

105TH CONGRESS  
1ST SESSION

# S. 1368

To provide individuals with access to health information of which they are the subject, ensure personal privacy with respect to personal medical records and health care-related information, impose criminal and civil penalties for unauthorized use of personal health information, and to provide for the strong enforcement of these rights.

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## IN THE SENATE OF THE UNITED STATES

NOVEMBER 4, 1997

Mr. LEAHY (for himself and Mr. KENNEDY) 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 provide individuals with access to health information of which they are the subject, ensure personal privacy with respect to personal medical records and health care-related information, impose criminal and civil penalties for unauthorized use of personal health information, and to provide for the strong enforcement of these rights.

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 Information Privacy and Security Act”.

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

- Sec. 1. Short title; table of contents.
- Sec. 2. Findings.
- Sec. 3. Purposes.
- Sec. 4. Definitions.

TITLE I—INDIVIDUAL'S RIGHTS

Subtitle A—Access to Protected Health Information by Subjects of the  
Information

- Sec. 101. Inspection and copying of protected health information.
- Sec. 102. Supplements to protected health information.
- Sec. 103. Notice of privacy practices.

Subtitle B—Establishment of Safeguards

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

TITLE II—RESTRICTIONS ON USE AND DISCLOSURE

Subtitle A—General Restriction

- Sec. 201. General rule regarding use and disclosure.
- Sec. 202. Authorizations for disclosure of protected health information.

Subtitle B—Limited Circumstances Providing for Disclosure Without  
Authorization

- Sec. 211. Emergency circumstances.
- Sec. 212. Public health.
- Sec. 213. Protection and advocacy agencies.
- Sec. 214. Oversight.
- Sec. 215. Disclosure for law enforcement purposes.

Subtitle C—Special Rules Governing Disclosure

- Sec. 221. Next of kin and directory information.
- Sec. 222. Health research.
- Sec. 223. Judicial and administrative purposes.
- Sec. 224. Individual representatives.
- Sec. 225. Prohibition against retaliation.

TITLE III—OFFICE OF HEALTH INFORMATION PRIVACY OF THE  
DEPARTMENT OF HEALTH AND HUMAN SERVICES

Subtitle A—Establishment

- Sec. 301. Establishment.

Subtitle B—Enforcement

CHAPTER 1—CRIMINAL PROVISIONS

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

Sec. 312. Debarment for crimes.

CHAPTER 2—CIVIL SANCTIONS

Sec. 321. Civil penalty.

Sec. 322. Procedures for imposition of penalties.

Sec. 323. Civil action by individuals.

TITLE IV—MISCELLANEOUS

Sec. 401. Relationship to other laws.

Sec. 402. Effective date.

1 **SEC. 2. FINDINGS.**

2 Congress finds that—

3 (1) individuals have a right of privacy with re-  
4 spect to their personal medical information and  
5 records;

6 (2) with respect to information about medical  
7 care and health status, the traditional right of con-  
8 fidentiality (between a health care provider and a  
9 patient) is at risk;

10 (3) an erosion of the right of privacy may re-  
11 duce the willingness of patients to confide in physi-  
12 cians and other practitioners and may inhibit such  
13 patients from seeking care;

14 (4) the use of electronic medical records offers  
15 many potential advantages compared to traditional  
16 paper-based systems if encompassed with strong pri-  
17 vacy safeguards, through the sharing and linking of  
18 medical records electronically which can reduce  
19 costs, improve efficiencies and enhance medical care  
20 while helping to avoid duplicate tests, prevent fraud

1 and protect against unintended dangerous drug  
2 interactions;

3 (5) the European Union has adopted a directive  
4 that provides that electronic medical records can not  
5 be sent from Union member nations to other na-  
6 tions, such as the United States, unless the non-  
7 member country assures the security and confiden-  
8 tiality of medical records under its national laws and  
9 practices;

10 (6) an individual's privacy right means that the  
11 individual's consent is needed to disclose his or her  
12 personally identifiable health information and that  
13 the individual has a right of access to that health in-  
14 formation;

15 (7) any disclosure of personally identifiable  
16 health information should be limited to that infor-  
17 mation or portion of the medical record necessary to  
18 fulfill the immediate and specific purpose of the dis-  
19 closure;

20 (8) an individual's health information is cur-  
21 rently accessible to many people who do not need the  
22 information to provide health care to the individual,  
23 often without the individual's knowledge or consent;

1           (9) in the report of the National Research  
2 Council of March, 1997, the Council concluded  
3 that—

4           (A) with respect to the protection of elec-  
5 tronic medical records, “few penalties exist for  
6 lax security” and that “few controls exist to  
7 prevent such information from being used in  
8 ways that could harm patients or invade their  
9 privacy”;

10          (B) “patients have little control over the  
11 ways in which information about their health is  
12 collected, used, or disseminated”;

13          (C) “[t]he greatest concerns regarding pa-  
14 tient privacy stem from the widespread dissemi-  
15 nation of information throughout the health  
16 care industry and related industries, often with-  
17 out the knowledge or consent of the patients  
18 . . . [i]n many cases, this information can be  
19 used in ways that are perceived as detrimental  
20 to patient privacy and contrary to the interests  
21 of patients. . . .”;

22          (D) consent to release medical information  
23 should be for specified information and pur-  
24 poses and for limited amounts of time after

1           which the medical provider “must obtain new  
2           authorization from the patient”;

3           (E) “health care providers should give pa-  
4           tients the right to request audits of all access  
5           to their electronic medical records and to review  
6           such logs”;

7           (F) with respect to the use of the social se-  
8           curity number as a universal patient identifier,  
9           the “use of the social security number raises  
10          many legitimate privacy concerns”; and

11          (G) a national office of privacy should be  
12          established since “consumers need a mechanism  
13          for learning about their rights and how they  
14          may seek recourse for violations of fair informa-  
15          tion practices, and they need to be protected  
16          from the possibility that their access to care  
17          may be jeopardized by exercising their estab-  
18          lished privacy rights”;

19          (10) medical research often depends on access  
20          to both identifiable and nonidentifiable patient medi-  
21          cal records and medical research is critically impor-  
22          tant to the health and well-being of all Americans;

23          (11) currently, there is technology available  
24          which can ease the process by which identifiable  
25          data can be stripped of all patient identifiers to sup-

1 port the necessary balance between medical research  
2 and privacy protections for individuals;

3 (12) the American Medical Association Council  
4 on Ethical Affairs has concluded that—

5 (A) a patient and a physician “should be  
6 advised about the existence of computerized  
7 data bases in which medical information con-  
8 cerning the patient is stored”;

9 (B) information regarding the existence of  
10 computerized data bases “should be commu-  
11 nicated to the physician and patient prior to the  
12 physician’s release of the medical information to  
13 the entity or entities maintaining the computer  
14 data bases”;

15 (C) a physician and patient “should be no-  
16 tified of the distribution of all reports reflecting  
17 identifiable patient data prior to distribution of  
18 the reports by the computer facility”; and

19 (D) there should be “approval by the pa-  
20 tient and notification of the physician prior to  
21 the release of patient-identifiable clinical and  
22 administrative data to individuals or organiza-  
23 tions external to the medical care environment”;

24 (13)(A) genetic information contains the  
25 uniquely private and personal genetic information of

1 an individual which is rapidly being deciphered and  
2 understood; and

3 (B) research in genetics continues to provide  
4 immense health benefits to individuals and their  
5 families, however, the improper use and unauthor-  
6 ized disclosure of genetic information may cause sig-  
7 nificant social and psychological harm to individuals,  
8 including stigmatization and discrimination;

9 (14) the Supreme Court found in *Jaffee v.*  
10 *Redmond* (116 S.Ct. 1923 (1996)) that—

11 (A) there is an imperative need for con-  
12 fidence and trust between a psychotherapist  
13 and a patient;

14 (B) this trust can only be established by  
15 an assurance of confidentiality; and

16 (C) preservation of such trust and con-  
17 fidentiality serves the public interest by facili-  
18 tating the provision of appropriate treatment  
19 for individuals; and

20 (15) section 264 of the Health Insurance Port-  
21 ability and Accountability Act of 1996 (42 U.S.C.  
22 1320d-2 note) establishes a deadline that Congress  
23 enact legislation, within 36 months after the date of  
24 enactment of such Act, to protect the privacy of per-  
25 sonal health information.

1 **SEC. 3. PURPOSES.**

2 It is the purpose of this Act to—

3 (1) recognize that there is a right to privacy  
4 with respect to health information, including genetic  
5 information, and that this right must be protected;

6 (2) establish an Office of Health Information  
7 Privacy within the Department of Health and  
8 Human Services to protect that right of privacy;

9 (3) provide individuals with—

10 (A) access to health information of which  
11 they are the subject; and

12 (B) the opportunity to challenge the accu-  
13 racy and completeness of such information by  
14 being able to file supplements of such records;

15 (4) provide individuals with the right to limit  
16 the use and disclosure of personally identifiable  
17 health information;

18 (5) create incentives to turn personal health in-  
19 formation into nonidentifiable health information for  
20 oversight, health research, public health, law en-  
21 forcement, judicial, and administrative purposes;

22 (6) establish strong and effective mechanisms  
23 to protect against the unauthorized and inappropri-  
24 ate use of personally identifiable health information  
25 that is created or maintained as part of health care

1 treatment, diagnosis, enrollment, payment, plan ad-  
 2 ministration, testing, or research processes;

3 (7) invoke the sweep of congressional powers,  
 4 including the power to enforce the 14th amendment,  
 5 to regulate commerce, and to abrogate the immunity  
 6 of the States under the 11th amendment, in order  
 7 to address violations of the rights of individuals to  
 8 privacy, to provide access to their medical records,  
 9 and to prevent unauthorized use of personal genetic  
 10 information; and

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

13 **SEC. 4. DEFINITIONS.**

14 In this Act:

15 (1) ADMINISTRATIVE BILLING INFORMATION.—

16 The term “administrative billing information”  
 17 means any of the following forms of protected health  
 18 information:

19 (A) Date of service, policy, patient and  
 20 practitioner or facility identifiers.

21 (B) Diagnostic codes, in accordance with  
 22 medicare billing codes, for which treatment is  
 23 being rendered or requested.

24 (C) Complexity of service codes, indicating  
 25 duration of treatment.

1 (D) Total billed charges.

2 (2) AGENT.—The term “agent” means a person  
3 who represents and acts for another under the con-  
4 tract or relation of agency, or whose function is to  
5 bring about, modify, affect, accept performance of,  
6 or terminate contractual obligations between the  
7 principal and a third person, and includes the em-  
8 ployees of such persons.

