Act, the Secretary shall fol-  
23 low the procedures authorized under sections  
24 581 through 590 of title 5, United States Code.

25 (B) ADVISORY GROUP.—

1 (i) DETERMINATION BY THE SEC-  
2 RETARY.—If the Secretary determines that  
3 a negotiated rulemaking committee shall  
4 not be established as permitted by section  
5 583 of title 5, United States Code, the  
6 Secretary shall appoint and consult with  
7 an advisory group of knowledgeable indi-  
8 viduals.

9 (ii) MEMBERSHIP.—The advisory  
10 group shall consist of at least 7 but no  
11 more than 12 individuals including rep-  
12 resentatives of—

13 (I) health care professionals and  
14 health care entities;

15 (II) health care consumers;

16 (III) third party payors/adminis-  
17 trators; and

18 (IV) privacy advocates.

19 (iii) RESPONSIBILITIES.—The advi-  
20 sory group shall review all proposed rules  
21 and regulations and submit recommenda-  
22 tions to the Secretary. The advisory group  
23 shall also assist the Secretary in establish-  
24 ing the standards for compliance with rules  
25 and regulations, in developing an annual

1 report to the Congress on the status of the  
2 requirements set forth in this Act, their  
3 cost impact, and any recommendations for  
4 modifications in order to ensure efficient  
5 and confidential electronic data inter-  
6 change of individually identifiable health  
7 care information.

8 (2) CONSULTATION.—The Secretary may pro-  
9 mulgate regulations in consultation with privacy, in-  
10 dustry, and consumer groups.

11 **SEC. 112. ACCOUNTING FOR DISCLOSURES.**

12 (a) IN GENERAL.—A health information trustee shall  
13 create and maintain, with respect to any protected health  
14 information disclosure that is not related to treatment, a  
15 record of the disclosure in accordance with regulations is-  
16 sued by the Secretary.

17 (b) RECORD OF DISCLOSURE PART OF PROTECTED  
18 HEALTH INFORMATION.—A record created and main-  
19 tained under subsection (a) shall be maintained as pro-  
20 tected health information for not less than 7 years.

1           **TITLE II—RESTRICTIONS ON**  
2                   **USE AND DISCLOSURE**

3   **SEC. 201. GENERAL RULES REGARDING USE AND DISCLO-**  
4                   **SURE.**

5           (a) **GENERAL RULE.**—A health information trustee  
6 may not disclose protected health information except as  
7 authorized under this title.

8           (b) **SCOPE OF DISCLOSURE.**—

9               (1) **COMPATIBILITY TO PURPOSE.**—Protected  
10 health information may not be used or disclosed to  
11 any person unless the use or disclosure is compatible  
12 with and related to the purposes for which the infor-  
13 mation was obtained.

14               (2) **LIMITATION ON INFORMATION.**—Every dis-  
15 closure of protected health information by a health  
16 information trustee shall be limited to the minimum  
17 amount of information necessary to accomplish the  
18 purpose for which the information is disclosed.

19           (c) **NO GENERAL REQUIREMENT TO DISCLOSE.**—  
20 Nothing in this title that permits a disclosure of health  
21 information shall be construed to require such disclosure.

22           (d) **IDENTIFICATION OF DISCLOSED INFORMATION**  
23 **AS PROTECTED INFORMATION.**—Except as provided in  
24 this title, a health information trustee may not disclose  
25 protected health information unless such information is

1 clearly identified as protected health information that is  
2 subject to this title.

3 (e) INFORMATION IN WHICH PROVIDERS ARE IDEN-  
4 TIFIED.—The Secretary shall issue regulations protecting  
5 information identifying providers in order to promote the  
6 availability of health care services.

7 **SEC. 202. AUTHORIZATIONS FOR DISCLOSURE OF PRO-**  
8 **TECTED HEALTH INFORMATION FOR TREAT-**  
9 **MENT OR PAYMENT.**

10 (a) WRITTEN AUTHORIZATIONS.—A health informa-  
11 tion trustee may disclose protected health information for  
12 purposes of treatment or payment pursuant to an author-  
13 ization executed by the individual who is the subject of  
14 the information (or a person acting for the individual pur-  
15 suant to State law) if each of the following requirements  
16 is met:

17 (1) WRITING.—The authorization is in writing  
18 or electronically authenticated, signed by the individ-  
19 ual who is the subject of the information, and dated.

