

**[DISCUSSION DRAFT]**105TH CONGRESS  
2D SESSION**H. R.** \_\_\_\_\_

---

**IN THE HOUSE OF REPRESENTATIVES**Mr. SHAYS introduced the following bill; which was referred to the Committee  
on \_\_\_\_\_**A BILL**

To establish Federal penalties for prohibited uses and disclosures of individually identifiable health information, to establish a right in an individual to inspect and copy their own health information, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*  
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

4 (a) **SHORT TITLE.**—This Act may be cited as the  
5 “Consumer Protection and Medical Record Confidentiality  
6 Act of 1998”.

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

3 **SEC. 2. FINDINGS.**

4 The Congress finds that—[To be supplied].

5 **SEC. 3. PURPOSES.**

6 [To be supplied]

7 **TITLE I—RESTRICTIONS ON USE**  
8 **AND DISCLOSURE**

9 **SEC. 101. GENERAL PROHIBITIONS AND EXCEPTIONS.**

10 (a) IN GENERAL.—Except as otherwise provided in  
11 this Act, the following actions and inactions on the part  
12 of a person are prohibited and shall be considered a viola-  
13 tion of this Act:

14 (1) Subject to the exceptions described in sub-  
15 paragraphs (A) and (C) through (G) of subsection  
16 (b)(2), a negligent or intentional disclosure of indi-  
17 vidualy identifiable health information, by a person  
18 granted authority under a written authorization with  
19 respect to the information that satisfies the require-  
20 ments of section 103, that is inconsistent with the  
21 provisions of the authorization.

22 (2) Subject to the exception described in sub-  
23 section (b)(2)(A), a negligent or intentional failure  
24 to provide for reasonable protections against disclo-

1       sures of individually identifiable health information  
2       that are prohibited under this Act, including—

3               (A) failure to establish and enforce reason-  
4               able and appropriate administrative, technical,  
5               and physical safeguards—

6                       (i) to ensure the confidentiality of in-  
7                       dividually identifiable health information;  
8                       and

9                       (ii) to protect against—

10                               (I) any reasonably anticipated  
11                               threats or hazards to the security or  
12                               integrity of such information; and

13                               (II) unauthorized uses or disclo-  
14                               sures of the information;

15               (B) failure to establish procedures for de-  
16               termining a response to a subpoena, warrant,  
17               court order, or other request from a govern-  
18               ment authority for disclosure of such informa-  
19               tion; [and

20               (C) failure to provide for secure destruc-  
21               tion of such information, where destruction of  
22               the information is desired.]

23               (3) Subject to the exception described in sub-  
24               section (b)(2)(A), with respect to a person whose  
25               employees, agents, or contractors come in contact

1 with individually identifiable health information in  
2 the course of their employment, agency, or contract  
3 execution, a negligent or intentional failure to estab-  
4 lish and implement written policies concerning com-  
5 pliance with this Act, including—

6 (A) failure to establish procedures for  
7 monitoring access to individually identifiable  
8 health information;

9 (B) failure to establish rules limiting ac-  
10 cess to such information to persons whose du-  
11 ties require such access; and

12 (C) failure to provide for the enforcement  
13 of such policies.

14 (4) A negligent or intentional failure to enter  
15 into a written agreement with an agent, contractor,  
16 or other person to whom individually identifiable  
17 health information is disclosed for a business pur-  
18 pose (such as persons who encode or encrypt infor-  
19 mation, data management contractors, [value added  
20 networks,] and utilization review and accreditation  
21 organizations), prior to such disclosure, specifying  
22 the limitations on their use and retention of such in-  
23 formation and informing them of their responsibil-  
24 ities under this Act.

25 (5) A negligent or intentional—

1 (A) failure to obtain the approval of an in-  
2 stitutional review board for a disclosure for re-  
3 search purposes of individually identifiable  
4 health information, where the obtaining of such  
5 approval is otherwise required by law;

6 (B) use or disclosure of individually identi-  
7 fiable health information in violation of a re-  
8 search protocol approved by an institutional re-  
9 view board; or

10 (C) failure to comply with any other re-  
11 quirements concerning use and disclosure of  
12 such information established by such a review  
13 board.

14 (6) Use or disclosure of anonymized informa-  
15 tion, or an encryption key or coding system used to  
16 anonymize information, in violation of section 102.

17 (7) A negligent or intentional disclosure of indi-  
18 vidually identifiable health information pursuant to  
19 a subpoena or discovery request related to a civil  
20 proceeding, in violation of section 104.

21 (8) A negligent or intentional disclosure of indi-  
22 vidually identifiable health information for a crimi-  
23 nal law enforcement purpose, in violation of section  
24 105, or a negligent or intentional use of information

1 obtained pursuant to such section in violation of the  
2 section.

3 (9) Subject to the exceptions described in sub-  
4 paragraphs (A) [and (B)] of subsection (b)(2), an  
5 intentional disclosure of individually identifiable  
6 health information that constitutes a sale or com-  
7 mercial publication of the information.

8 (10) Use of fraud, duress, deceit, or misrepre-  
9 sentation to obtain access to individually identifiable  
10 health information.