9 (3) DISCLOSE.—The term “disclose” means to  
10 release, transfer, permit access to, or otherwise di-  
11 vulge protected health information to any person  
12 other than the individual who is the subject of such  
13 information. Such term includes the initial disclosure  
14 and any subsequent redisclosures of individually  
15 identifiable health care information.

16 (4) EMPLOYER.—The term “employer” means  
17 a person engaged in business affecting commerce  
18 who has employees.

19 (5) HEALTH CARE.—The term “health care”  
20 means—

21 (A) preventive, diagnostic, therapeutic, re-  
22 habilitative, maintenance, or palliative care, in-  
23 cluding appropriate assistance with disease or  
24 symptom management and maintenance, coun-  
25 seling, service, or procedure—

1 (i) with respect to the physical or  
2 mental condition of an individual; or

3 (ii) affecting the structure or function  
4 of the human body or any part of the  
5 human body, including the banking of  
6 blood, sperm, organs, or any other tissue;  
7 and

8 (B) any sale or dispensing of a drug, de-  
9 vice, equipment, or other health care related  
10 item to an individual, or for the use of an indi-  
11 vidual, pursuant to a prescription.

12 (6) HEALTH CARE PROVIDER.—The term  
13 “health care provider” means a person, who with re-  
14 spect to a specific item of protected health informa-  
15 tion, receives, creates, uses, maintains, or discloses  
16 the information while acting in whole or in part in  
17 the capacity of—

18 (A) a person who is licensed, certified, reg-  
19 istered, or otherwise authorized by Federal or  
20 State law to provide an item or service that  
21 constitutes health care in the ordinary course of  
22 business, or practice of a profession;

23 (B) a Federal or State program that di-  
24 rectly provides items or services that constitute  
25 health care to beneficiaries; or

1 (C) an officer or employee of a person de-  
2 scribed in subparagraph (A) or (B) that is en-  
3 gaged in the provision of health care.

4 (7) HEALTH OR LIFE INSURER.—The term  
5 “health or life insurer” means a health insurance is-  
6 suer as defined in section 9805(b)(2) of the Internal  
7 Revenue Code of 1986 or a life insurance company  
8 as defined in section 816 of such Code and includes  
9 the employees of such person.

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

12 (A) performs or oversees the performance  
13 of an assessment, investigation, or prosecution  
14 relating to compliance with legal or fiscal stand-  
15 ards relating to health care fraud or fraudulent  
16 claims regarding health care, health services or  
17 equipment, or related activities and items; and

18 (B) is a public executive branch agency,  
19 acting on behalf of a public executive branch  
20 agency, acting pursuant to a requirement of a  
21 public executive branch agency, or carrying out  
22 activities under a Federal or State law govern-  
23 ing the assessment, evaluation, determination,  
24 investigation, or prosecution described in sub-

1 paragraph (A) and includes the employees of  
2 such person.

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 or arranging for  
8 the provision of health benefits, whether or not fund-  
9 ed through the purchase of insurance. Such term in-  
10 cludes employee welfare benefit plans and group  
11 plans as such plans are defined in sections 3 and  
12 607 of the Employee Retirement Income Security  
13 Act of 1974 (29 U.S.C. 1002 and 1167).

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

18 (A) pursuant to section 222 (relating to  
19 health research); or

20 (B) while acting in whole or in part in the  
21 capacity of an officer or employee or agent of  
22 a person who receives the information described  
23 in subparagraph (A).

24 (11) LAW ENFORCEMENT INQUIRY.—The term  
25 “law enforcement inquiry” means a lawful executive

1 branch investigation or official proceeding inquiring  
2 into a violation of, or failure to comply with, any  
3 criminal or civil statute or any regulation, rule, or  
4 order issued pursuant to such a statute.

5 (12) NONIDENTIFIABLE HEALTH INFORMA-  
6 TION.—The term “nonidentifiable health informa-  
7 tion” means any information that would otherwise  
8 be protected health information except that it does  
9 not reveal the identity of the individual whose health  
10 or health care is the subject of the information and  
11 there is no reasonable basis to believe that the infor-  
12 mation could be used to identify that individual.

13 (13) OFFICE OF HEALTH INFORMATION PRI-  
14 VACY.—The term “Office of Health Information Pri-  
15 vacy” means the Office of Health Information Pri-  
16 vacy established under section 301.

17 (14) PERSON.—The term “person” means a  
18 government, governmental subdivision of an execu-  
19 tive branch agency or authority; corporation; com-  
20 pany; association; firm; partnership; society; estate;  
21 trust; joint venture; individual; individual represent-  
22 ative; tribal government; and any other legal entity.

23 (15) PROTECTED HEALTH INFORMATION.—The  
24 term “protected health information” means any in-  
25 formation, including genetic information, demo-

1 graphic information, and tissue samples collected  
2 from an individual, whether oral or recorded in any  
3 form or medium, that—

4 (A) is created or received by a health care  
5 provider, health researcher, health plan, health  
6 oversight agency, public health authority, em-  
7 ployer, health or life insurer, school or univer-  
8 sity; and

9 (B)(i) relates to the past, present, or fu-  
10 ture physical or mental health or condition of  
11 an individual (including individual cells and  
12 their components), the provision of health care  
13 to an individual, or the past, present, or future  
14 payment for the provision of health care to an  
15 individual; and

16 (ii)(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 (16) PUBLIC HEALTH AUTHORITY.—The term  
21 “public health authority” means an authority or in-  
22 strumentality of the United States, a tribal govern-  
23 ment, a State, or a political subdivision of a State  
24 that is—

1 (A) primarily responsible for public health  
2 matters; and

3 (B) primarily engaged in activities such as  
4 injury reporting, public health surveillance, and  
5 public health investigation or intervention.

6 (17) SCHOOL OR UNIVERSITY.—The term  
7 “school or university” means an institution or place  
8 for instruction or education, including an elementary  
9 school, secondary school, or institution of higher  
10 learning, a college, or an assemblage of colleges unit-  
11 ed under one corporate organization or government.

12 (18) SECRETARY.—The term “Secretary”  
13 means the Secretary of Health and Human Services.

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

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

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

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

7 (a) **RIGHT OF INDIVIDUAL.—**

8 (1) **IN GENERAL.—**A health care provider,  
9 health researcher, health plan, employer, health or  
10 life insurer, school, or university, or the agent of any  
11 such individual or entity, shall permit an individual  
12 who is the subject of protected health information,  
13 or the individual’s designee, to inspect and copy pro-  
14 tected health information concerning the individual,  
15 including records created under sections 102 and  
16 112, that such entity maintains.

17 (2) **PROCEDURES AND FEES.—**An entity de-  
18 scribed in paragraph (1) may set forth appropriate  
19 procedures to be followed for inspection and copying  
20 under such paragraph and may require an individual  
21 to pay fees associated with such inspection and copy-  
22 ing in an amount that is not in excess of the actual  
23 costs of providing such copying. Such fees may not  
24 be assessed where such an assessment would have

1 the effect of prohibiting an individual from gaining  
2 access to the information involved.

3 (b) DEADLINE.—An entity described in subsection  
4 (a) shall comply with a request for inspection or copying  
5 of protected health information under this section not  
6 later than 15 business days after the date on which the  
7 entity receives the request.

8 (c) RULES GOVERNING AGENTS.—An agent of an en-  
9 tity described in subsection (a) shall provide for the in-  
10 spection and copying of protected health information if—

11 (1) the protected health information is retained  
12 by the agent; and

13 (2) the agent has been asked by the entity in-  
14 volved to fulfill the requirements of this section.

15 **SEC. 102. SUPPLEMENTS TO PROTECTED HEALTH INFOR-**  
16 **MATION.**

17 (a) IN GENERAL.—Not later than 45 days after the  
18 date on which a health care provider, health researcher,  
19 health plan, employer, health or life insurer, school, or uni-  
20 versity, or the agent of any such individual or entity, re-  
21 ceives from an individual a request in writing to supple-  
22 ment information, such entity shall—

23 (1) add the supplement requested to the  
24 records;

1           (2) inform the individual of the supplement that  
2           has been added; and

3           (3) make reasonable efforts to inform any per-  
4           son to whom the portion of the unsupplemented in-  
5           formation was previously disclosed, of any nontech-  
6           nical supplement that has been made.

7           (b) REFUSAL TO SUPPLEMENT.—If an entity de-  
8           scribed in subsection (a) declines to make the supplement  
9           requested under such subsection, the entity shall inform  
10          the individual in writing of—

11           (1) the reasons for declining to make the sup-  
12          plement;

13           (2) any procedures for further review of the de-  
14          clining of such supplement; and

15           (3) the individual's right to file with the entity  
16          a concise statement setting forth the requested sup-  
17          plement and the individual's reasons for disagreeing  
18          with the declining entity and the individual's right to  
19          include a copy of this refusal in his or her health  
20          record.

21          (c) STATEMENT OF DISAGREEMENT.—If an individ-  
22          ual has filed a statement of disagreement under subsection  
23          (b)(3), the entity involved, in any subsequent disclosure  
24          of the disputed portion of the information—

1           (1) shall include, at the individual's request, a  
2           copy of the individual's statement; and

3           (2) may include a concise statement of the rea-  
4           sons for not making the requested supplement.

5           (d) RULES GOVERNING AGENTS.—The agent of an  
6           entity described in subsection (a) shall not be required to  
7           make supplements to protected health information, except  
8           where—

9           (1) the protected health information is retained  
10          by the agent; and

11          (2) the agent has been asked by such entity to  
12          fulfill the requirements of this section.

13 **SEC. 103. NOTICE OF PRIVACY PRACTICES.**

14          (a) PREPARATION OF WRITTEN NOTICE.—A health  
15          care provider, health plan, health oversight agency, public  
16          health authority, employer, health researcher, health or  
17          life insurer, school, or university, or the agent of any such  
18          individual or entity, shall prepare a written notice of the  
19          privacy practices of the entity that shall include—

20          (1) the procedures for an individual to author-  
21          ize disclosures of protected health information, and  
22          to object to, modify, and revoke such authorizations;

23          (2) the right of an individual to inspect, copy,  
24          and supplement the protected health information;

1           (3) the right of an individual not to have em-  
2           ployment or the receipt of services conditioned upon  
3           the execution by the individual of an authorization  
4           for disclosure;

5           (4) a description of the categories or types of  
6           employees, by general category or by general job de-  
7           scription, who have access to or use of protected  
8           health information within the entity;

9           (5) a simple, concise description of any infor-  
10          mation systems used to store or transmit protected  
11          health information, including a description of any  
12          linkages made with other electronic systems or  
13          databases outside the entity;

14          (6) the right of the individual to request seg-  
15          regation of protected health information, and to re-  
16          strict the use of such information by employees,  
17          agents, and contractors of an entity;

18          (7) the circumstances under which the informa-  
19          tion may be used or disclosed without an authoriza-  
20          tion executed by the individual; and

21          (8) a statement that an individual may self pay  
22          for health care in order that no identifying informa-  
23          tion be disclosed to anyone other than the health  
24          care provider unless such disclosure is related to the  
25          medical treatment or is authorized by mandatory re-

1       porting requirements or other similar information  
2       collection duties as required by law.