20 (2) SEPARATE FORM.—Separate forms author-  
21 izing disclosures for treatment and payment proc-  
22 esses are provided to the individual.

23 (3) INFORMATION DESCRIBED.—The informa-  
24 tion to be disclosed is specified, or is described in  
25 the authorization.

1           (4) TRUSTEE DESCRIBED.—The trustee who is  
2 authorized to disclose such information is specifically  
3 identified, or is described in the authorization.

4           (5) RECIPIENT DESCRIBED.—The person to  
5 whom the information is to be disclosed is specifi-  
6 cally identified, or is described in the authorization.

7           (6) RIGHT TO REVOKE OR AMEND.—The au-  
8 thorization contains an acknowledgement that the  
9 individual who is the subject of the information has  
10 the right to revoke or amend the authorization.

11           (7) STATEMENT OF INTENDED DISCLOSURES.—  
12 The authorization contains an acknowledgment that  
13 the individual who is the subject of the information  
14 has read a statement of the disclosures that the per-  
15 son who receives the protected health information in-  
16 tends to make.

17           (8) INFORMATION RESTRICTED.—The author-  
18 ization includes a proviso that the information will  
19 be disclosed solely for a purpose that is compatible  
20 with and related to the purposes for which the infor-  
21 mation was collected or received by the trustee.

22           (9) EXPIRATION DATE SPECIFIED.—The au-  
23 thorization specifies a date or event at which the au-  
24 thorization expires.

1 (b) REVOCATION OR AMENDMENT OF AUTHORIZA-  
2 TION.—

3 (1) IN GENERAL.—The authorization contains  
4 an acknowledgment that the individual may in writ-  
5 ing revoke or amend an authorization described in  
6 subsection (a), at any time, except that with respect  
7 to disclosure of protected health information to per-  
8 mit validation of expenditures for health care that  
9 has previously been authorized the authorization  
10 may not be revoked.

11 (2) NOTICE OF REVOCATION.—A health infor-  
12 mation trustee who discloses protected health infor-  
13 mation pursuant to an authorization described in  
14 subsection (a) that has been revoked shall not be  
15 subject to any liability or penalty under this Act if  
16 the trustee had no actual or constructive notice of  
17 the revocation.

18 (c) MODEL AUTHORIZATIONS.—The Secretary, after  
19 notice and opportunity for public comment, shall develop  
20 and disseminate model written authorizations of the type  
21 described in subsection (a) and model statements of in-  
22 tended disclosures of the type described in subsection  
23 (a)(6).

24 (d) COPY.—A health information trustee who dis-  
25 closes protected health information pursuant to an author-

1 ization under this section shall maintain a copy of the au-  
2 thorization.

3 **SEC. 203. AUTHORIZATIONS FOR DISCLOSURE OF PRO-**  
4 **TECTED HEALTH INFORMATION, OTHER**  
5 **THAN FOR TREATMENT OR PAYMENT.**

6 (a) WRITTEN AUTHORIZATIONS.—A health informa-  
7 tion trustee may disclose protected health information  
8 pursuant to an authorization executed by the individual  
9 who is the subject of the information if the following con-  
10 ditions are met:

11 (1) GENERAL REQUIREMENTS.—The require-  
12 ments of section 202(a) (1) through (6) are met.

13 (2) STATEMENT OF INTENDED DISCLOSURES.—  
14 The statement of intended disclosure shall be in  
15 writing, on a form that is separate from the author-  
16 ization for disclosure, and shall be received by the  
17 individual authorizing the disclosure on or before the  
18 date the authorization is executed.

19 (3) AUTHORIZATION NOT REQUESTED IN CON-  
20 NECTION WITH PROVISION OF HEALTH CARE.—The  
21 authorization is not requested on a day on which the  
22 trustee provides health care to the individual re-  
23 quested to provide the authorization.

24 (4) EXPIRATION DATE SPECIFIED.—The au-  
25 thorization specifies a date or event upon which the

1 authorization expires, which shall not exceed 1 year  
2 from the date of the execution of the authorization.