11 (b) EXCEPTIONS.—

12 (1) IN GENERAL.—An action or an inaction  
13 otherwise prohibited under a paragraph of sub-  
14 section (a) is not prohibited when—

15 (A) the paragraph of subsection (a) makes  
16 the prohibition subject to one or more of the ex-  
17 ceptions described in paragraph (2) of this sub-  
18 section; and

19 (B) the action or inaction satisfies the re-  
20 quirements, described in paragraph (2), of one  
21 or more of the exceptions that are applicable to  
22 the prohibition.

23 (2) DESCRIPTIONS.—The exceptions described  
24 in this paragraph are the following:

1 (A) The action or inaction is on the part  
2 of an individual whose health or health care is  
3 the subject of the information (or an authorized  
4 representative of such an individual, pursuant  
5 to section 402).

6 [(B) The action is a disclosure to a person  
7 having a written authorization permitting the  
8 disclosure that satisfies the requirements of sec-  
9 tion 103.]

10 (C) The action is a disclosure for the pur-  
11 pose of providing, or facilitating the provision  
12 of, health care to an individual described in  
13 subparagraph (A).

14 (D) The action is a disclosure for the pur-  
15 pose of facilitating payment activities related to  
16 health care provided to an individual described  
17 in subparagraph (A).

18 (E) The action is a disclosure pursuant to  
19 a specific affirmative authorization, or a re-  
20 quirement, under State or Federal law, for use  
21 in legally authorized—

22 (i) disease or injury reporting;

23 (ii) public health surveillance;

24 (iii) public health investigation or  
25 intervention;

1 (iv) management audits, financial au-  
2 dits, or program monitoring and evalua-  
3 tion; or

4 (v) licensure, certification, accredita-  
5 tion, utilization review, or quality assur-  
6 ance activities.

7 (F) The action is a disclosure pursuant to  
8 an authorization granted in a contract provid-  
9 ing health care benefits for an individual de-  
10 scribed in subparagraph (A), for the purpose of  
11 licensure, certification, accreditation, utilization  
12 review, or quality assurance activities.

13 (G) The action is a disclosure in accord-  
14 ance with a research protocol approved by an  
15 institutional review board.

16 **SEC. 102. SPECIAL RULES FOR ANONYMIZED INFORMA-**  
17 **TION.**

18 (a) DEFINITION.—For purposes of this Act, the term  
19 “anonymized information” means individually identifiable  
20 health information from which personal identifiers and  
21 means of directly contacting any subject of the informa-  
22 tion (including name, address, and social security num-  
23 ber), have been removed, encrypted, or replaced with a  
24 code, in a manner such that the identity of any such sub-  
25 ject is not apparent from the facts contained in the infor-

1 mation, but may, in the case of encrypted or coded infor-  
2 mation, be determined by a person with access to the  
3 encryption key or coding system. Such term does not in-  
4 clude any such encryption key or coding system.

5 (b) USE OF ANONYMIZED INFORMATION.—A person  
6 may use anonymized information for any lawful purpose,  
7 if the person, in such use, does not—

8 (1) attempt to identify any individual with re-  
9 spect to whom information has been removed,  
10 encrypted, or replaced with a code; or

11 (2) intentionally use the information in any way  
12 that results in the identification of any such individ-  
13 ual.

14 (c) DISCLOSURE.—

15 (1) ANONYMIZED INFORMATION.—For purposes  
16 of this Act, anonymized information shall not be  
17 considered individually identifiable health informa-  
18 tion. Subject to restrictions applicable under other  
19 Federal and State laws, a person may disclose  
20 anonymized information.

21 (2) ENCRYPTION KEY OR CODE.—For purposes  
22 of this Act, an encryption key or coding system that  
23 may be used to determine the identity of any indi-  
24 vidual with respect to whom information has been  
25 removed, encrypted, or replaced with a code, in

1 order to create anonymized information, shall be  
2 considered individually identifiable health informa-  
3 tion. Except as otherwise provided in this Act, a per-  
4 son may not negligently or intentionally disclose any  
5 such encryption key or coding system.

6 (d) DECODED INFORMATION.—Formerly anonymized  
7 information that has been manipulated to reveal a part  
8 of the information that had been removed, encrypted, or  
9 replaced with a code in order to render it anonymized in-  
10 formation is individually identifiable health information  
11 and is subject, beginning on the date of such manipula-  
12 tion, to all of the requirements of this part relating to indi-  
13 vidually identifiable information.

14 **SEC. 103. AUTHORIZATIONS FOR DISCLOSURE OF INFOR-**  
15 **MATION.**

16 (a) IN GENERAL.—For purposed of section 101, an  
17 authorization satisfies the requirements of this section if  
18 it—

19 (1) is in writing;

20 (2) is executed by an individual whose health or  
21 health care is the subject of the information (or an  
22 authorized representative of such an individual, pur-  
23 suant to section 402); and

24 (3) satisfies the requirements of—

1 (A) the law, applicable to such authoriza-  
2 tions, of the State of the residence of such indi-  
3 vidual; or

4 (B) subsection (b).

5 (b) FEDERAL REQUIREMENTS.—An authorization  
6 satisfies the requirements in this subsection if it includes  
7 the following:

8 (1) A general statement of the purposes for  
9 which the individually identifiable health information  
10 disclosed pursuant to the authorization may be used.