3       (b) PROVISION AND POSTING OF WRITTEN NO-  
4       TICE.—

5               (1) PROVISION.—An entity described in sub-  
6       section (a) shall provide a copy of the written notice  
7       of privacy practices required under such sub-  
8       section—

9                       (A) at the time an authorization is sought  
10                      for disclosure of protected health information;  
11                      and

12                     (B) upon the request of an individual.

13               (2) POSTING.—An entity described in sub-  
14       section (a) shall post, in a clear and conspicuous  
15       manner, a brief summary of the privacy practices of  
16       the entity.

17       (c) MODEL NOTICE.—The director of the Office of  
18       Health Information Privacy, after notice and opportunity  
19       for public comment, shall develop and disseminate model  
20       notices of privacy practices, and model summary notices  
21       for posting, for use under this section.

1           **Subtitle B—Establishment of**  
2                           **Safeguards**

3 **SEC. 111. ESTABLISHMENT OF SAFEGUARDS.**

4           (a) IN GENERAL.—A health care provider, health  
5 plan, health oversight agency, public health authority, em-  
6 ployer, health researcher, law enforcement official, health  
7 or life insurer, school, or university, or the agent of any  
8 such individual or entity, shall establish and maintain ap-  
9 propriate administrative, organizational, technical, and  
10 physical safeguards and procedures to ensure the con-  
11 fidentiality, security, accuracy, and integrity of protected  
12 health information created, received, obtained, main-  
13 tained, used, transmitted, or disposed of by such entity.

14           (b) MODEL GUIDELINES.—The director of the Office  
15 of Health Information Privacy, after notice and oppor-  
16 tunity for public comment, shall develop and disseminate  
17 model guidelines for the establishment of safeguards for  
18 use under this section such as, where appropriate, individ-  
19 ual authentication of uses of computer systems, access  
20 controls, audit trails, physical security, protection of re-  
21 mote access points and protection of external electronic  
22 communications, periodic security assessments, incident  
23 internal reports in sanctions, and such other systems as  
24 new technologies and problems develop. The director shall

1 update and disseminate such new guidelines, as appro-  
2 priate to take advantage of new technologies.

3 **SEC. 112. ACCOUNTING FOR DISCLOSURES.**

4 (a) IN GENERAL.—

5 (1) RECORD OF DISCLOSURE.—A health care  
6 provider, health plan, health oversight agency, public  
7 health authority, employer, health researcher, law  
8 enforcement official, health or life insurer, school, or  
9 university, or the agent of any such individual or en-  
10 tity, shall establish and maintain, with respect to  
11 any protected health information disclosure that is  
12 not related to payment or treatment, a record of the  
13 disclosure in accordance with regulations issued by  
14 the director of the Office of Health Information Pri-  
15 vacy.

16 (2) AGENT.—An agent shall maintain a record  
17 of disclosures made pursuant to subtitles B and C  
18 of title III.

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

22 (c) ELECTRONIC RECORDS.—A health care provider,  
23 health plan, health oversight agency, public health author-  
24 ity, employer, health researcher, law enforcement official,  
25 health or life insurer, school, or university, or the agent

1 of any such individual or entity, shall, to the extent prac-  
2 ticable, maintain an electronic record, or the ability to gen-  
3 erate such a record, concerning each attempt that is made  
4 by such an entity, or by any other person, whether author-  
5 ized or unauthorized, successful or unsuccessful, to access  
6 protected health information maintained by such entity in  
7 electronic form. The record shall include the identity of  
8 the specific individual attempting to gain such access, or  
9 a way to identify that individual, and other appropriate  
10 information, and information sufficient to identify the in-  
11 formation sought.

12 **TITLE II—RESTRICTIONS ON**  
13 **USE AND DISCLOSURE**

14 **Subtitle A—General Restriction**

15 **SEC. 201. GENERAL RULE REGARDING USE AND DISCLO-**  
16 **SURE.**

17 A health care provider, health plan, health oversight  
18 agency, public health authority, employer, health re-  
19 searcher, law enforcement official, health or life insurer,  
20 school, or university, or the agent of any such individual  
21 or entity, may not disclose protected health information  
22 except as authorized under this title.

1 **SEC. 202. AUTHORIZATIONS FOR DISCLOSURE OF PRO-**  
2 **TECTED HEALTH INFORMATION.**

3 (a) WRITTEN AUTHORIZATIONS.—A health care pro-  
4 vider, health plan, health oversight agency, public health  
5 authority, employer, health researcher, health or life in-  
6 surer, school, or university, or the agent of any such indi-  
7 vidual or entity, may disclose protected health information  
8 pursuant to an authorization executed by the individual  
9 who is the subject of the information that meets the re-  
10 quirements of subsection (b).

11 (b) REQUIREMENTS FOR INDIVIDUAL AUTHORIZA-  
12 TION.—To be valid, an authorization to disclose individ-  
13 ually identifiable health care information shall—

14 (1) identify the type of person (by title, general  
15 job description, or other functional description) or  
16 entity authorized to disclose protected health infor-  
17 mation;

18 (2) describe the nature of the health care infor-  
19 mation to be disclosed;

20 (3) identify the type of person or entity (includ-  
21 ing identification made with respect to employees  
22 through use of a job description, title, or other func-  
23 tional description) to whom the information is to be  
24 disclosed, including individuals employed by or oper-  
25 ating within the entity;

26 (4) describe the purpose of the disclosure;

1           (5) permit an individual to indicate that a par-  
2           ticular person or entity listed on the authorization is  
3           not authorized to receive protected health informa-  
4           tion concerning the individual, except that a physi-  
5           cian directly responsible for providing necessary  
6           medical care, and those directly assisting such physi-  
7           cian, shall be permitted access to files related to pro-  
8           viding that medical care;

9           (6) provide the means by which an individual  
10          may indicate that some of the individual's protected  
11          health information should be segregated;

12          (7) permit an individual to indicate that pro-  
13          tected health information, other than administrative  
14          billing information, shall not be transmitted outside  
15          the entity in a computerized, digital, optical, or  
16          other electronic format;

17          (8) be subject to revocation by the individual  
18          and indicate that the authorization is valid until rev-  
19          ocation by the individual or until an event or date  
20          specified; and

21          (9)(A) be either—

22                  (i) in writing, dated, and signed by the in-  
23                  dividual; or

1 (ii) in electronic form, dated and authenti-  
2 cated by the individual using a unique identi-  
3 fier; and

4 (B) not have been revoked under paragraph (8).

5 (c) LIMITATION ON AUTHORIZATIONS.—

6 (1) IN GENERAL.—Subject to paragraphs (3)  
7 and (4), an entity described in subsection (a) that  
8 seeks an authorization under such subsection may  
9 not condition the delivery of treatment or payment  
10 for services on the receipt of an authorization.

11 (2) AUTHORIZATION FOR PAYMENT PUR-  
12 POSES.—An entity described in subsection (a) that  
13 seeks an authorization under such subsection may  
14 not condition delivery of health care or payment for  
15 services upon receipt of an authorization to link, ag-  
16 gregate, match, index or associate protected health  
17 information contained within a computerized, digital,  
18 optical or other electronic format with other such in-  
19 formation held by another entity.

20 (3) RIGHT TO REQUIRE SELF PAYMENT.—If an  
21 individual has refused to provide an authorization of  
22 disclosure of administrative billing information to a  
23 person or entity and such authorization is necessary  
24 for a health care provider to receive payment for  
25 services delivered, the person or entity seeking the

1 authorization may require the individual to self-pay  
2 for the services.

3 (4) AUTHORIZATION FOR TREATMENT PUR-  
4 POSES.—If a health care provider that is seeking an  
5 authorization for disclosure of an individual’s pro-  
6 tected health information believes that the disclosure  
7 of such information is necessary so as not to endan-  
8 ger the health or treatment of the individual, the  
9 health care provider may condition the provision of  
10 services upon the execution of the authorization by  
11 the individual.

12 (d) MODEL AUTHORIZATIONS.—The Secretary, after  
13 notice and opportunity for public comment, shall develop  
14 and disseminate model written authorizations of the type  
15 described in subsection (a) and model statements of the  
16 limitations on authorizations. Any authorization obtained  
17 on a model authorization form developed by the Secretary  
18 pursuant to the preceding sentence shall be deemed to  
19 meet the authorization requirements of this section.

20 (e) GENERAL RULES APPLYING TO AUTHORIZATIONS  
21 FOR DISCLOSURE.—

22 (1) SCOPE OF DISCLOSURE.—The disclosure of  
23 protected health information under an authorization  
24 provided under this section shall be limited to the  
25 minimum amount of information necessary to ac-

1        accomplish the purpose for which the authorization  
2        was executed.

3            (2) USE OF DISCLOSURE FOR PURPOSE  
4        ONLY.—A recipient of information pursuant to an  
5        authorization under this section may use or disclose  
6        such information solely to carry out the purpose for  
7        which the information was authorized for release.

8            (3) NO GENERAL REQUIREMENT TO DIS-  
9        CLOSE.—Nothing in this section permitting the dis-  
10       closure of protected health information shall be con-  
11       strued to require such disclosure.

12           (4) IDENTIFICATION OF DISCLOSED INFORMA-  
13        TION AS PROTECTED HEALTH INFORMATION.—Pro-  
14        tected health information disclosed pursuant to an  
15        authorization under this section shall be clearly iden-  
16        tified as protected health information that is subject  
17        to this Act.

18        (f) SEGREGATION OF FILES.—An entity described in  
19        subsection (a) shall comply with the request of an individ-  
20        ual who is the subject of protected health information to—

21            (1) segregate any type or amount of protected  
22        health information, other than administrative billing  
23        information, held by the entity;

24            (2) limit the use or disclosure of the segregated  
25        health information within the entity to those persons

1 specifically designated by the subject of the pro-  
2 tected health information; and

3 (3) maintain such information outside any  
4 networked computerized, digital, optical or other  
5 electronic system.

6 (g) REVOCATION OF AUTHORIZATION.—

7 (1) IN GENERAL.—An individual may in writing  
8 revoke or amend an authorization under this section  
9 at any time, unless the disclosure that is the subject  
10 of the authorization is required to effectuate pay-  
11 ment for health care that has been provided to the  
12 individual.

