

107TH CONGRESS
2^D SESSION

H. R. 5646

To restore standards to protect the privacy of individually identifiable health information that were weakened by the August 2002 modifications, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

OCTOBER 16, 2002

Mr. MARKEY (for himself, Mr. WAXMAN, Mr. DINGELL, Mr. BERMAN, and Mr. CAPUANO) introduced the following bill; which was referred to the Committee on the Energy and Commerce, and in addition to the Committees on Ways and Means, and Education and the Workforce, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

To restore standards to protect the privacy of individually identifiable health information that were weakened by the August 2002 modifications, 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.**

4 This Act may be cited as the “Stop Taking Our
5 Health Privacy (STOHP) Act of 2002”.

6 **SEC. 2. FINDINGS.**

7 The Congress finds as follows:

1 (1) People in the United States are deeply con-
2 cerned about the confidentiality of their health infor-
3 mation. According to a recent survey conducted by
4 the Princeton Survey Research Associates, 1 in 6
5 people in the United States has done something out
6 of the ordinary to keep personal health information
7 confidential, including withholding information, pro-
8 viding inaccurate information, or, in some cases,
9 avoiding care entirely.

10 (2) Pursuant to the Health Insurance Port-
11 ability and Accountability Act of 1996 (Public Law
12 104–191; 110 Stat. 1936 et seq.) (commonly re-
13 ferred to as “HIPAA”), the Clinton Administration
14 issued comprehensive medical privacy regulations
15 which were promulgated in final form in December
16 2000.

17 (3) Such regulations established a sound foun-
18 dation of privacy protections by prohibiting the use
19 or disclosure of an individual’s health information
20 unless specifically authorized by the regulations or
21 by the individual. The regulations also provided indi-
22 viduals with the right to be notified of the privacy
23 practices of health plans, health care providers, and
24 health care clearinghouses regarding disclosure of
25 their health information, the right to access and

1 copy their own health records, and the right to re-
2 quest corrections of their health records, among
3 other provisions.

4 (4) Such regulations took effect in April 2001
5 and require health care providers, health plans
6 (other than small health plans) and health care
7 clearinghouses to comply not later than April 2003.

8 (5) In August 2002, the Bush Administration
9 issued a final rule that significantly weakened med-
10 ical privacy protections in the December 2000 med-
11 ical privacy rule.

12 (6) The Bush Administration undermined med-
13 ical privacy protections by eliminating the rule's re-
14 quirement that covered entities obtain patient con-
15 sent before using and disclosing patient health infor-
16 mation for treatment, payment, and health care op-
17 erations. This change means that patients' medical
18 records can be used and disclosed without their per-
19 mission for a wide range of purposes including busi-
20 ness activities that have nothing to do with the
21 treatment of a patient, such as the sale or merger
22 of a health maintenance organization. This change
23 also allows the use and disclosure of information in
24 existing medical records even though patients dis-
25 closed the information with the understanding and

1 expectation that it would not be further used or dis-
2 closed without their consent. The elimination of con-
3 sent compromises the confidentiality at the heart of
4 physician-patient relationships, which is indispen-
5 sable for the delivery of high-quality, thorough care.

6 (7) The Bush Administration also undermined
7 medical privacy protections by expanding the cir-
8 cumstances under which patients' information can
9 be shared without their knowledge or consent to in-
10 clude activities that consumers typically consider
11 marketing. This change was accomplished by nar-
12 rowing the scope of activities that are regulated by
13 the provisions of the rule governing marketing.
14 Under this change, pharmacies and other providers
15 can use a consumer's medical information without
16 consent to mail the consumer unsolicited drug prod-
17 uct recommendations, without having to disclose fees
18 paid by drug companies for sending such commu-
19 nications or provide the consumer an opportunity to
20 decline to receive such communications in the future.

21 (8) The Bush Administration further under-
22 mined medical privacy protections by changing the
23 language in the section of the rule governing public
24 health to allow the disclosure of medical information
25 without patient permission to entities regulated by

1 the Food and Drug Administration, such as pharma-
2 ceutical companies and medical device manufactur-
3 ers, for an expanded and broad range of purposes
4 which may include marketing campaigns. In con-
5 trast, the December 2000 rule allowed nonconsen-
6 sual disclosure of patient health information for an
7 exclusive list of public health related activities, such
8 as for the purpose of reporting serious side effects
9 from a prescription drug to the Food and Drug Ad-
10 ministration.

11 (9) Reversal of the Bush Administration's
12 changes to the December 2000 medical privacy rule
13 is integral to any effort to ensure medical privacy
14 protection for consumers and preserve access to
15 high-quality health care in the United States.

16 (10) Core medical privacy protections of the
17 December 2000 medical privacy rule should be re-
18 stored by—

19 (A) reinstating the patient consent require-
20 ment for treatment, payment, and health care
21 operations, while ensuring that the requirement
22 does not impede important health care activities
23 such as filling pharmaceutical prescriptions and
24 making referrals;

1 (B) returning to the December 2000 defi-
2 nition of “marketing” and thus ensuring that
3 activities typically considered marketing, such
4 as drug companies paying pharmacies to send
5 product recommendations to patients, fall under
6 the rule’s privacy protections relating to the use
7 of patient health information for marketing ac-
8 tivities; and

9 (C) eliminating the broad “public health”
10 exemption created by the August 2002 rule.

11 **SEC. 3. PURPOSE.**

12 The purpose of this Act is to restore patient privacy
13 protections essential for high-quality health care that were
14 undermined by the Bush Administration’s August 2002
15 modifications of the December 2000 medical privacy rule.