11 (2) A general description of the persons who  
12 are authorized to use such information.

13 (3) A valid signature of an individual whose  
14 health or health care is the subject of the informa-  
15 tion (or an authorized representative of such individ-  
16 ual).

17 (4) The date of the signature.

18 (5) An expiration date upon which the author-  
19 ization is no longer valid.

20 (6) Reasonable procedures permitting such indi-  
21 vidual or representative to revoke the authorization.

22 (c) EFFECT OF GOOD FAITH RELIANCE ON AUTHOR-  
23 IZATION.—A person shall not be liable, or subject to pun-  
24 ishment under State or Federal law, for a disclosure of

1 individually identifiable health information, where the dis-  
2 closure—

3 (1) was made in good faith reliance on an au-  
4 thorization executed by the individual that satisfies  
5 the requirements of this section; and

6 (2) was consistent with the provisions of the au-  
7 thorization.

8 **SEC. 104. DISCLOSURE IN CIVIL PROCEEDINGS.**

9 (a) IN GENERAL.—A person may not disclose individ-  
10 ually identifiable health information for use in a civil law  
11 enforcement investigation, a civil administrative action, or  
12 a civil action brought in Federal or State court, in the  
13 absence of—

14 (1) an otherwise valid discovery request, an ad-  
15 ministrative subpoena or summons, or a judicial sub-  
16 poena; and

17 (2) an order issued by the presiding judge or  
18 official upon a determination that the need for the  
19 information of the person requesting the disclosure  
20 outweighs the privacy interest of each individual  
21 whose health or health care is the subject of the in-  
22 formation.

23 (b) CONSTRUCTION.—This section shall not be con-  
24 strued to supersede any ground that may otherwise apply  
25 under Federal or State law for an objection to the dislo-

1 sure of individually identifiable health information in any  
2 civil action.

3 **SEC. 105. DISCLOSURE FOR CRIMINAL LAW ENFORCEMENT**

4 **PURPOSES.**

5 (a) IN GENERAL.—A person may not disclose individ-  
6 ually identifiable health information for a criminal law en-  
7 forcement purpose, in the absence of—

8 (1) a subpoena issued under the authority of a  
9 grand jury;

10 (2) an administrative subpoena or summons or  
11 a judicial subpoena or warrant; or

12 (3) a request otherwise authorized by law from  
13 a law enforcement agency.

14 (b) DESTRUCTION OR RETURN OF INFORMATION.—

15 When the proceeding for which individually identifiable  
16 health information was disclosed is concluded, including  
17 any derivative matters arising from such proceeding, the  
18 person to whom the disclosure was made shall either de-  
19 stroy the individually identifiable health information, or  
20 return it to the person from whom it was obtained.

21 (c) REDACTIONS.—To the extent practicable, and  
22 consistent with the requirements of due process, a criminal  
23 law enforcement agency shall redact personally identifying  
24 information from individually identifiable health informa-

1 tion prior to the public disclosure of such information in  
2 a judicial or administrative proceeding.

3 (d) USE OF INFORMATION.—Individually identifiable  
4 health information obtained by a criminal law enforcement  
5 agency pursuant to this section may only be used for pur-  
6 poses of a legitimate criminal law enforcement activity.

## 7 **TITLE II—INDIVIDUALS' RIGHTS**

### 8 **SEC. 201. INSPECTION AND COPYING OF HEALTH INFORMA-** 9 **TION.**

10 (a) IN GENERAL.—Subject to subsections (b) and (c),  
11 a person who is a health care provider, health plan, em-  
12 ployer, health or life insurer, school, or university shall  
13 permit an individual who is the subject of individually  
14 identifiable health information, or the individual's des-  
15 ignee, to inspect and copy individually identifiable health  
16 information concerning the individual, including records  
17 created under section 202, that the person maintains. The  
18 person may set forth appropriate procedures to be followed  
19 for such inspection and copying and may require an indi-  
20 vidual to pay reasonable fees associated with such inspec-  
21 tion and copying.

22 (b) EFFECT OF OTHER LAW.—

23 (1) DISCLOSURE PROHIBITED BY OTHER  
24 LAW.—A person described in subsection (a) may not  
25 permit the inspection or copying of individually iden-

1        tifiable health information under such subsection, if  
2        such inspection or copying is prohibited by any pro-  
3        vision of law other than this Act.

4            (2) DISCLOSURE LIMITED BY OTHER LAW.—A  
5        person described in subsection (a) shall limit the in-  
6        spection or copying of individually identifiable health  
7        information under such subsection to the extent re-  
8        quired by, and consistent with, any limitation on  
9        such inspection or copying in any provision of law  
10       other than this Act that is applicable to the person.

11       (c) ADDITIONAL EXCEPTIONS.—A person described  
12       in subsection (a) is not required to permit the inspection  
13       or copying of individually identifiable health information  
14       if any of the following exceptions apply:

15            (1) ENDANGERMENT TO LIFE OR SAFETY.—  
16        The person determines that the disclosure of the in-  
17        formation could reasonably be expected to endanger  
18        the life or physical safety of any individual.