13 (2) HEALTH PLANS.—With respect to a health  
14 plan, the authorization of an individual is deemed to  
15 be revoked at the time of the cancellation or non-re-  
16 newal of enrollment in the health plan, except as  
17 may be necessary to complete plan administration  
18 and payment requirements related to the individual's  
19 period of enrollment.

20 (3) ACTIONS.—An individual may not maintain  
21 an action against a person for disclosure of person-  
22 ally identifiable health information—

23 (A) if the disclosure was made based on a  
24 good faith reliance on the individual's author-  
25 ization at the time disclosure was made;

1 (B) in a case in which the authorization is  
2 revoked, if the disclosing entity had no actual  
3 or constructive notice of the revocation; or

4 (C) if the disclosure was for the purpose of  
5 protecting another individual from imminent  
6 physical harm, if authorized under section 211.

7 (h) RECORD OF INDIVIDUAL'S AUTHORIZATIONS AND  
8 REVOCATIONS.—Each person collecting or storing person-  
9 ally identifiable health information shall maintain a record  
10 for a period of 7 years of each authorization of an individ-  
11 ual and any revocation thereof, and such record shall be-  
12 come part of the personally identifiable health information  
13 concerning such individual.

14 (i) NO WAIVER.— Except as provided for in this Act,  
15 an authorization to disclose personally identifiable health  
16 information by an individual shall not be construed as a  
17 waiver of any rights that the individual has under other  
18 Federal or State laws, the rules of evidence, or common  
19 law.

20 (j) RULE OF CONSTRUCTION.—Except as provided in  
21 subsection (a), nothing in this section shall be construed  
22 to prevent the electronic or computerized exchange of ad-  
23 ministrative billing information for the purpose of a claims  
24 payment.

25 (k) DEFINITION.—For purposes of this section—

1           (1) the term “segregate” means to place a des-  
2           ignated subset of protected health information in a  
3           location or computer file that is separate from the  
4           location or computer file used to store general pro-  
5           tected health information and where access to or use  
6           of any information so segregated may be effectively  
7           limited to those individuals who are authorized to  
8           access or use such information; and

9           (2) the terms “signed” refers to both signatures  
10          in ink and electronic signatures, and “written” re-  
11          fers to both paper and computerized formats.

12 **Subtitle B—Limited Circumstances**  
13 **Providing for Disclosure With-**  
14 **out Authorization**

15 **SEC. 211. EMERGENCY CIRCUMSTANCES.**

16          (a) GENERAL RULE.—In the event of a threat of im-  
17          minent physical or mental harm to the subject of protected  
18          health information, any person may, in order to allay or  
19          remedy such threat, disclose protected health information  
20          about such subject to a health care practitioner, health  
21          care facility, law enforcement authority, or emergency  
22          medical personnel to protect the health or safety of such  
23          subject.

24          (b) HARM TO OTHERS.—In the event of a threat of  
25          harm to an individual other than the subject of protected

1 health information, any person may disclose protected  
2 health information about such subject where—

3           (1) there is an identifiable threat of serious in-  
4 jury or death to an identifiable individual or group  
5 of individuals;

6           (2) the subject of the protected health informa-  
7 tion has the ability to carry out such threat; and

8           (3) the release of such information is necessary  
9 to prevent or significantly reduce the possibility of  
10 such threat.

11 (c) LIMITATIONS.—

12           (1) SCOPE OF DISCLOSURE.—Every disclosure  
13 of protected health information under this section  
14 shall be limited to the minimum amount of informa-  
15 tion necessary to achieve the purposes of this sec-  
16 tion.

17           (2) USE OR DISCLOSURE FOR PURPOSE  
18 ONLY.—A recipient of information pursuant to this  
19 section may use or disclose such information solely  
20 to carry out the purposes of this section.

21           (3) IDENTIFICATION OF DISCLOSED INFORMA-  
22 TION AS PROTECTED HEALTH INFORMATION.—Pro-  
23 tected health information disclosed under this sec-  
24 tion must be clearly identified as protected health in-  
25 formation that is subject to this Act.

1 **SEC. 212. PUBLIC HEALTH.**

2 (a) GENERAL RULE.—A health care provider, health  
3 plan, public health authority, health researcher, employer,  
4 law enforcement official, health or life insurer, school or  
5 university, or the agent of any such individual or entity,  
6 may disclose protected health information concerning an  
7 individual to a public health authority where—

8 (1) there is a specific nexus between the indi-  
9 vidual's identity and a threat of a specific disease,  
10 death, or injury to any individual or to the public  
11 health; and

12 (2) the individual's identity would allow such  
13 public health authority to prevent or significantly re-  
14 duce the possibility of injury or death to any individ-  
15 ual or the public health, such as the creation and  
16 use of disease registries established under Federal or  
17 State law.

18 (b) EXCEPTION.—An entity described in subsection  
19 (a) shall not be liable for the disclosure of protected health  
20 information—

21 (1) to a public health authority based upon a  
22 good faith belief and credible representation made by  
23 such authority that such information was required to  
24 protect an individual or the public health from a  
25 threat of a specific disease, injury, or death; or

1           (2) if such disclosure is made pursuant to Fed-  
2           eral or state laws which are designed to protect the  
3           public health or safety.

4 **SEC. 213. PROTECTION AND ADVOCACY AGENCIES.**

5           (a) GENERAL RULE.—Any person who creates or re-  
6           ceives protected health information under this title may  
7           disclose protected health information to an agency charged  
8           by law to protect the health and safety of individuals when  
9           such agency can establish that there is probable cause to  
10          believe that an individual who is the subject of the pro-  
11          tected health information is vulnerable to abuse or neglect  
12          by an entity providing health or social services to such in-  
13          dividual.

14          (b) LIMITATIONS.—

15                (1) SCOPE OF DISCLOSURE.—Every disclosure  
16                of protected health information under this section  
17                shall be limited to the minimum amount of informa-  
18                tion necessary to achieve the purposes of this sec-  
19                tion.

20                (2) USE OR DISCLOSURE FOR PURPOSE  
21                ONLY.—A recipient of information pursuant to this  
22                section may use or disclose such information solely  
23                to achieve the purposes of this section.

24                (3) IDENTIFICATION OF DISCLOSED INFORMA-  
25                TION AS PROTECTED HEALTH INFORMATION.—Pro-

1        tected health information disclosed under this sec-  
2        tion must be clearly identified as protected health in-  
3        formation that is subject to this Act.

4        **SEC. 214. OVERSIGHT.**

5        (a) GENERAL RULE.—A health care provider, health  
6        plan, public health authority, health researcher, employer,  
7        law enforcement official, health or life insurer, school or  
8        university, or the agent of any such individual or entity,  
9        may disclose protected health information concerning an  
10       individual to a health oversight agency to enable the agen-  
11       cy to perform a health oversight function authorized by  
12       law only if the agency—

13                (1) does not record the name, social security  
14                number, or other identifying information of the indi-  
15                vidual from patient or client files;

16                (2) identifies the individual in all workpapers  
17                and electronic records by either relying upon a unit  
18                record number contained in the file or by using an-  
19                other formula to scramble or otherwise safeguard  
20                the identifying information; and

21                (3) does not remove protected health informa-  
22                tion from the premises, custody or control of such  
23                entity.

24        (b) NONIDENTIFIABLE INFORMATION.—An entity de-  
25        scribed in subsection (a) may disclose health information

1 concerning an individual to a health oversight agency to  
2 perform a health oversight function authorized by law  
3 when any information that could reasonably be expected  
4 to identify the individual has been removed or concealed.

5 (c) PROHIBITION IN USE IN ACTION AGAINST INDI-  
6 VIDUALS.—Protected health information about an individ-  
7 ual that is disclosed under this section may not be used  
8 in, or disclosed to any person for use in, an administrative,  
9 civil, or criminal action or investigation directed against  
10 the individual.

11 (d) AUTHORIZATION BY A SUPERVISOR.—For pur-  
12 poses of this section, the individual with authority to au-  
13 thorize the oversight function involved shall provide to the  
14 entity described in subsections (a) or (b) a statement that  
15 the protected health information is being sought for a le-  
16 gally authorized oversight function.

17 (e) LIMITATIONS.—

18 (1) SCOPE OF DISCLOSURE.—Every disclosure  
19 of protected health information under this section  
20 shall be limited to the minimum amount of informa-  
21 tion necessary to achieve the purposes of this sec-  
22 tion.

23 (2) USE OF DISCLOSURE FOR PURPOSE  
24 ONLY.—A recipient of information pursuant to this

1 section may use or disclose such information solely  
2 to achieve the purposes of this section.

3 (3) NO GENERAL REQUIREMENT TO DIS-  
4 CLOSE.—Nothing in this section permitting the dis-  
5 closure of protected health information shall be con-  
6 strued to require such disclosure.

7 (4) IDENTIFICATION OF DISCLOSED INFORMA-  
8 TION AS PROTECTED HEALTH INFORMATION.—Pro-  
9 tected health information disclosed under this sec-  
10 tion must be clearly identified as protected health in-  
11 formation that is subject to this Act.

12 **SEC. 215. DISCLOSURE FOR LAW ENFORCEMENT PUR-**  
13 **POSES.**

14 (a) LAW ENFORCEMENT ACCESS TO PROTECTED  
15 HEALTH INFORMATION.—A health care provider, health  
16 researcher, health plan, health oversight agency, employer,  
17 health or life insurer, school, university, or the agent of  
18 any such individual or entity, or person who receives pro-  
19 tected health information pursuant to section 211, may  
20 disclose protected health information to a law enforcement  
21 authority only if the disclosure is made pursuant to a  
22 court order issued by a court of competent jurisdiction in  
23 accordance with subsections (b) and (c) or otherwise or-  
24 dered by a Court of competent jurisdiction.

1 (b) COURT ORDERS FOR ACCESS TO PROTECTED  
2 HEALTH INFORMATION.—A court order for the disclosure  
3 of protected health information under subsection (a) may  
4 be issued only if the law enforcement authority involved  
5 submits a written application upon oath or affirmation  
6 and demonstrates by clear and convincing evidence that—

7 (1) the protected health information sought is  
8 necessary to a legitimate law enforcement inquiry  
9 into a particular violation of criminal law being con-  
10 ducted by the authority;

11 (2) the investigative or evidentiary needs of the  
12 law enforcement authority cannot be satisfied by  
13 nonidentifiable health information or by any other  
14 information; and

15 (3) the law enforcement need for the informa-  
16 tion outweighs the privacy interest of the individual  
17 to whom the information pertains.

18 (c) NOTICE.—

19 (1) IN GENERAL.—Except as provided in para-  
20 graph (2), no order for the disclosure of protected  
21 health information about an individual may be is-  
22 sued by a court under this section unless notice of  
23 the application for the order has been served on the  
24 individual who is the subject of the information in-

1       involved and the individual has been afforded an op-  
2       portunity to oppose the issuance of the order.