3 (b) LIMITATION ON AUTHORIZATIONS.—A health in-  
4 formation trustee may not condition delivery of treatment  
5 or payment for services on the receipt of an authorization  
6 described in subsection (a).

7 (c) REVOCATION OR AMENDMENT OF AUTHORIZA-  
8 TION.—

9 (1) IN GENERAL.—An individual may in writing  
10 revoke or amend an authorization described in sub-  
11 section (a).

12 (2) NOTICE OF REVOCATION.—A health infor-  
13 mation trustee who discloses protected health infor-  
14 mation pursuant to an authorization that has been  
15 revoked shall not be subject to any liability or pen-  
16 alty under this title if the trustee had no actual or  
17 constructive notice of the revocation.

18 (d) MODEL AUTHORIZATIONS.—The Secretary, after  
19 notice and opportunity for public comment, shall develop  
20 and disseminate model written authorizations of the type  
21 described in subsection (a) and model statements of the  
22 intended disclosures of the type described in subsection  
23 (a)(2).

1 (e) AUTHORIZATION NOT REQUIRED.—This section  
2 does not apply to sections 204, 205, 206, 207, 208, 209,  
3 210, 211, and 212.

4 **SEC. 204. CREATION OF NONIDENTIFIABLE INFORMATION.**

5 (a) CREATION OF NONIDENTIFIABLE INFORMA-  
6 TION.—A health information trustee may disclose pro-  
7 tected health information to a certified health information  
8 service for the purpose of creating nonidentifiable health  
9 information.

10 (b) CERTIFICATION OF HEALTH INFORMATION  
11 SERVICES.—

12 (1) REGULATIONS.—The Secretary, after notice  
13 and opportunity for public comment, shall issue reg-  
14 ulations establishing certification requirements for  
15 health information services under this title. Such  
16 regulations shall include requirements that the  
17 health information service establish and maintain  
18 appropriate administrative, technical, and physical  
19 safeguards to ensure the confidentiality, security, ac-  
20 curacy, and integrity of protected health informa-  
21 tion.

22 (2) CERTIFICATION.—The Secretary shall cer-  
23 tify a health information service that meets the cer-  
24 tification requirements established by the Secretary  
25 under paragraph (1).

1 **SEC. 205. NEXT OF KIN AND DIRECTORY INFORMATION.**

2 (a) NEXT OF KIN.—A health care provider, or a per-  
3 son who receives protected health information under sec-  
4 tion 206, may disclose protected health information re-  
5 garding an individual to the individual's next of kin, to  
6 an individual representative of the individual, or to an in-  
7 dividual with whom that individual has a significant per-  
8 sonal relationship if—

9 (1) the individual who is the subject of the in-  
10 formation—

11 (A) has been notified of the individual's  
12 right to object and has not objected to the dis-  
13 closure;

14 (B) is not competent to be notified about  
15 the right to object; or

16 (C) exigent circumstances exist such that  
17 it would not be practicable to notify the individ-  
18 ual of the right to object; and

19 (2) the information disclosed relates to health  
20 care currently being provided to that individual.

21 (b) DIRECTORY INFORMATION.—

22 (1) DISCLOSURE.—Except as provided in para-  
23 graph (2), a health information trustee may disclose  
24 the information described in subparagraph (B) to  
25 any person if—

1 (A) the individual who is the subject of the  
2 information—

3 (i) has been notified of the individ-  
4 ual's right to object and has not objected  
5 to the disclosure;

6 (ii) is not competent to be notified  
7 about the right to object; or

8 (iii) exigent circumstances exist such  
9 that it would not be practicable to notify  
10 the individual of the right to object; and

11 (B) the information consists only of 1 or  
12 more of the following items:

13 (i) the name of the individual who is  
14 the subject of the information;

15 (ii) the general health status of the in-  
16 dividual, described as critical, poor, fair,  
17 stable, or satisfactory or in terms denoting  
18 similar conditions; and

19 (iii) the location of the individual on  
20 premises controlled by a provider.

21 (2) EXCEPTION.—If disclosure of the location  
22 of the individual reveals specific information about  
23 the physical or mental condition of the individual,  
24 the individual must expressly authorize such disclo-  
25 sure.