16 **SEC. 4. RESTORATION OF PRIVACY PROTECTIONS.**

17 (a) CONSENT FOR USES OR DISCLOSURES TO CARRY
18 OUT TREATMENT, PAYMENT, OR HEALTH CARE OPER-
19 ATIONS.—

20 (1) IN GENERAL.—The modifications made to
21 section 164.506 of title 45, Code of Federal Regula-
22 tions, by the August 2002 medical privacy rule shall
23 have no force or effect.

24 (2) CLARIFICATION REGARDING INSTANCES
25 WHEN CONSENT IS NOT REQUIRED.—In addition to

1 the circumstances described in the December 2000
2 medical privacy rule, and notwithstanding any provi-
3 sion to the contrary, such section 164.506 shall be
4 construed and applied so as to permit a health care
5 provider to use or disclose an individual's protected
6 health information without obtaining the prior con-
7 sent of the individual in the following circumstances:

8 (A) A health care provider may use or dis-
9 close an individual's protected health informa-
10 tion to fill or dispense a prescription, search for
11 drug interactions related to that prescription,
12 and determine eligibility and obtain authoriza-
13 tion for payment regarding that prescription, if
14 the health care provider obtains written consent
15 from the individual as soon as practicable.

16 (B) A health care provider may use or dis-
17 close an individual's protected health informa-
18 tion to carry out treatment of that individual
19 if—

20 (i) the individual and the health care
21 provider have not had in-person commu-
22 nication regarding such treatment;

23 (ii) obtaining consent would be im-
24 practicable;

1 (iii) the health care provider deter-
2 mines, in the exercise of professional judg-
3 ment, that the individual's consent is clear-
4 ly inferred from the circumstances, such as
5 an order or referral from another health
6 care provider; and

7 (iv) the health care provider obtains
8 written consent from the individual as soon
9 as practicable.

10 (b) MARKETING.—

11 (1) IN GENERAL.—The modifications made by
12 the August 2002 medical privacy rule to the defini-
13 tion of the term “marketing” in section 164.501 of
14 title 45, Code of Federal Regulations, shall have no
15 force or effect.

16 (2) TREATMENT OF CERTAIN COMMUNICA-
17 TIONS.—The exception for oral communications in
18 paragraph (2)(i) of the definition of the term “mar-
19 keting” in section 164.501 of title 45, Code of Fed-
20 eral Regulations, as contained in the December 2000
21 medical privacy rule, shall have no force or effect.

22 (3) AUTHORIZATIONS FOR MARKETING.—Sec-
23 tion 164.508 of title 45, Code of Federal Regula-
24 tions, shall be construed and applied so as to require
25 that, if an authorization is required for a use or dis-

1 closure for marketing, the authorization shall be
2 considered invalid unless it—

3 (A) uses the term “marketing”;

4 (B) states that the purpose of the use or
5 disclosure involved is marketing;

6 (C) describes the specific marketing uses
7 and disclosures authorized, including whether
8 the protected health information involved—

9 (i) may be used for purposes internal
10 to the covered entity;

11 (ii) may be disclosed to, and used by,
12 a business associate of the covered entity;
13 and

14 (iii) may be disclosed to, and used by,
15 any person or entity other than a business
16 associate of the covered entity; and

17 (D) states that the use or disclosure of
18 protected health information for marketing will
19 directly result in remuneration to the covered
20 entity from a third party, in any case in which
21 a covered entity expects, or reasonably should
22 expect, that such remuneration will occur.

23 (c) PUBLIC HEALTH.—The modifications made to
24 section 164.512(b)(1)(iii) of title 45, Code of Federal Reg-

1 ulations, by the August 2002 medical privacy rule shall
2 have no force or effect.

3 **SEC. 5. DEFINITIONS; EFFECTIVE DATE.**

4 (a) IN GENERAL.—For purposes of this Act:

5 (1) DECEMBER 2000 MEDICAL PRIVACY RULE.—

6 The term “December 2000 medical privacy rule”
7 means the final rule on standards for privacy of in-
8 dividually identifiable health information published
9 on December 28, 2000, in the Federal Register (65
10 Fed. Reg. 82462), including the provisions of title
11 45, Code of Federal Regulations, revised or added
12 by such rule.

13 (2) AUGUST 2002 MEDICAL PRIVACY RULE.—

14 The term “August 2002 medical privacy rule”
15 means the final rule, published on August 14, 2002,
16 in the Federal Register (67 Fed. Reg. 53182), that
17 modified the December 2000 medical privacy rule.

18 (b) OTHER TERMS DEFINED.—For purposes of this
19 Act:

20 (1) BUSINESS ASSOCIATE; COVERED ENTITY;

21 HEALTH CARE PROVIDER.—The terms “business as-
22 sociate”, “covered entity”, and “health care pro-
23 vider” shall have the meaning given such terms in
24 section 160.103 of title 45, Code of Federal Regula-

1 tions, as contained in the December 2000 medical
2 privacy rule.

3 (2) DISCLOSURE; INDIVIDUAL, PROTECTED
4 HEALTH INFORMATION; TREATMENT; USE.—The
5 terms “disclosure”, “individual”, “protected health
6 information”, “treatment”, and “use” shall have the
7 meaning given such terms in section 164.501 of title
8 45, Code of Federal Regulations, as contained in the
9 December 2000 medical privacy rule.

10 (c) EFFECTIVE DATE; NO REGULATIONS RE-
11 QUIRED.—This Act shall take effect on the date of the
12 enactment of this Act and does not require the issuance
13 of regulations.

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