3               (2) NOTICE NOT REQUIRED.—An order for the  
4       disclosure of protected health information about an  
5       individual may be issued without notice to the indi-  
6       vidual if the court finds, by clear and convincing evi-  
7       dence, that notice would be impractical because—

8                       (A) the name and address of the individual  
9       are unknown; or

10                      (B) notice would risk destruction or un-  
11       availability of the evidence.

12       (d) CONDITIONS.—Upon the granting of an order for  
13       disclosure of protected health information under this sec-  
14       tion, the court shall impose appropriate safeguards to en-  
15       sure the confidentiality of such information and to protect  
16       against unauthorized or improper use or disclosure.

17       (e) LIMITATION ON USE AND DISCLOSURE FOR  
18       OTHER LAW ENFORCEMENT INQUIRIES.—Protected  
19       health information about an individual that is disclosed  
20       under this section may not be used in, or disclosed to any  
21       person for use in, any administrative, civil, or criminal ac-  
22       tion or investigation directed against the individual, unless  
23       the action or investigation arises out of, or is directly re-  
24       lated to, the law enforcement inquiry for which the infor-  
25       mation was obtained.

1 (f) DESTRUCTION OR RETURN OF INFORMATION.—

2 When the matter or need for which protected health infor-  
3 mation was disclosed to a law enforcement agency or  
4 grand jury has concluded, including any derivative matters  
5 arising from such matter or need, the law enforcement  
6 agency or grand jury shall either destroy the protected  
7 health information, or return it to the person from whom  
8 it was obtained.

9 (g) REDACTIONS.—To the extent practicable, and  
10 consistent with the requirements of due process, a law en-  
11 forcement agency shall redact personally identifying infor-  
12 mation from protected health information prior to the  
13 public disclosure of such protected information in a judi-  
14 cial or administrative proceeding.

15 (h) LIMITATIONS.—

16 (1) SCOPE OF DISCLOSURE.—Every disclosure  
17 of protected health information under this section  
18 shall be limited to the minimum amount of informa-  
19 tion necessary to fulfill the purposes of this section.

20 (2) USE OR DISCLOSURE FOR PURPOSE  
21 ONLY.—A recipient of information pursuant to this  
22 section may use or disclose such information solely  
23 to fulfill the purposes of this section.

24 (3) IDENTIFICATION OF DISCLOSED INFORMA-  
25 TION AS PROTECTED HEALTH INFORMATION.—Pro-

1        tected health information disclosed under this sec-  
 2        tion must be clearly identified as protected health in-  
 3        formation that is subject to this Act.

4        (i) EXCEPTION.—This section shall not be construed  
 5        to limit or restrict the ability of law enforcement authori-  
 6        ties to gain information while in hot pursuit of a suspect  
 7        or if other exigent circumstances exist.

## 8                    **Subtitle C—Special Rules** 9                    **Governing Disclosure**

### 10 **SEC. 221. NEXT OF KIN AND DIRECTORY INFORMATION.**

11        (a) NEXT OF KIN.—A health care provider, or a per-  
 12        son who receives protected health information under sec-  
 13        tion 211, may not disclose protected health information  
 14        regarding an individual to the individual’s next of kin, or  
 15        to another person whom the individual has identified, un-  
 16        less at the time of the treatment of the individual—

17                    (1) the individual who is the subject of the in-  
 18        formation—

19                    (A) has been notified of the individual’s  
 20        right to object to such disclosure and the indi-  
 21        vidual has not objected to the disclosure; or

22                    (B) is in a physical or mental condition  
 23        such that the individual is not capable of object-  
 24        ing, and there are no prior indications that the  
 25        individual would object; and

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

3 (b) DIRECTORY INFORMATION.—

4           (1) DISCLOSURE.—

5           (A) IN GENERAL.—Except as provided in  
6 paragraph (2), an entity described in subsection  
7 (a) may not disclose the information described  
8 in subparagraph (B) to any person unless, at  
9 the time of the admission of the individual who  
10 is the subject of the information to a facility,  
11 the individual—

12           (i) has been notified of the individ-  
13 ual's right to object and the individual has  
14 not objected to the disclosure; or

15           (ii) is in a physical or mental condi-  
16 tion such that the individual is not capable  
17 of objecting and there are no prior indica-  
18 tions that the individual would object.

19           (B) INFORMATION.—Information described  
20 in this subparagraph is information that con-  
21 sists only of 1 or more of the following items:

22           (i) The name of the individual who is  
23 the subject of the information.

24           (ii) The general health status of the  
25 individual, described as critical, poor, fair,

1                   stable, or satisfactory or in terms denoting  
2                   similar conditions.

3                   (iii) The location of the individual on  
4                   premises controlled by a provider.

5                   (2) EXCEPTION.—

6                   (A) LOCATION.—Paragraph (1)(B)(iii)  
7                   shall not apply if disclosure of the location of  
8                   the individual would reveal specific information  
9                   about the physical or mental condition of the  
10                  individual, unless the individual expressly au-  
11                  thorizes such disclosure.

12                  (B) DIRECTORY OR NEXT OF KIN INFOR-  
13                  MATION.—A disclosure may not be made under  
14                  this section if the health care provider involved  
15                  has reason to believe that the disclosure of di-  
16                  rectory or next of kin information could lead to  
17                  the physical or mental harm of the individual,  
18                  unless the individual expressly authorizes such  
19                  disclosure.

20                  (c) IDENTIFICATION OF DECEASED INDIVIDUAL.—  
21                  An entity described in subsection (a) may disclose pro-  
22                  tected health information if such disclosure is necessary  
23                  to assist in the identification of a deceased individual.

24                  (d) RIGHTS OF MINORS.—

1           (1) INDIVIDUALS WHO ARE 18 OR LEGALLY CA-  
2 PABLE.—In the case of an individual—

3           (A) who is 18 years of age or older, all  
4 rights of the individual shall be exercised by the  
5 individual; or

6           (B) who, acting alone, can obtain a type of  
7 health care without violating any applicable law,  
8 and who has sought such care, the individual  
9 shall exercise all rights of an individual under  
10 this title with respect to protected health infor-  
11 mation relating to such health care.

12          (2) INDIVIDUALS UNDER 18.—Except as pro-  
13 vided in subparagraph (1)(B) of this subsection, in  
14 the case of an individual who is—

15          (A) under 14 years of age, all of the indi-  
16 vidual's rights under this title shall be exercised  
17 through the parent or legal guardian; or

18          (B) 14 through 17 years of age, the rights  
19 of inspection and supplementation, and the  
20 right to authorize use and disclosure of pro-  
21 tected health information of the individual shall  
22 be exercised by the individual, or by the parent  
23 or legal guardian of the individual.

1 (e) GENERAL RULES APPLYING TO DISCLOSURES OF  
2 PROTECTED HEALTH INFORMATION WITH RESPECT TO  
3 NEXT OF KIN AND DIRECTORY INFORMATION.—

4 (1) SCOPE OF DISCLOSURE.—Every disclosure  
5 of protected health information under this section  
6 shall be limited to the minimum amount of informa-  
7 tion necessary to achieve the purposes of this sec-  
8 tion.

9 (2) NO GENERAL REQUIREMENT TO DIS-  
10 CLOSE.—Nothing in this section permitting the dis-  
11 closure of protected health information shall be con-  
12 strued to require such disclosure.

13 **SEC. 222. HEALTH RESEARCH.**

14 (a) IN GENERAL.—The requirements and protections  
15 provided for under part 46 of title 45, Code of Federal  
16 Regulations (as in effect on the date of enactment of this  
17 Act), shall apply to research conducted by all research fa-  
18 cilities using personally identifiable health information.  
19 The Secretary shall promulgate regulations to implement  
20 this subsection through notice and comment rulemaking.

21 (b) EVALUATION.—Not later than 1 year after the  
22 date of enactment of this Act, the Secretary shall prepare  
23 and submit to Congress detailed recommendations on  
24 whether written informed consent should be required, and

1 if so, under what circumstances, before personally identifi-  
2 able data can be used for medical research.

3 (c) RECOMMENDATIONS.—The recommendations re-  
4 quired to be submitted under subsection (b) shall in-  
5 clude—

6 (1) a detailed explanation of current institu-  
7 tional review board practices, including under what  
8 circumstances informed consent is being waived and  
9 the extent to which the privacy of individuals is  
10 taken into account as a factor before allowing waiv-  
11 ers;

12 (2) a summary of how technology could be used  
13 to strip identifying data for the purposes of re-  
14 search;

15 (3) an analysis of the risks and benefits of re-  
16 quiring informed consent versus the waiving in-  
17 formed consent; and

18 (4) an analysis of the risks and benefits of  
19 using protected health information for research pur-  
20 poses other than the health research project for  
21 which such information was obtained.

22 (d) COMPLIANCE WITH DEADLINE.—Notwithstand-  
23 ing any other provision of law, if the Secretary does not  
24 submit the recommendations to Congress by the date de-  
25 scribed in subsection (b), the authority of the Secretary

1 to permit the conduct of medical research using personally  
2 identifiable data without written informed consent shall be  
3 terminated.

4 (e) CONSULTATION.—In carrying out this section, the  
5 Secretary shall consult with individuals who have distin-  
6 guished themselves in the fields of health research, pri-  
7 vacy, related technology, consumer interests in health in-  
8 formation, health data standards, and the provision of  
9 health services.

10 (f) CONGRESSIONAL NOTICE.—Not later than 6  
11 months after the date on which the Secretary submits to  
12 Congress the recommendations required under subsection  
13 (b), the Secretary shall propose to implement such rec-  
14 ommendations through notice and comment rulemaking  
15 and shall advise Congress of such proposal.

16 (g) TERMINATION OF INCONSISTENT AUTHORITY.—  
17 Notwithstanding any other provision of law, if the Sec-  
18 retary determines that prior written informed consent is  
19 appropriate for some or all research using personally iden-  
20 tifiable health information, the authority of the Secretary  
21 to promulgate regulations inconsistent with that deter-  
22 mination shall be terminated 6 months after the date on  
23 which such determination is made pursuant to this Act.

24 (h) OTHER REQUIREMENTS.—

1           (1) OBLIGATIONS OF THE RECIPIENT.—A per-  
2           son who receives protected health information pursu-  
3           ant to this section—

4                   (A) shall remove or destroy, at the earliest  
5                   opportunity consistent with the purposes of the  
6                   project involved, information that would enable  
7                   an individual to be identified, unless—

8                           (i) an institutional review board has  
9                           determined that there is a health or re-  
10                          search justification for the retention of  
11                          such identifiers; and

12                           (ii) there is an adequate plan to pro-  
13                          tect the identifiers from disclosure consist-  
14                          ent with this section; and

15           (2) PERIODIC REVIEW AND TECHNICAL ASSIST-  
16           ANCE.—

17                   (A) INSTITUTIONAL REVIEW BOARD.—Any  
18                   institutional review board that authorizes re-  
19                   search under this section shall provide the Sec-  
20                   retary with the names and addresses of the in-  
21                   stitutional review board members.