1 (c) DECEASED INDIVIDUAL.—

2 (1) IDENTIFICATION.—A health information  
3 trustee may disclose protected health information if  
4 necessary to assist in the identification of a deceased  
5 individual.

6 (2) REGULATIONS.—The Secretary shall de-  
7 velop and establish through regulation a procedure  
8 for obtaining protected health information relating  
9 to a deceased individual when there is no individual  
10 representative for such individual.

11 **SEC. 206. EMERGENCY CIRCUMSTANCES.**

12 Any person who receives protected health information  
13 under this title may disclose protected health information  
14 in emergency circumstances when necessary to protect the  
15 health or safety of an individual from serious, imminent  
16 harm.

17 **SEC. 207. OVERSIGHT.**

18 (a) IN GENERAL.—A health information trustee may  
19 disclose protected health information to a health oversight  
20 agency for an oversight function authorized by law.

21 (b) USE IN ACTION AGAINST INDIVIDUALS.—Pro-  
22 tected health information about an individual that is dis-  
23 closed under this section may not be used in, or disclosed  
24 to any person for use in, an administrative, civil, or crimi-  
25 nal action or investigation directed against the individual

1 unless the action or investigation arises out of and is di-  
2 rectly related to—

- 3           (1) receipt of health care or payment for health  
4           care; or  
5           (2) an action involving a fraudulent claim relat-  
6           ed to health.

7 **SEC. 208. PUBLIC HEALTH.**

8           A health care provider, health plan, health re-  
9           searcher, public health authority, employer, insurer, school  
10          or university, or certified health information network serv-  
11          ice, or person who receives protected health information  
12          under section 206, may disclose protected health informa-  
13          tion to a public health authority or other person author-  
14          ized by law for use in a legally authorized—

- 15                 (1) disease or injury report;  
16                 (2) public health surveillance; or  
17                 (3) public health investigation or intervention.

18 **SEC. 209. HEALTH RESEARCH.**

19           (a) IN GENERAL.—A health information trustee may  
20          disclose protected health information to a health re-  
21          searcher if a certified institutional review board deter-  
22          mines that the research project engaged in by the health  
23          researcher—

- 24                 (1) requires use of the protected health infor-  
25                 mation for the effectiveness of the project; and

1           (2) is of sufficient importance to outweigh the  
2 intrusion into the privacy of the individual who is  
3 the subject of the information that would result from  
4 the disclosure.

5           (b) OBLIGATIONS OF RECIPIENT.—A person who re-  
6 ceives protected health information pursuant to subsection

7 (a)—

8           (1) shall remove or destroy, at the earliest op-  
9 portunity consistent with the purposes of the project,  
10 information that would enable an individual to be  
11 identified, unless—

12           (A) a certified institutional review board  
13 has determined that there is a health or re-  
14 search justification for retention of such identi-  
15 fiers; and

16           (B) there is an adequate plan to protect  
17 the identifiers from disclosure that is inconsis-  
18 tent with this section; and

19           (2) shall use protected health information solely  
20 for purposes of the health research project for which  
21 disclosure was authorized by a certified institutional  
22 review board under subsection (a).

23           (c) SPECIAL RULE FOR RESEARCHERS OTHER THAN  
24 ACADEMIC CENTERS OR HEALTH CARE FACILITIES.—If  
25 a health researcher is not located in an academic center,

1 a health care facility or public health agency, the deter-  
2 minations required by a certified institutional review board  
3 shall be approved by the Secretary before the determina-  
4 tion is issued.

5 (d) CERTIFICATION OF INSTITUTIONAL REVIEW  
6 BOARDS.—

7 (1) REGULATIONS.—The Secretary, after notice  
8 and opportunity for public comment, shall issue reg-  
9 ulations establishing certification requirements for  
10 institutional review boards under this title. Such reg-  
11 ulations shall be based on regulations issued under  
12 section 491(a) of the Public Health Service Act. The  
13 regulations shall ensure that institutional review  
14 boards certified under this paragraph have the quali-  
15 fications to assess and protect the confidentiality of  
16 research subjects.