19            (2) CONFIDENTIAL SOURCE.—The information  
20        identifies, or could reasonably lead to the identifica-  
21        tion of, a person who provided information under a  
22        promise of confidentiality to a health care provider  
23        concerning the individual who is the subject of the  
24        information.

1 (3) INFORMATION COMPILED IN ANTICIPATION  
2 OF LITIGATION.—The information is compiled prin-  
3 cipally—

4 (A) in the anticipation of a civil, criminal,  
5 or administrative action or proceeding; or

6 (B) for use in such action or proceeding.

7 (4) RESEARCH PURPOSES.—The information  
8 was collected for or during a clinical trial monitored  
9 by an institutional review board, and such trial is  
10 not complete.

11 (d) DENIAL OF A REQUEST FOR INSPECTION OR  
12 COPYING.—If a person described in subsection (a) denies  
13 an individual's request for inspection or copying pursuant  
14 to subsection (b) or (c), the person shall inform the indi-  
15 vidual of—

16 (1) the reasons for the denial of the request for  
17 inspection or copying;

18 (2) any procedures for further review of the de-  
19 nial; and

20 (3) the individual's right to file with the person  
21 a concise statement setting forth the request for in-  
22 spection or copying.

23 (e) STATEMENT REGARDING REQUEST.—If an indi-  
24 vidual has filed a statement under subsection (d)(3), the  
25 person, in any subsequent disclosure of the portion of the

1 information requested under subsection (a), shall in-  
2 clude—

3 (1) a copy of the individual's statement; and

4 (2) a concise statement of the reasons for deny-  
5 ing the request for inspection or copying.

6 (f) DEADLINE.—A person described in subsection (a)  
7 shall comply with or deny, in accordance with subsection  
8 (d), a request for inspection or copying of individually  
9 identifiable health information under this section not later  
10 than 30 days after the date on which the person receives  
11 the request.

12 (g) RULES GOVERNING AGENTS.—An agent of a per-  
13 son described in subsection (a) shall not be required to  
14 provide for the inspection and copying of individually iden-  
15 tifiable health information, except where—

16 (1) the individually identifiable health informa-  
17 tion is retained by the agent; and

18 (2) the agent has been asked by the person to  
19 fulfill the requirements of this section.

20 (h) RULE OF CONSTRUCTION.—This section shall not  
21 be construed to require a person described in subsection  
22 (a) to conduct a formal, informal, or other hearing or pro-  
23 ceeding concerning a request for inspection or copying of  
24 individually identifiable health information.

1 **SEC. 202. AMENDMENT OF INDIVIDUALLY IDENTIFIABLE**  
2 **HEALTH INFORMATION.**

3 (a) IN GENERAL.—Not later than 45 days after the  
4 date on which a person who is a health care provider,  
5 health plan, employer, health or life insurer, school, or uni-  
6 versity receives from an individual who is a subject of indi-  
7 vidually identifiable health information a request in writ-  
8 ing to amend the information, the person—

9 (1) shall make the amendment requested;

10 (2) shall inform the individual of the amend-  
11 ment that has been made; and

12 (3) shall make reasonable efforts to inform any  
13 person who is identified by the individual, who is not  
14 an officer, employer, or agent of the entity, and to  
15 whom the unamended portion of the information was  
16 previously disclosed, of any nontechnical amendment  
17 that has been made.

18 (b) REFUSAL TO AMEND.—If a person described in  
19 subsection (a) refuses to make an amendment requested  
20 by an individual under such subsection, the person shall  
21 inform the individual of—

22 (1) the reasons for the refusal to make the  
23 amendment;

24 (2) any procedures for further review of the re-  
25 fusal; and

1           (3) the individual's right to file with the person  
2           a concise statement setting forth the requested  
3           amendment and the individual's reasons for dis-  
4           agreeing with the refusal.

5           (c) STATEMENT OF DISAGREEMENT.—If an individ-  
6           ual has filed a statement of disagreement with a person  
7           under subsection (b)(3), the person, in any subsequent dis-  
8           closure of the disputed portion of the information—

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

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

13          (d) RULES GOVERNING AGENTS.—The agent of a  
14          person described in subsection (a) shall not be required  
15          to make amendments to individually identifiable health in-  
16          formation, except where—

17          (1) the information is retained by the agent;  
18          and

19          (2) the agent has been asked by such person to  
20          fulfill the requirements of this section.

21          (e) REPEATED REQUESTS FOR AMENDMENTS.—If a  
22          person described in subsection (a) receives a duplicative  
23          request for an amendment of information as provided for  
24          in such subsection and a statement of disagreement with  
25          respect to the request has been filed pursuant to sub-

1 section (c), the person shall inform the individual of such  
2 filing and shall not be required to carry out the procedures  
3 required under this section.

4 (f) **RULE OF CONSTRUCTION.**—This section shall not  
5 be construed—

6 (1) to require a person described in subsection  
7 (a) to conduct a formal, informal, or other hearing  
8 or proceeding concerning a request for an amend-  
9 ment to individually identifiable health information;

10 (2) to permit an individual to amend his or her  
11 record as to the type, duration, or quality of treat-  
12 ment the individual believes he or she should have  
13 been provided; or

14 (3) to require the alteration of any arrangement  
15 or obligation with respect to the delivery of health  
16 care.