22                   (B) TECHNICAL ASSISTANCE.—The Sec-  
23                   retary may provide technical assistance to insti-  
24                   tutional review boards described in this sub-  
25                   section.

1 (C) MONITORING.—The Secretary shall pe-  
2 riodically monitor institutional review boards  
3 described in this subsection.

4 (D) REPORTS.—Not later than 3 years  
5 after the date of enactment of this Act, the Sec-  
6 retary shall report to Congress regarding the  
7 activities of institutional review boards de-  
8 scribed in this subsection.

9 (i) LIMITATION.—Nothing in this section shall be  
10 construed to permit personally identifiable health informa-  
11 tion that is received by a researcher under this section  
12 to be accessed for purposes other than research or as au-  
13 thorized by the individual.

14 **SEC. 223. JUDICIAL AND ADMINISTRATIVE PURPOSES.**

15 (a) IN GENERAL.—A health care provider, health  
16 plan, health oversight agency, employer, insurer, health or  
17 life insurer, school or university, or the agent of any such  
18 individual or entity, or person who receives protected  
19 health information under section 211, may disclose pro-  
20 tected health information—

21 (1) pursuant to the standards and procedures  
22 established in the Federal Rules of Civil Procedure,  
23 the Federal Rules of Criminal Procedure, or com-  
24 parable rules of other courts or administrative agen-  
25 cies, in connection with litigation or proceedings to

1       which the individual who is the subject of the infor-  
2       mation is a party and in which the individual has  
3       placed his or her physical or mental condition at  
4       issue;

5               (2) to a court, and to others ordered by the  
6       court, if in response to a court order issued by a  
7       court of competent jurisdiction in accordance with  
8       subsections (b) and (c); or

9               (3) if necessary to present to a court an appli-  
10      cation regarding the provision of treatment of an in-  
11      dividual or the appointment of a guardian pursuant  
12      to a law requiring the reporting of specific medical  
13      information to law enforcement authorities.

14      (b) COURT ORDERS FOR ACCESS TO PROTECTED  
15      HEALTH INFORMATION.—A court order for the disclosure  
16      of protected health information under subsection (a) may  
17      be issued only if the person seeking disclosure submits a  
18      written application upon oath or affirmation and dem-  
19      onstrates by clear and convincing evidence that—

20               (1) the protected health information sought is  
21      necessary for the adjudication of a material fact in  
22      dispute in a civil or criminal proceeding;

23               (2) the adjudicative need cannot be satisfied by  
24      nonidentifiable health information or by any other  
25      information; and

1           (3) the need for the information outweighs the  
2           privacy interest of the individual to whom the infor-  
3           mation pertains.

4           (c) NOTICE.—

5           (1) IN GENERAL.—Except as provided in para-  
6           graph (2), no order for the disclosure of protected  
7           health information about an individual may be is-  
8           sued by a court unless notice of the application for  
9           the order has been served on the individual and the  
10          individual has been afforded an opportunity to op-  
11          pose the issuance of the order.

12          (2) NOTICE NOT REQUIRED.—An order for the  
13          disclosure of protected health information about an  
14          individual may be issued without notice to the indi-  
15          vidual if the court finds, by clear and convincing evi-  
16          dence, that notice would be impractical because—

17                  (A) the name and address of the individual  
18                  are unknown; or

19                  (B) notice would risk destruction or un-  
20                  availability of the evidence.

21          (d) OBLIGATIONS OF RECIPIENT.—

22          (1) IN GENERAL.—A person seeking protected  
23          health information pursuant to paragraph (1) of  
24          subsection (a)—

1 (A) shall notify the individual or the indi-  
2 vidual's attorney of the request for the informa-  
3 tion;

4 (B) shall provide the health care provider,  
5 health plan, health oversight agency, employer,  
6 insurer, health or life insurer, school or univer-  
7 sity, or agent, or person involved with a signed  
8 document attesting—

9 (i) that the individual has placed his  
10 or her physical or mental condition at issue  
11 in litigation or proceedings in which the in-  
12 dividual is a party; and

13 (ii) the date on which the individual  
14 or the individual's attorney was notified  
15 under subparagraph (A); and

16 (C) shall not accept any requested pro-  
17 tected health information from the health care  
18 provider, health plan, health oversight agency,  
19 employer, insurer, health or life insurer, school  
20 or university, or agent, or person until the ter-  
21 mination of the 10-day period beginning on the  
22 date notice was given under subparagraph (A).

23 (2) DISCLOSURE FOR PURPOSE ONLY.—A per-  
24 son who receives protected health information pursu-  
25 ant to subsection (a) may disclose the information

1       only to accomplish the purpose for which the pro-  
2       tected health information was obtained.

3       (e) LIMITATIONS.—

4           (1) SCOPE OF DISCLOSURE.—Every disclosure  
5       of protected health information under this section  
6       shall be limited to the minimum amount of informa-  
7       tion necessary to achieve the purposes of this sec-  
8       tion.

9           (2) NO GENERAL REQUIREMENT TO DIS-  
10       CLOSE.—Nothing in this section permitting the dis-  
11       closure of protected health information shall be con-  
12       strued to require such disclosure.

13           (3) IDENTIFICATION OF DISCLOSED INFORMA-  
14       TION AS PROTECTED HEALTH INFORMATION.—Pro-  
15       tected health information disclosed under this sec-  
16       tion must be clearly identified as protected health in-  
17       formation that is subject to this Act.

18       **SEC. 224. INDIVIDUAL REPRESENTATIVES.**

19       (a) IN GENERAL.—Except as provided in subsections  
20       (b) and (c), a person who is authorized by law (based on  
21       grounds other than the individual being a minor), or by  
22       an instrument recognized under law, to act as an agent,  
23       attorney, proxy, or other legal representative of a pro-  
24       tected individual, may, to the extent so authorized, exer-

1 cise and discharge the rights of the individual under this  
2 Act.

3 (b) HEALTH CARE POWER OF ATTORNEY.—A person  
4 who is authorized by law (based on grounds other than  
5 being a minor), or by an instrument recognized under law,  
6 to make decisions about the provision of health care to  
7 an individual who is incapacitated, may exercise and dis-  
8 charge the rights of the individual under this Act to the  
9 extent necessary to effectuate the terms or purposes of  
10 the grant of authority.

11 (c) NO COURT DECLARATION.—If a physician or  
12 other health care provider determines that an individual,  
13 who has not been declared to be legally incompetent, suf-  
14 fers from a medical condition that prevents the individual  
15 from acting knowingly or effectively on the individual's  
16 own behalf, the right of the individual to authorize disclo-  
17 sure under this Act may be exercised and discharged in  
18 the best interest of the individual by—

19 (1) a person described in subsection (b) with re-  
20 spect to the individual;

21 (2) a person described in subsection (a) with re-  
22 spect to the individual, but only if a person de-  
23 scribed in paragraph (1) cannot be contacted after  
24 a reasonable effort;

1           (3) the next of kin of the individual, but only  
2           if a person described in paragraph (1) or (2) cannot  
3           be contacted after a reasonable effort; or

4           (4) the health care provider, but only if a per-  
5           son described in paragraph (1), (2), or (3) cannot be  
6           contacted after a reasonable effort.

7           (d) APPLICATION TO DECEASED INDIVIDUALS.—The  
8           provisions of this Act shall continue to apply to protected  
9           health information concerning a deceased individual for a  
10          period of 2 years following the death of that individual.

11          (e) EXERCISE OF RIGHTS ON BEHALF OF A DE-  
12          CEASED INDIVIDUAL.—A person who is authorized by law  
13          or by an instrument recognized under law, to act as an  
14          executor of the estate of a deceased individual, or other-  
15          wise to exercise the rights of the deceased individual, may,  
16          to the extent so authorized, exercise and discharge the  
17          rights of such deceased individual under this Act for a pe-  
18          riod of 2 years following the death of that individual. If  
19          no such designee has been authorized, the rights of the  
20          deceased individual may be exercised as provided for in  
21          subsection (c).

22          **SEC. 325. PROHIBITION AGAINST RETALIATION.**

23          A health care provider, health researcher, health  
24          plan, health oversight agency, employer, health or life in-  
25          surer, school or university, or the agent of any such indi-

1 vidual or entity, or person who receives protected health  
2 information under section 211 may not adversely affect  
3 another person, directly or indirectly, because such person  
4 has exercised a right under this Act, disclosed information  
5 relating to a possible violation of this Act, or associated  
6 with, or assisted a person in the exercise of a right under  
7 this Act.

8 **TITLE III—OFFICE OF HEALTH**  
9 **INFORMATION PRIVACY OF**  
10 **THE DEPARTMENT OF**  
11 **HEALTH AND HUMAN SERV-**  
12 **ICES**

13 **Subtitle A—Establishment**

14 **SEC. 301. ESTABLISHMENT.**

15 (a) IN GENERAL.—There is established within the  
16 Department of Health and Human Services an office to  
17 be known as the Office of Health Information Privacy.  
18 The Office shall be headed by a director, who shall be ap-  
19 pointed by the Secretary.

20 (b) DUTIES.—The Director of the Office of Health  
21 Information Privacy shall—

22 (1) receive and investigate complaints of alleged  
23 violations of this Act;

24 (2) provide for the conduct of audits where ap-  
25 propriate;

1           (3) provide guidance to the Secretary in the im-  
2           plementation of this Act;

3           (4) prepare and submit the report described in  
4           subsection (c);

5           (5) consult with, and provide recommendation  
6           to, the Secretary concerning improvements in the  
7           privacy and security of protected health information  
8           and concerning medical privacy research needs; and

9           (6) carry out any other activities determined  
10          appropriate by the Secretary.

11          (c) REPORT ON COMPLIANCE.—Not later than Janu-  
12          ary 1, 1999, and every January 1 thereafter, the Director  
13          of the Office of Health Information Privacy shall prepare  
14          and submit to Congress a report concerning the number  
15          of complaints of alleged violations of this Act that are re-  
16          ceived during the year for which the report is being pre-  
17          pared. Such report shall describe the complaints and any  
18          remedial action taken concerning such complaints.