17 (2) CERTIFICATION.—The Secretary shall cer-  
18 tify an institutional review board that meets the cer-  
19 tification requirements established by the Secretary  
20 under paragraph (1).

21 **SEC. 210. JUDICIAL AND ADMINISTRATIVE PURPOSES.**

22 (a) IN GENERAL.—A health care provider, health  
23 plan, health oversight agency, employer, school, university,  
24 insurer, or person who receives protected health informa-

1 tion under section 206, may disclose protected health in-  
2 formation—

3 (1) pursuant to the Federal Rules of Civil Pro-  
4 cedure, the Federal Rules of Criminal Procedure, or  
5 comparable rules of other courts or administrative  
6 agencies, in connection with litigation or proceedings  
7 to which the individual who is the subject of the in-  
8 formation is a party and in which the individual has  
9 placed his or her physical or mental condition at  
10 issue;

11 (2) to a court, and to others ordered by the  
12 court, if the protected health information is devel-  
13 oped in response to a court-ordered physical or men-  
14 tal examination; or

15 (3) pursuant to a law requiring the reporting of  
16 specific medical information to law enforcement au-  
17 thorities.

18 (b) OBLIGATIONS OF RECIPIENT.—A person seeking  
19 protected health information pursuant to subsection (a)—

20 (1) shall notify the individual or the individual's  
21 attorney of the request for the information;

22 (2) shall provide the health information trustee  
23 with a signed document attesting—

24 (A) that the individual has placed his or  
25 her physical or mental condition at issue in liti-

1           gation or proceedings in which the individual is  
2           a party; and

3           (B) the date on which the individual or the  
4           individual's attorney was notified under para-  
5           graph (1); and

6           (3) shall not accept any requested protected  
7           health information from the trustee until the termi-  
8           nation of the 10-day period beginning on the date  
9           notice was given under paragraph (1).

10 **SEC. 211. NON-LAW ENFORCEMENT SUBPOENAS.**

11           (a) **IN GENERAL.**—A health care provider, health  
12           plan, health oversight agency, employer, insurer, school or  
13           university, or person who receives protected health infor-  
14           mation under section 206, may disclose protected health  
15           information under this section if the disclosure is pursuant  
16           to a subpoena issued on behalf of a party who has com-  
17           plied with the access provisions of subsection (b).

18           (b) **ACCESS PROCEDURES.**—A person may not obtain  
19           protected health information about an individual pursuant  
20           to a subpoena unless—

21           (1) a copy of the subpoena together with a no-  
22           tice of the individual's right to challenge the sub-  
23           poena in accordance with subsection (c), has been  
24           served upon the individual on or before the date of  
25           return of the subpoena; and—

1           (2)(A) 15 days have passed since the date of  
2           service on the individual, and within that time period  
3           the individual has not indicated a challenge in ac-  
4           cordance with subsection (c)(1); or

5           (B) disclosure is ordered by a court under sub-  
6           section (c)(2).

7           (c) CHALLENGE PROCEDURES.—

8           (1) MOTION TO QUASH SUBPOENA.—After serv-  
9           ice of a copy of the subpoena seeking protected  
10          health information under subsection (b), the individ-  
11          ual who is the subject of the protected health infor-  
12          mation may file in any court of competent jurisdic-  
13          tion a motion to quash the subpoena.

14          (2) STANDARD FOR DECISION.—

15           (A) IN GENERAL.—The court shall grant a  
16          motion under paragraph (1) unless the respon-  
17          dent demonstrates that—

18                   (i) there is reasonable ground to be-  
19                   lieve the information is relevant to a law-  
20                   suit or other judicial or administrative pro-  
21                   ceeding; and

22                   (ii) the need of the respondent for the  
23                   information outweighs the privacy interest  
24                   of the individual.

1 (B) CRITERIA FOR DECISION.—In deter-  
2 mining whether the need of the respondent for  
3 the information outweighs the privacy interest  
4 of the individual, the court shall consider—

5 (i) the particular purpose for which  
6 the information was collected;

7 (ii) the degree to which disclosure of  
8 the information would embarrass, injure,  
9 or invade the privacy of the individual;

10 (iii) the effect of the disclosure on the  
11 individual's future health care;

12 (iv) the importance of the information  
13 to the lawsuit or proceeding; and

14 (v) any other relevant factor.