17 **SEC. 203. NOTICE OF CONFIDENTIALITY PRACTICES.**

18 (a) **PREPARATION OF WRITTEN NOTICE.**—A health  
19 care provider, health plan, health oversight agency, public  
20 health authority, employer, health or life insurer, health  
21 researcher, school, or university shall post or provide, in  
22 writing and in a clear and conspicuous manner, notice of  
23 the person's confidentiality practices, that shall include—

1 (1) a description of an individual's rights with  
2 respect to individually identifiable health informa-  
3 tion;

4 (2) the uses and disclosures of individually  
5 identifiable health information authorized under this  
6 Act;

7 (3) the procedures established by the person for  
8 authorizing disclosures of individually identifiable  
9 health information and for revoking such authoriza-  
10 tions;

11 (4) the procedures established by the person for  
12 the exercise of the individual's rights; and

13 (5) the procedures established by the person for  
14 providing copies of the notice.

15 (b) MODEL NOTICE.—The Secretary, after notice  
16 and opportunity for public comment, shall develop and dis-  
17 seminate model notices of confidentiality practices, for use  
18 under this section. Use of the model notice developed by  
19 the Secretary shall serve as a complete defense in any civil  
20 action to an allegation that a violation of this section has  
21 occurred.

## 22 **TITLE III—ENFORCEMENT**

### 23 **SEC. 301. CRIMINAL PENALTIES.**

24 (a) OFFENSE.—A person who knowingly and in viola-  
25 tion of this Act obtains individually identifiable health in-

1 formation, uses such information, or discloses such infor-  
2 mation to another person, knowing that such obtaining,  
3 use, or disclosure is unlawful, shall be punished as pro-  
4 vided in subsection (b).

5 (b) PENALTIES.—A person described in subsection  
6 (a) shall—

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

9 (2) if the offense is committed under false pre-  
10 tenses, be fined not more than \$100,000, imprisoned  
11 not more than 5 years, or both; and

12 (3) if the offense is committed with intent to  
13 sell, transfer, or use individually identifiable health  
14 information for commercial advantage, personal  
15 gain, or malicious harm, be fined not more than  
16 \$250,000, imprisoned not more than 10 years, or  
17 both.

18 **SEC. 302. CIVIL ACTION.**

19 (a) IN GENERAL.—An individual who is aggrieved by  
20 a violation of this Act may bring a civil action to recover  
21 such preliminary and equitable relief as the court deter-  
22 mines to be appropriate.

23 (b) ATTORNEY'S FEES.—In the case of a civil action  
24 brought under subsection (a) in which the plaintiff has  
25 substantially prevailed, the court may assess against the

1 respondent a reasonable attorney's fee and other litigation  
2 costs and expenses (including expert fees) reasonably in-  
3 curred.

4 (c) LIMITATION.—No action may be commenced  
5 under this subsection by an individual more than 2 years  
6 after the date on which the violation was, or should rea-  
7 sonably have been, discovered by the individual.

8 (d) NO LIABILITY FOR PERMISSIBLE DISCLO-  
9 SURES.—A person who makes a disclosure of individually  
10 identifiable health information about an individual that is  
11 permitted under this Act shall not be liable to the individ-  
12 ual for such disclosure under common law.

13 **SEC. 303. PROGRAM EXCLUSIONS.**

14 (a) EXCLUSION FROM PARTICIPATION IN FEDERAL  
15 AND STATE HEALTH CARE PROGRAMS.—Section 1128(b)  
16 of the Social Security Act (42 U.S.C. 1320a-7(b)) is  
17 amended by adding at the end the following:

18 “(16) FAILURE LAWFULLY TO TREAT INDIVID-  
19 UALLY IDENTIFIABLE HEALTH INFORMATION.—Any  
20 individual or entity that the Secretary determines  
21 has failed substantially to comply with a provision of  
22 the Consumer Protection and Medical Record Con-  
23 fidentiality Act of 1998.”

24 (b) EXCLUSION OF PROVIDERS FROM PARTICIPATION  
25 IN FEDERAL EMPLOYEES HEALTH BENEFITS PRO-

1 GRAM.—Section 8902a(b) of title 5, United States Code,  
2 is amended by adding at the end the following:

3 “(6) Any provider that the Secretary of Health  
4 and Human Services has determined has failed sub-  
5 stantially to comply with a provision of the  
6 Consumer Protection and Medical Record Confiden-  
7 tiality Act of 1998.”

8 **TITLE IV—GENERAL**  
9 **PROVISIONS**

10 **SEC. 401. STANDARDS FOR ELECTRONIC DISCLOSURES.**

11 The Secretary shall promulgate standards for disclos-  
12 ing, authorizing the use and disclosure of, and authen-  
13 ticating, individually identifiable health information in  
14 electronic form, in a manner consistent with this Act.