## 19                   **Subtitle B—Enforcement**

### 20                   CHAPTER 1—CRIMINAL PROVISIONS

#### 21          **SEC. 311. WRONGFUL DISCLOSURE OF PROTECTED** 22                   **HEALTH INFORMATION.**

23          (a) IN GENERAL.—Part I of title 18, United States  
24          Code, is amended by adding at the end the following:

1 **“CHAPTER 124—WRONGFUL DISCLOSURE**  
 2 **OF PROTECTED HEALTH INFORMATION**

“Sec.

“2801. Wrongful disclosure of protected health information.

3 **“§ 2801. Wrongful disclosure of protected health in-**  
 4 **formation**

5 “(a) OFFENSE.—The penalties described in sub-  
 6 section (b) shall apply to a person that knowingly and in-  
 7 tentiously—

8 “(1) obtains protected health information relat-  
 9 ing to an individual in violation of title II of the  
 10 Medical Information Privacy and Security Act; or

11 “(2) discloses protected health information to  
 12 another person in violation of title II of the Medical  
 13 Information Privacy and Security Act.

14 “(b) PENALTIES.—A person described in subsection  
 15 (a) shall—

16 “(1) be fined not more than \$50,000, impris-  
 17 oned not more than 1 year, or both;

18 “(2) if the offense is committed under false pre-  
 19 tenses, be fined not more than \$250,000, imprisoned  
 20 not more than 5 years, or any combination of such  
 21 penalties;

22 “(3) if the offense is committed with the intent  
 23 to sell, transfer, or use protected health information  
 24 for commercial advantage, personal gain, or mali-

1 cious harm, be fined not more than \$500,000, im-  
 2 prisoned not more than 10 years, excluded from par-  
 3 ticipation in any Federally funded health care pro-  
 4 grams, or any combination of such penalties.

5 “(c) **SUBSEQUENT OFFENSES.**—In the case of a per-  
 6 son described in subsection (a), the maximum penalties  
 7 described in subsection (b) shall be doubled for every sub-  
 8 sequent conviction for an offense arising out of a violation  
 9 or violations related to a set of circumstances that are dif-  
 10 ferent from those involved in the previous violation or set  
 11 of related violations described in such subsection (a).”.

12 (b) **CLERICAL AMENDMENT.**—The table of chapters  
 13 for part I of title 18, United States Code, is amended by  
 14 inserting after the item relating to chapter 123 the follow-  
 15 ing new item:

“124. Wrongful disclosure of protected health information ..... 2801”.

16 **SEC. 312. DEBARMENT FOR CRIMES.**

17 (a) **PURPOSE.**—The purpose of this section is to pro-  
 18 mote the prevention and deterrence of instances of inten-  
 19 tional criminal actions which violate criminal laws which  
 20 are designed to protect the privacy of protected health in-  
 21 formation in a manner consistent with this Act.

22 (b) **DEBARMENT.**—Not later than 270 days after the  
 23 date of enactment of this Act, the Attorney General, in  
 24 consultation with the Secretary, shall promulgate regula-  
 25 tions and establish procedures to permit the debarment

1 of health care providers, health researchers, health or life  
2 insurers, or schools or universities from receiving benefits  
3 under any Federal health programs if the managers or  
4 officers of such entities are found guilty of violating sec-  
5 tion 2801 of title 18, United States Code, have civil pen-  
6 alties imposed against such officers or managers under  
7 section 321 in connection with the illegal disclosure of pro-  
8 tected health information, or are found guilty of making  
9 a false statement or obstructing justice related to attempt-  
10 ing to conceal or concealing such illegal disclosure. Such  
11 regulations shall take into account the need for continuity  
12 of medical care and may provide for a delay of any debar-  
13 ment imposed under this section to take into account the  
14 medical needs of patients.

15 (c) CONSULTATION.—Before publishing a proposed  
16 rule to implement subsection (b), the Attorney General  
17 shall consult with State law enforcement officials, health  
18 care providers, patient privacy rights’ advocates, and other  
19 appropriate individuals and entities, to gain additional in-  
20 formation regarding the debarment of entities under sub-  
21 section (b) and the best methods to ensure the continuity  
22 of medical care.

23 (d) REPORT.—The Attorney General shall annually  
24 prepare and submit to the Committee on the Judiciary of  
25 the House of Representatives and the Committee on the

1 Judiciary of the Senate a report concerning the activities  
 2 and debarment actions taken by the Attorney General  
 3 under this section.

4 (e) ASSISTANCE TO PREVENT CRIMINAL VIOLA-  
 5 TIONS.—The Attorney General, in cooperation with any  
 6 other appropriate individual, organization, or agency, may  
 7 provide advice, training, technical assistance, and guid-  
 8 ance regarding ways to reduce the incidence of improper  
 9 disclosure of protected health information.

10 (f) RELATIONSHIP TO OTHER AUTHORITIES.—A de-  
 11 barment imposed under this section shall not reduce or  
 12 diminish the authority of a Federal, State, or local govern-  
 13 mental agency or court to penalize, imprison, fine, sus-  
 14 pend, debar, or take other adverse action against a person,  
 15 in a civil, criminal, or administrative proceeding.

16 CHAPTER 2—CIVIL SANCTIONS

17 **SEC. 321. CIVIL PENALTY.**

18 (a) VIOLATION.—A health care provider, health re-  
 19 searcher, health plan, health oversight agency, public  
 20 health agency, law enforcement agency, employer, health  
 21 or life insurer, school, or university, or the agent of any  
 22 such individual or entity, who the Office of Health Infor-  
 23 mation Privacy, in consultation with the Attorney General,  
 24 determines has substantially and materially failed to com-

1 ply with this Act shall be subject, in addition to any other  
2 penalties that may be prescribed by law—

3 (1) in a case in which the violation relates to  
4 title I, to a civil penalty of not more than \$500 for  
5 each such violation, but not to exceed \$5000 in the  
6 aggregate for multiple violations;

7 (2) in a case in which the violation relates to  
8 title II, to a civil penalty of not more than \$10,000  
9 for each such violation, but not to exceed \$50,000  
10 in the aggregate for multiple violations; or

11 (3) in a case in which the Office finds that such  
12 violations have occurred with such frequency as to  
13 constitute a general business practice, to a civil pen-  
14 alty of not more than \$100,000.

15 (b) PROCEDURES FOR IMPOSITION OF PENALTIES.—  
16 Section 1128A of the Social Security Act, other than sub-  
17 sections (a) and (b) and the second sentence of subsection  
18 (f) of that section, shall apply to the imposition of a civil,  
19 monetary, or exclusionary penalty under this section in the  
20 same manner as such provisions apply with respect to the  
21 imposition of a penalty under section 1128A of such Act.

22 **SEC. 322. PROCEDURES FOR IMPOSITION OF PENALTIES.**

23 (a) INITIATION OF PROCEEDINGS.—

24 (1) IN GENERAL.—The director of the Office of  
25 Health Information Privacy, in consultation with the

1 Attorney General, may initiate a proceeding to de-  
2 termine whether to impose a civil money penalty  
3 under section 321. The director may not initiate an  
4 action under this section with respect to any viola-  
5 tion described in section 321 after the expiration of  
6 the 6-year period beginning on the date on which  
7 such violation was alleged to have occurred. The di-  
8 rector may initiate an action under this section by  
9 serving notice of the action in any manner author-  
10 ized by Rule 4 of the Federal Rules of Civil Proce-  
11 dure.

12 (2) NOTICE AND OPPORTUNITY FOR HEAR-  
13 ING.—The director of the Office of Health Informa-  
14 tion Privacy shall not make a determination adverse  
15 to any person under paragraph (1) until the person  
16 has been given written notice and an opportunity for  
17 the determination to be made on the record after a  
18 hearing at which the person is entitled to be rep-  
19 resented by counsel, to present witnesses, and to  
20 cross-examine witnesses against the person.

21 (3) ESTOPPEL.—In a proceeding under para-  
22 graph (1) that—

23 (A) is against a person who has been con-  
24 victed (whether upon a verdict after trial or  
25 upon a plea of guilty or nolo contendere) of a

1 crime under section 2801 of title 18, United  
2 States Code; and

3 (B) involves the same conduct as in the  
4 criminal action;

5 the person is estopped from denying the essential  
6 elements of the criminal offense.

7 (4) SANCTIONS FOR FAILURE TO COMPLY.—

8 The official conducting a hearing under this section  
9 may sanction a person, including any party or attor-  
10 ney, for failing to comply with an order or proce-  
11 dure, failing to defend an action, or other mis-  
12 conduct as would interfere with the speedy, orderly,  
13 or fair conduct of the hearing. Such sanction shall  
14 reasonably relate to the severity and nature of the  
15 failure or misconduct. Such sanction may include—

16 (A) in the case of refusal to provide or per-  
17 mit discovery, drawing negative factual infer-  
18 ences or treating such refusal as an admission  
19 by deeming the matter, or certain facts, to be  
20 established;

21 (B) prohibiting a party from introducing  
22 certain evidence or otherwise supporting a par-  
23 ticular claim or defense;

24 (C) striking pleadings, in whole or in part;

25 (D) staying the proceedings;

1 (E) dismissal of the action;

2 (F) entering a default judgment;

3 (G) ordering the party or attorney to pay  
4 attorneys' fees and other costs caused by the  
5 failure or misconduct; and

6 (H) refusing to consider any motion or  
7 other action which is not filed in a timely man-  
8 ner.

9 (b) SCOPE OF PENALTY.—In determining the  
10 amount or scope of any penalty imposed pursuant to sec-  
11 tion 321, the director of the Office of Health Information  
12 Privacy shall take into account—

13 (1) the nature of claims and the circumstances  
14 under which they were presented;

15 (2) the degree of culpability, history of prior of-  
16 fenses, and financial condition of the person present-  
17 ing the claims; and

18 (3) such other matters as justice may require.

19 (c) REVIEW OF DETERMINATION.—

20 (1) IN GENERAL.—Any person adversely af-  
21 fected by a determination of the director of the Of-  
22 fice of Health Information Privacy under this sec-  
23 tion may obtain a review of such determination in  
24 the United States Court of Appeals for the circuit  
25 in which the person resides, or in which the claim

1 was presented, by filing in such court (within 60  
2 days following the date the person is notified of the  
3 determination of the director) a written petition re-  
4 questing that the determination be modified or set  
5 aside.

6 (2) FILING OF RECORD.—A copy of the petition  
7 filed under paragraph (1) shall be forthwith trans-  
8 mitted by the clerk of the court to the director of  
9 the Office of Health Information Privacy, and there-  
10 upon the director shall file in the Court the record  
11 in the proceeding as provided in section 2112 of title  
12 28, United States Code. Upon such filing, the court  
13 shall have jurisdiction of the proceeding and of the  
14 question determined therein, and shall have the  
15 power to make and enter upon the pleadings, testi-  
16 mony, and proceedings set forth in such record a de-  
17 cree affirming, modifying, remanding for further  
18 consideration, or setting aside, in whole or in part,  
19 the determination of the director and enforcing the  
20 same to the extent that such order is affirmed or  
21 modified.