15 (3) ATTORNEY'S FEES.—In the case of a mo-  
16 tion brought under paragraph (1) in which the indi-  
17 vidual has substantially prevailed, the court may as-  
18 sess against the respondent a reasonable attorney's  
19 fee and other litigation costs and expenses (including  
20 expert fees) reasonably incurred.

21 **SEC. 212. LAW ENFORCEMENT.**

22 (a) GOVERNMENT SUBPOENAS AND WARRANTS.—

23 (1) IN GENERAL.—A health information trustee  
24 shall disclose protected health information under this  
25 section if the disclosure is pursuant to—

1 (A) a subpoena issued under the authority  
2 of a grand jury; or

3 (B) an administrative subpoena or sum-  
4 mons or a judicial subpoena or warrant,  
5 which meets the conditions of paragraph (2).

6 (2) PROBABLE CAUSE REQUIREMENT.—A gov-  
7 ernment authority may not obtain protected health  
8 information about an individual under paragraph (1)  
9 for use in a law enforcement inquiry unless there is  
10 probable cause to believe that the information is rel-  
11 evant to a legitimate law enforcement inquiry being  
12 conducted by the government authority.

13 (3) WARRANTS.—A government authority that  
14 obtains protected health information about an indi-  
15 vidual pursuant to a warrant shall, not later than 30  
16 days after the date the warrant was executed, serve  
17 the individual with, or mail to the last known ad-  
18 dress of the individual, a notice that protected health  
19 information about the individual was obtained, to-  
20 gether with a notice of the individual's right to chal-  
21 lenge the warrant.

22 (4) SUBPOENA OR SUMMONS.—Except as pro-  
23 vided in paragraph (5), a government authority may  
24 not obtain protected health information about an in-  
25 dividual pursuant to a subpoena or summons unless

1 a copy of the subpoena or summons has been served  
2 on the individual, if the identity of the individual is  
3 known, on or before the date of the return of the  
4 subpoena or summons, together with notice of the  
5 individual's right to challenge the subpoena or sum-  
6 mons. If the identity of the individual is not known  
7 at the time the subpoena or summons is served, the  
8 individual shall be served not later than 30 days  
9 thereafter, with notice that protected health infor-  
10 mation about the individual was obtained together  
11 with notice of the individual's right to challenge the  
12 subpoena or summons.

13 (5) APPLICATION FOR DELAY.—

14 (A) IN GENERAL.—A government author-  
15 ity may apply ex parte and under seal to an ap-  
16 propriate court to delay (for an initial period of  
17 not longer than 90 days) service of the notice  
18 regarding execution of the warrant as required  
19 under paragraph (3) or a copy of the subpoena  
20 as required under paragraph (4). The govern-  
21 ment authority may apply to the court for ex-  
22 tensions of the delay.

23 (B) EX PARTE ORDER.—The court shall  
24 enter an ex parte order delaying or extending  
25 the delay of notice, an order prohibiting the dis-

1 closure of the request for, or the disclosure of,  
2 the protected health information, and an order  
3 requiring the disclosure of the protected health  
4 information if the court finds that—

5 (i) the inquiry being conducted is  
6 within the lawful jurisdiction of the gov-  
7 ernment authority seeking the protected  
8 health information;

9 (ii) there is probable cause to believe  
10 that the protected health information being  
11 sought is relevant to a legitimate law en-  
12 forcement inquiry;

13 (iii) the government authority's need  
14 for the information outweighs the privacy  
15 interest of the individual who is the subject  
16 of the information; and

17 (iv) there is reasonable ground to be-  
18 lieve that receipt of notice by the individual  
19 will result in—

20 (I) endangering the life or phys-  
21 ical safety of any individual;

22 (II) flight from prosecution;

23 (III) destruction of or tampering  
24 with evidence or the information being  
25 sought;

1 (IV) intimidation of potential wit-  
2 nesses; or

3 (V) disclosure of the existence or  
4 nature of a confidential law enforce-  
5 ment investigation or grand jury in-  
6 vestigation that is likely to seriously  
7 jeopardize such investigation.