15 **SEC. 402. AUTHORIZED REPRESENTATIVES.**

16 (a) **IN GENERAL.**—Except as provided in subsections  
17 (b) and (c), a person who is authorized by law, or by an  
18 instrument recognized under law, to act as an agent, at-  
19 torney, proxy, or other legal representative for an individ-  
20 ual, otherwise to exercise the rights of the individual, may,  
21 to the extent so authorized, exercise and discharge the  
22 rights of the individual under this Act.

23 (b) **HEALTH CARE POWER OF ATTORNEY.**—A person  
24 who is not described in subsection (a), but is authorized  
25 by law or by an instrument recognized under law to make

1 decisions about the provision of health care to an individ-  
2 ual who is incapacitated, may exercise and discharge the  
3 rights of the individual under this Act, to the extent nec-  
4 essary to effectuate the terms or purposes of the grant  
5 of authority.

6 (c) NO COURT DECLARATION.—If a health care pro-  
7 vider determines that an individual, who has not been de-  
8 clared to be legally incompetent, suffers from a medical  
9 condition that prevents the individual from acting know-  
10 ingly or effectively on the individual's own behalf, the right  
11 of the individual to authorize disclosure under this Act  
12 may be exercised and discharged in the best interest of  
13 the individual by—

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

16 (2) a person described in subsection (a) with re-  
17 spect to the individual, but only if a person de-  
18 scribed in paragraph (1) cannot be contacted after  
19 a reasonable effort;

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

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

1 (d) APPLICATION TO DECEASED INDIVIDUALS.—The  
2 provisions of this Act shall continue to apply to individ-  
3 ually identifiable health information concerning a deceased  
4 individual for a period of 2 years following the death of  
5 that individual.

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

17 **SEC. 403. RELATIONSHIP TO OTHER LAWS.**

18 (a) IN GENERAL.—

19 (1) STATE LAW.—Except as otherwise provided  
20 in this section, a State may not establish, continue  
21 in effect, or enforce any State law to the extent that  
22 the law is inconsistent with, or imposes additional  
23 requirements with respect to, a duty or a prohibition  
24 under this part.

1           (2) FEDERAL LAW.—This Act shall not be con-  
2           strued as repealing, explicitly or implicitly, other  
3           Federal laws or regulations relating to individually  
4           identifiable health information or relating to an indi-  
5           vidual's access to health care services.

6           (b) ENFORCEMENT.—A State may establish or en-  
7           force criminal and civil penalties and remedies with re-  
8           spect to a failure to comply with a provision of this Act.

9           (c) PRIVILEGES.—This Act does not preempt or mod-  
10          ify State common or statutory law to the extent such law  
11          concerns a privilege of a witness or person in a court of  
12          the State. This Act does not supersede or modify Federal  
13          common or statutory law to the extent such law concerns  
14          a privilege of a witness or person in a court of the United  
15          States. The execution of an authorization pursuant to sec-  
16          tion 103 may not be construed as a waiver of any such  
17          privilege.

18          (d) CERTAIN DUTIES UNDER LAW.—Nothing in this  
19          Act shall be construed to preempt, supersede, or modify  
20          the operation of any State law that—

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

23                 (2) requires the reporting of abuse or neglect  
24                 information about any individual;

1 (3) regulates information concerning an individ-  
2 ual's mental health or communicable disease status;

3 (4) governs a minor's rights to access individ-  
4 ually identifiable health information or health care  
5 services; or

6 (5) authorizes the collecting, analysis, or dis-  
7 semination of information from a person described  
8 in section 301(a) for the purpose of developing use,  
9 cost effectiveness, performance, or quality data.

10 (e) RELATIONSHIP TO CLINICAL RESEARCH AND RE-  
11 PORTS.—This Act shall not apply to individually identifi-  
12 able health information that is created, received, main-  
13 tained, used, disclosed, or transmitted by any person in  
14 connection with—

15 (1) any activity conducted pursuant to an inves-  
16 tigational new drug exemption, or for which approval  
17 of an institutional review board is required by the  
18 Food and Drug Administration; or

19 (2) any record required to be maintained or re-  
20 port required to be filed by the Food and Drug Ad-  
21 ministration.

22 (f) FEDERAL PRIVACY ACT.—

23 (1) MEDICAL EXEMPTIONS.—Sections 552a of  
24 title 5, United States Code, is amended by adding  
25 at the end the following:

1       “(w) MEDICAL EXEMPTIONS.—The head of an agen-  
2 cy that is subject to the Consumer Protection and Medical  
3 Record Confidentiality Act of 1998 shall promulgate rules,  
4 in accordance with the requirements (including general no-  
5 tice) of subsections (b)(1), (b)(2), (b)(3), (c), and (e) of  
6 section 553 of this title, to exempt a system of records  
7 within the agency, to the extent that the system of records  
8 contains individually identifiable health information (as  
9 defined in section 405 of such Act), from all provisions  
10 of this section except subsections (b)(6), (d), (e)(1), (e)(2),  
11 subparagraphs (A) and (C) and (E) through (I) of sub-  
12 section (e)(4), and subsections (e)(5), (e)(6), (e)(9),  
13 (e)(12), (l), (n), (o), (p), (r), and (u).”