22 (3) CONSIDERATION OF OBJECTIONS.—No ob-  
23 jection that has not been raised before the director  
24 of the Office of Health Information Privacy with re-  
25 spect to a determination described in paragraph (1)

1 shall be considered by the court, unless the failure  
2 or neglect to raise such objection shall be excused  
3 because of extraordinary circumstances.

4 (4) FINDINGS.—The findings of the director of  
5 the Office of Health Information Privacy with re-  
6 spect to questions of fact in an action under this  
7 subsection, if supported by substantial evidence on  
8 the record considered as a whole, shall be conclusive.  
9 If any party shall apply to the court for leave to ad-  
10 duce additional evidence and shall show to the satis-  
11 faction of the court that such additional evidence is  
12 material and that there were reasonable grounds for  
13 the failure to adduce such evidence in the hearing  
14 before the director, the court may order such addi-  
15 tional evidence to be taken before the director and  
16 to be made a part of the record. The director may  
17 modify findings as to the facts, or make new find-  
18 ings, by reason of additional evidence so taken and  
19 filed, and shall file with the court such modified or  
20 new findings, and such findings with respect to  
21 questions of fact, if supported by substantial evi-  
22 dence on the record considered as a whole, and the  
23 recommendations of the director, if any, for the  
24 modification or setting aside of the original order,  
25 shall be conclusive.

1           (5) EXCLUSIVE JURISDICTION.—Upon the filing  
2 of the record with the court under paragraph (2),  
3 the jurisdiction of the court shall be exclusive and its  
4 judgment and decree shall be final, except that the  
5 same shall be subject to review by the Supreme  
6 Court of the United States, as provided for in sec-  
7 tion 1254 of title 28, United States Code.

8 (d) RECOVERY OF PENALTIES.—

9           (1) IN GENERAL.—Civil money penalties im-  
10 posed under this chapter may be compromised by  
11 the director of the Office of Health Information Pri-  
12 vacy and may be recovered in a civil action in the  
13 name of the United States brought in United States  
14 district court for the district where the claim was  
15 presented, or where the claimant resides, as deter-  
16 mined by the director. Amounts recovered under this  
17 section shall be paid to the director and deposited as  
18 miscellaneous receipts of the Treasury of the United  
19 States.

20           (2) DEDUCTION FROM AMOUNTS OWING.—The  
21 amount of any penalty, when finally determined  
22 under this section, or the amount agreed upon in  
23 compromise under paragraph (1), may be deducted  
24 from any sum then or later owing by the United

1 States or a State to the person against whom the  
2 penalty has been assessed.

3 (e) DETERMINATION FINAL.—A determination by  
4 the director of the Office of Health Information Privacy  
5 to impose a penalty under section 321 shall be final upon  
6 the expiration of the 60-day period referred to in sub-  
7 section (c)(1). Matters that were raised or that could have  
8 been raised in a hearing before the director or in an appeal  
9 pursuant to subsection (c) may not be raised as a defense  
10 to a civil action by the United States to collect a penalty  
11 under section 321.

12 (f) SUBPOENA AUTHORITY.—

13 (1) IN GENERAL.—For the purpose of any  
14 hearing, investigation, or other proceeding author-  
15 ized or directed under this section, or relative to any  
16 other matter within the jurisdiction of the Attorney  
17 General hereunder, the Attorney General, acting  
18 through the director of the Office of Health Infor-  
19 mation Privacy shall have the power to issue subpoe-  
20 nas requiring the attendance and testimony of wit-  
21 nesses and the production of any evidence that re-  
22 lates to any matter under investigation or in ques-  
23 tion before the director. Such attendance of wit-  
24 nesses and production of evidence at the designated  
25 place of such hearing, investigation, or other pro-

1 ceeding may be required from any place in the Unit-  
2 ed States or in any Territory or possession thereof.

3 (2) SERVICE.—Subpoenas of the director under  
4 paragraph (1) shall be served by anyone authorized  
5 by the director by delivering a copy thereof to the  
6 individual named therein.

7 (3) PROOF OF SERVICE.—A verified return by  
8 the individual serving the subpoena under this sub-  
9 section setting forth the manner of service shall be  
10 proof of service.

11 (4) FEES.—Witnesses subpoenaed under this  
12 subsection shall be paid the same fees and mileage  
13 as are paid witnesses in the district court of the  
14 United States.

15 (5) REFUSAL TO OBEY.—In case of contumacy  
16 by, or refusal to obey a subpoena duly served upon,  
17 any person, any district court of the United States  
18 for the judicial district in which such person charged  
19 with contumacy or refusal to obey is found or re-  
20 sides or transacts business, upon application by the  
21 director of the Office of Health Information Privacy,  
22 shall have jurisdiction to issue an order requiring  
23 such person to appear and give testimony, or to ap-  
24 pear and produce evidence, or both. Any failure to

1 obey such order of the court may be punished by the  
2 court as contempt thereof.

3 (g) INJUNCTIVE RELIEF.—Whenever the director of  
4 the Office of Health Information Privacy has reason to  
5 believe that any person has engaged, is engaging, or is  
6 about to engage in any activity which makes the person  
7 subject to a civil monetary penalty under section 321, the  
8 director may bring an action in an appropriate district  
9 court of the United States (or, if applicable, a United  
10 States court of any territory) to enjoin such activity, or  
11 to enjoin the person from concealing, removing, encumber-  
12 ing, or disposing of assets which may be required in order  
13 to pay a civil monetary penalty if any such penalty were  
14 to be imposed or to seek other appropriate relief.

15 (h) AGENCY.—A principal is liable for penalties  
16 under section 321 for the actions of the principal's agent  
17 acting within the scope of the agency.

18 **SEC. 323. CIVIL ACTION BY INDIVIDUALS.**

19 (a) IN GENERAL.—Any individual whose rights under  
20 this Act have been knowingly or negligently violated may  
21 bring a civil action to recover—

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

24 (2) the greater of compensatory damages or liq-  
25 uidated damages of \$5,000.

1 (b) PUNITIVE DAMAGES.—In any action brought  
2 under this section in which the individual has prevailed  
3 because of a knowing violation of a provision of this Act,  
4 the court may, in addition to any relief awarded under  
5 subsection (a), award such punitive damages as may be  
6 warranted.

7 (c) ATTORNEY'S FEES.—In the case of a civil action  
8 brought under subsection (a) in which the individual has  
9 substantially prevailed, the court may assess against the  
10 respondent a reasonable attorney's fee and other litigation  
11 costs and expenses (including expert fees) reasonably in-  
12 curred.

13 (d) LIMITATION.—No action may be commenced  
14 under this section more than 3 years after the date on  
15 which the violation was or should reasonably have been  
16 discovered.

## 17 **TITLE IV—MISCELLANEOUS**

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

19 (a) FEDERAL AND STATE LAWS.—Nothing in this  
20 Act shall be construed as preempting, superseding or re-  
21 pealing, explicitly or implicitly, other Federal or State laws  
22 or regulations relating to protected health information or  
23 relating to an individual's access to protected health infor-  
24 mation or health care services if such laws or regulations  
25 provide protections for the rights of individuals to the pri-

1 vacy of, and access to, their health information that are  
2 greater than those provided for in this Act.

3 (b) PRIVILEGES.—Nothing in this Act shall be con-  
4 strued to preempt or modify any provisions of State statu-  
5 tory or common law to the extent that such law concerns  
6 a privilege of a witness or person in a court of that State.  
7 This Act shall not be construed to supersede or modify  
8 any provision of Federal statutory or common law to the  
9 extent such law concerns a privilege of a witness or person  
10 in a court of the United States. Authorizations pursuant  
11 to section 202 shall not be construed as a waiver of any  
12 such privilege.

13 (c) CERTAIN DUTIES UNDER LAW.—Nothing in this  
14 Act shall be construed to preempt, supersede, or modify  
15 the operation of any State law that—

16 (1) provides for the reporting of vital statistics  
17 such as birth or death information;

18 (2) requires the reporting of abuse or neglect  
19 information about any individual;

20 (3) regulates the disclosure or reporting of in-  
21 formation concerning an individual's mental health  
22 or communicable disease status otherwise permis-  
23 sible under this Act; or

24 (4) governs a minor's rights to access protected  
25 health information or health care services.

1 (d) FEDERAL PRIVACY ACT.—

2 (1) MEDICAL EXEMPTIONS.—Section 552a of  
3 title 5, United States Code, is amended by adding  
4 at the end thereof the following: “The head of an  
5 agency that is a health care provider, health plan,  
6 health oversight agency, employer, insurer, health or  
7 life insurer, school or university, or person who re-  
8 ceives protected health information under section  
9 211 of the Medical Information Privacy and Security  
10 Act shall promulgate rules, in accordance with the  
11 requirements (including general notice) of sub-  
12 sections (b)(1), (b)(2), (b)(3), (c), (e) of section 553  
13 of this title, to exempt a system of records within  
14 the agency, to the extent that the system of records  
15 contains protected health information (as defined in  
16 section 4(19) of such Act), from all provisions of  
17 this section except subsections (b)(6), (d), (e)(1),  
18 (e)(2), subparagraphs (A) through (C) and (E)  
19 through (I) of subsection (e)(4), and subsections  
20 (e)(5), (e)(6), (e)(9), (e)(12), (l), (n), (o), (p), , (r),  
21 and (u).”.

22 (2) TECHNICAL AMENDMENT.—Section  
23 552a(f)(3) of title 5, United States Code, is amend-  
24 ed by striking “pertaining to him,” and all that fol-

1        lows through the semicolon and inserting “pertain-  
2        ing to the individual.”

3        (e) CONSTITUTION.—Nothing in this Act shall be  
4        construed to alter, diminish, or otherwise weaken existing  
5        legal standards under the Constitution regarding the con-  
6        fidentiality of protected health information.

7        **SEC. 402. EFFECTIVE DATE.**

8        (a) EFFECTIVE DATE.—Unless specifically provided  
9        for otherwise, this Act shall take effect on the date that  
10       is 12 months after the promulgation of the regulations re-  
11       quired under subsection (b) but in no event later than the  
12       date that is 30 months after the date of enactment of this  
13       Act or 6 months after the promulgation of such regula-  
14       tions, whichever is earlier.

15       (b) REGULATIONS.—Not later than 12 months after  
16       the date of enactment of this Act, or as specifically pro-  
17       vided for otherwise, the director of the Office of Health  
18       Information Privacy shall promulgate regulations imple-  
19       menting this Act.

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