8 (6) INFORMATION IN RESPONSE TO LAW EN-  
9 FORCEMENT INQUIRY.—Protected health informa-  
10 tion about an individual that is disclosed under this  
11 section may not be used in, or disclosed to any per-  
12 son for use in any administrative, civil or criminal  
13 action or investigation directed against the individ-  
14 ual unless the action or investigation arises out of or  
15 is directly related to the law enforcement inquiry for  
16 which the information was obtained.

17 (b) CHALLENGE PROCEDURES FOR LAW ENFORCE-  
18 MENT WARRANTS, SUBPOENAS, AND SUMMONSES.—

19 (1) MOTION TO QUASH.—Within 15 days after  
20 the date of service of a notice of execution of a war-  
21 rant or a copy of a subpoena or summons, of a gov-  
22 ernment authority seeking protected health informa-  
23 tion about an individual under subsection (a), the in-  
24 dividual may file a motion to quash.

1           (2) STANDARD FOR DECISION.—The court shall  
2 grant a motion under paragraph (1) unless the gov-  
3 ernment demonstrates there is probable cause to be-  
4 lieve the protected health information is relevant to  
5 a legitimate law enforcement inquiry being con-  
6 ducted by the government authority and the govern-  
7 ment authority’s need for the information outweighs  
8 the privacy interest of the individual.

9           (3) ATTORNEY’S FEES.—In the case of a mo-  
10 tion brought under paragraph (1) in which the indi-  
11 vidual has substantially prevailed, the court may as-  
12 sess against the government authority reasonable at-  
13 torney’s fees and other litigation costs (including ex-  
14 pert fees) reasonably incurred.

15           (4) NO INTERLOCUTORY APPEAL.—A ruling de-  
16 denying a motion to quash under this section shall not  
17 be deemed to be a final order, and no interlocutory  
18 appeal may be taken therefrom by the individual.

19           (c) EXCEPTIONS.—A health information trustee may  
20 disclose protected health information to a law enforcement  
21 agency if the information is requested for use—

22           (1) in an investigation or prosecution of a  
23 health information trustee;

24           (2) in the identification of a victim or witness  
25 in a law enforcement inquiry; or

1           (3) in connection with the investigation of  
2           criminal activity committed against the trustee or on  
3           premises controlled by the trustee.

4 **SEC. 213. STANDARDS FOR ELECTRONIC DISCLOSURES.**

5           The Secretary shall promulgate standards for disclos-  
6           ing, authorizing and authenticating protected health infor-  
7           mation in electronic form in accordance with this title.

8                           **TITLE III—SANCTIONS**

9                           **Subtitle A—Civil Sanctions**

10 **SEC. 301. CIVIL PENALTY.**

11           (a) VIOLATION.—Any health information trustee who  
12           the Secretary determines has substantially and materially  
13           failed to comply with this Act shall be subject, in addition  
14           to any other penalties that may be prescribed by law, to—

15                   (1) a civil penalty of not more than \$10,000 for  
16                   each such violation, but not to exceed \$50,000 in the  
17                   aggregate for multiple violations; and

18                   (2) a civil penalty of not more than \$250,000  
19                   or exclusion from participation in medicare and med-  
20                   icaid, or any other federally funded health care pro-  
21                   grams, if the Secretary finds that such violations  
22                   have occurred with such frequency as to constitute  
23                   a general business practice.

24           (b) PROCEDURES FOR IMPOSITION OF PENALTIES.—

25           Section 1128A of the Social Security Act, other than sub-

1 sections (a) and (b) and the second sentence of subsection  
2 (f) of that section, shall apply to the imposition of a civil,  
3 monetary, or exclusionary penalty under this section in the  
4 same manner as such provisions apply with respect to the  
5 imposition of a penalty under section 1128A of such Act.

6 **SEC. 302. CIVIL ACTION.**

7 (a) IN GENERAL.—An individual who is aggrieved by  
8 conduct in violation of this title may bring a civil action  
9 to recover—

10 (1) such preliminary and equitable relief as the  
11 court determines to be appropriate;

12 (2) the greater of actual damages or liquidated  
13 damages of \$5,000; and

14 (3) punitive damages.