14       (2) TECHNICAL AMENDMENT.—Section  
15 552a(f)(3) of title 5, United States Code, is amend-  
16 ed by striking “pertaining to him,” and all that fol-  
17 lows through the semicolon and inserting “pertain-  
18 ing to the individual;”

19       (g) APPLICATION TO CERTAIN FEDERAL AGEN-  
20 CIES.—

21       (1) DEPARTMENT OF DEFENSE.—

22       (A) EXCEPTIONS.—The Secretary of De-  
23 fense may, by regulation, establish exceptions to  
24 the requirements of this Act to the extent such  
25 Secretary determines that disclosure of individ-

1 ually identifiable health information relating to  
2 members of the Armed Forces from systems of  
3 records operated by the Department of Defense  
4 is necessary under circumstances different from  
5 those permitted under this Act for the proper  
6 conduct of national defense functions by mem-  
7 bers of the Armed Forces.

8 (B) APPLICATION TO CIVILIAN EMPLOY-  
9 EES.—The Secretary of Defense may, by regu-  
10 lation, establish for civilian employees of the  
11 Department of Defense and employees of De-  
12 partment of Defense contractors, limitations on  
13 the right of such persons to revoke or amend  
14 authorizations for disclosures under section 103  
15 when such authorizations were provided by such  
16 employees as a condition of employment and  
17 the disclosure is determined necessary by the  
18 Secretary of Defense to the proper conduct of  
19 national defense functions by such employees.

20 (2) DEPARTMENT OF TRANSPORTATION.—

21 (A) EXCEPTIONS.—The Secretary of  
22 Transportation may, with respect to members  
23 of the Coast Guard, exercise the same powers  
24 as the Secretary of Defense may exercise under  
25 paragraph (1)(A).

1 (B) APPLICATION TO CIVILIAN EMPLOY-  
2 EES.—The Secretary of Transportation may,  
3 with respect to civilian employees of the Coast  
4 Guard and Coast Guard contractors, exercise  
5 the same powers as the Secretary of Defense  
6 may exercise under paragraph (1)(B).

7 (3) DEPARTMENT OF VETERANS AFFAIRS.—  
8 The limitations on use and disclosure of individually  
9 identifiable health information under this Act shall  
10 not be construed to prevent any exchange of such in-  
11 formation within and among components of the De-  
12 partment of Veterans Affairs that determine eligi-  
13 bility for or entitlement to, or that provide, benefits  
14 under laws administered by the Secretary of Veteran  
15 Affairs.

16 **SEC. 404. EFFECTIVE DATE.**

17 (a) IN GENERAL.—Except as provided in subsection  
18 (b), this Act shall take effect on the date that is 18 months  
19 after the date of the enactment of this Act.

20 (b) PROVISIONS EFFECTIVE IMMEDIATELY.—A pro-  
21 vision of this Act shall take effect on the date of the enact-  
22 ment of this Act if the provision authorizes or requires  
23 the Secretary of Defense, the Secretary of Transportation,  
24 or the Secretary of Health and Human Services to de-

1 velop, establish, or promulgate regulations or model no-  
2 tices.

3 (c) DEADLINE FOR REGULATIONS.—The Secretary  
4 shall promulgate regulations implementing this Act not  
5 later than the date that is 12 months after the date of  
6 the enactment of this Act.

7 **SEC. 405. DEFINITIONS.**

8 As used in this Act:

9 (1) EMPLOYER.—The term “employer” has the  
10 meaning given such term under section 3(5) of the  
11 Employee Retirement Income Security Act of 1974  
12 (29 U.S.C. 1002(5)), except that such term shall in-  
13 clude only employers of two or more employees.

14 (2) HEALTH CARE.—The term “health care”  
15 means—

16 (A) preventive, diagnostic, therapeutic, re-  
17 habilitative, maintenance, or palliative care, in-  
18 cluding appropriate assistance with disease or  
19 symptom management and maintenance, coun-  
20 seling, service, or procedure—

21 (i) with respect to the physical or  
22 mental condition of an individual; or

23 (ii) affecting the structure or function  
24 of the human body or any part of the  
25 human body, including the banking of

1 blood, sperm, organs, or any other tissue;  
2 and

3 (B) any sale or dispensing of a drug, de-  
4 vice, equipment, or other health care related  
5 item to an individual, or for the use of an indi-  
6 vidual, pursuant to a prescription.

7 (3) HEALTH CARE PROVIDER.—The term  
8 “health care provider” means a person, who with re-  
9 spect to a specific item of individually identifiable  
10 health information, receives, creates, uses, main-  
11 tains, or discloses the information while acting in  
12 whole or in part in the capacity of—

13 (A) a person who is licensed, certified, reg-  
14 istered, or otherwise authorized by Federal or  
15 State law to provide an item or service that  
16 constitutes health care in the ordinary course of  
17 business, or practice of a profession;

18 (B) a Federal or State program that di-  
19 rectly provides items or services that constitute  
20 health care to beneficiaries; or

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

23 (4) HEALTH OR LIFE INSURER.—The term  
24 “health or life insurer” means a health insurance is-  
25 surer as defined in section 9805(b)(2) of the Internal