15 (b) ATTORNEY'S FEES.—In the case of a civil action  
16 brought under subsection (a) in which the individual has  
17 substantially prevailed, the court may assess against the  
18 respondent a reasonable attorney's fee and other litigation  
19 costs and expenses (including expert fees) reasonably in-  
20 curred.

21 (c) LIMITATION.—No action may be commenced  
22 under this section more than 3 years after the date on  
23 which the violation was or should reasonably have been  
24 discovered.

## 1       **Subtitle B—Criminal Sanctions**

### 2       **SEC. 311. WRONGFUL DISCLOSURE OF PROTECTED** 3       **HEALTH INFORMATION.**

4       (a) OFFENSE.—A person who knowingly—

5           (1) obtains protected health information relat-  
6       ing to an individual in violation of this title; or

7           (2) discloses protected health information to an-  
8       other person in violation of this title, shall be pun-  
9       ished as provided in subsection (b).

10      (b) PENALTIES.—A person described in subsection

11   (a) shall—

12           (1) be fined not more than \$50,000, imprisoned  
13       not more than 1 year, or both;

14           (2) if the offense is committed under false pre-  
15       tenses, be fined not more than \$250,000, imprisoned  
16       not more than 5 years, excluded from participation  
17       in medicare and medicaid, or any other federally  
18       funded health care programs, or any combination of  
19       such penalties; and

20           (3) if the offense is committed with intent to  
21       sell, transfer, or use protected health information for  
22       commercial advantage, personal gain, or malicious  
23       harm, be fined not more than \$500,000, imprisoned  
24       not more than 10 years, excluded from participation  
25       in medicare and medicaid, or any other federally

1 funded health care programs, or any combination of  
2 such penalties.

### 3 **TITLE IV—MISCELLANEOUS**

#### 4 **SEC. 401. RELATIONSHIP TO OTHER LAWS.**

5 (a) STATE LAW.—Except as provided in subsections  
6 (b), (c), and (d), this Act preempts State law.

7 (b) PRIVILEGES.—Nothing in this title shall be con-  
8 strued to preempt or modify State common or statutory  
9 law to the extent such law concerns a privilege of a witness  
10 or person in a court of the State. This title shall not be  
11 construed to supersede or modify Federal common or stat-  
12 utory law to the extent such law concerns a privilege of  
13 a witness or person in a court of the United States. Au-  
14 thorizations pursuant to sections 202 and 203 shall not  
15 be construed as a waiver of any such privilege.

16 (c) CERTAIN DUTIES UNDER STATE OR FEDERAL  
17 LAW.—Nothing in this title shall be construed to preempt,  
18 supersede, or modify the operation of—

19 (1) any law that provides for the reporting of  
20 vital statistics such as birth or death information;

21 (2) any law requiring the reporting of abuse or  
22 neglect information about any individual;

23 (3) any State law relating to public or mental  
24 health that prevents or otherwise restricts disclosure

1 of protected health information otherwise allowed  
2 under this title;

3 (4) any law that governs a minor's rights to ac-  
4 cess protected health information;

5 (5) subpart II of part E of title XXVI of the  
6 Public Health Service Act (relating to notifications  
7 of emergency response employees of possible expo-  
8 sure to infectious diseases);

9 (6) any Federal law or regulation governing  
10 confidentiality of alcohol and drug patient records;

11 (7) the Americans With Disabilities Act of  
12 1990; or

13 (8) any Federal or State statute that estab-  
14 lishes a privilege for records used in health profes-  
15 sional peer review activities.

16 **SEC. 402. NO LIABILITY FOR PERMISSIBLE DISCLOSURES.**

17 A health information trustee who makes a disclosure  
18 of protected health information about an individual that  
19 is permitted by this title shall not be liable to the individ-  
20 ual for such disclosure under common law.

21 **SEC. 403. EFFECTIVE DATE.**

22 (a) EFFECTIVE DATE.—This Act shall take effect 12  
23 months after the date of enactment of this Act.

1       (b) REGULATIONS.—The Secretary shall promulgate  
2 regulations implementing this Act not later than 6 months  
3 after the date of enactment of this Act.

○

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S 1360 IS—4