1 Revenue Code of 1986 or a life insurance company  
2 as defined in section 816 of such Code.

3 (5) HEALTH OVERSIGHT AGENCY.—The term  
4 “health oversight agency” means a person who, with  
5 respect to a specific item of individually identifiable  
6 health information, receives, creates, uses, main-  
7 tains, or discloses the information while acting in  
8 whole or in part in the capacity of—

9 (A) a person who performs or oversees the  
10 performance of an assessment, evaluation, de-  
11 termination, or investigation, relating to the li-  
12 censing, accreditation, or credentialing of health  
13 care providers; or

14 (B) a person who—

15 (i) performs or oversees the perform-  
16 ance of an audit, assessment, evaluation,  
17 determination, or investigation relating to  
18 the effectiveness of, compliance with, or  
19 applicability of, legal, fiscal, medical, or  
20 scientific standards or aspects of perform-  
21 ance related to the delivery of, or payment  
22 activities related to, health care; and

23 (ii) is a public agency, acting on be-  
24 half of a public agency, acting pursuant to  
25 a requirement of a public agency, or carry-

1                   ing out activities under a Federal or State  
2                   law governing the assessment, evaluation,  
3                   determination, investigation, or prosecution  
4                   described in subparagraph (A).

5                   (6) HEALTH PLAN.—The term “health plan”  
6                   means any health insurance plan, including any hos-  
7                   pital or medical service plan, dental or other health  
8                   service plan, health maintenance organization plan,  
9                   plan offered by a provider-sponsored organization  
10                  (as defined in section 1855(d) of the Social Security  
11                  Act (42 U.S.C. 1395w-25(d))), or other program  
12                  providing or arranging for the provision of health  
13                  benefits, whether or not funded through the pur-  
14                  chase of insurance.

15                  (7) HEALTH RESEARCHER.—The term “health  
16                  researcher” means a person, or an officer, employee  
17                  or independent contractor of a person, who receives  
18                  individually identifiable health information as part of  
19                  a research project that involves data with respect to  
20                  human subjects.

21                  (8) INDIVIDUALLY IDENTIFIABLE HEALTH IN-  
22                  FORMATION.—The term “individually identifiable  
23                  health information” means any information, includ-  
24                  ing demographic information, collected from an indi-

1       vidual, whether oral or recorded in any form or me-  
2       dium, that—

3               (A) is created or received by a health care  
4       provider, health plan, health oversight agency,  
5       public health authority, employer, health or life  
6       insurer, school or university; and

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

14              (ii)(I) identifies an individual;

15              (II) with respect to which there is a rea-  
16     sonable basis to believe that the information  
17     can be used to identify an individual; or

18              (III) has been provided in an encrypted  
19     format that does not directly identify an indi-  
20     vidual, but that provides a method for  
21     decrypting the information.

22              (9) INSTITUTIONAL REVIEW BOARD.—The term  
23     “institutional review board” means an entity estab-  
24     lished to review proposed health research with re-  
25     spect to potential risks to human subjects pursuant

1 to Federal regulations adopted under section  
2 1902(b) of the Public Health Service Act (42 U.S.C.  
3 300v-1(b)).

4 (10) PAYMENT ACTIVITIES.—The term “pay-  
5 ment activities”—

6 (A) means activities undertaken—

7 (i) by, or on behalf of, a health plan  
8 to determine its responsibility for coverage  
9 under the plan and the actual payment  
10 under such plan; or

11 (ii) by a health care provider to obtain  
12 payment for items or services provided  
13 under a health plan or provided based on  
14 a determination by the health plan of re-  
15 sponsibility for coverage under the plan;  
16 and

17 (B) includes the following activities, when  
18 performed in a manner consistent with subpara-  
19 graph (A):

20 (i) Billing, claims management, medi-  
21 cal data processing, practice management,  
22 or other administrative services.

23 (ii) Determinations of coverage or ad-  
24 judication of health benefit claims.

1 (iii) Review of health care services  
2 with respect to medical necessity, coverage  
3 under a health plan, appropriateness of  
4 care, or justification of charges.

5 (11) PERSON.—The term “person” means a  
6 natural person, a government, governmental subdivi-  
7 sion, agency or authority, a company, corporation,  
8 estate, firm, trust, partnership, association, joint  
9 venture, society, joint stock company, or any other  
10 legal entity.

11 (12) PUBLIC HEALTH AUTHORITY.—The term  
12 “public health authority” means an authority or in-  
13 strumentality of the United States, a tribal govern-  
14 ment, a State, or a political subdivision of a State  
15 that is—

16 (A) primarily responsible for public health  
17 matters; and

18 (B) primarily engaged in activities such as  
19 injury reporting, public health surveillance, and  
20 public health investigation or intervention.

21 (13) SCHOOL OR UNIVERSITY.—The term  
22 “school or university” means an institution or place  
23 for instruction or education, including an elementary  
24 school, secondary school, or institution of higher

1 learning, a college, or an assemblage of colleges unit-  
2 ed under one corporate organization or government.

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

5 (15) STATE.—The term “State” includes the  
6 District of Columbia, Puerto Rico, the Virgin Is-  
7 lands, Guam, American Samoa, and the Northern  
8 Mariana Islands.

9 (16) WRITING.—The term “writing” means  
10 writing in either a paper-based or computer-based  
11 form, including electronic signatures.