I

108TH CONGRESS
1ST SESSION

H. R. 1709

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

APRIL 10, 2003

Mr. MARKEY (for himself, Mr. ROHRABACHER, Mr. WAXMAN, and Mr. DINGELL) introduced the following bill; which was referred to the Committee on 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

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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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Stop Taking Our Health Privacy (STOHP) Act of 2003''.

SEC. 2. FINDINGS.

The Congress finds as follows:

(1) People in the United States are deeply concerned about the confidentiality of their health information. According to a survey conducted by the Princeton Survey Research Associates, 1 in 6 people in the United States has done something out of the ordinary to keep personal health information confidential, including withholding information, providing inaccurate information, or, in some cases, avoiding care entirely.

(2) Pursuant to the Health Insurance Portability and Accountability Act of 1996, commonly referred to as ''HIPAA'' (Public Law 104–191; 110 Stat. 1936 et seq.), the Department of Health and Human Services issued comprehensive medical privacy regulations, which were promulgated in final form in December 2000.

(3) These regulations established a sound foundation of privacy protections by prohibiting the use or disclosure of an individual's health information unless specifically authorized by the regulations or by the individual. The regulations also required health care providers such as physicians and health clinics, health plans, and health care clearinghouses, which are responsible for handling transactions such as billing between health plans and providers, to no-

tify individuals about privacy practices regarding disclosure of health information. The regulations also provided individuals with the right to access and copy their own health records, and the right to request corrections of their health records, among other provisions.

(4) The regulations took effect on April 14, 2000, and required health care providers, health plans (other than small health plans), and health care clearinghouses to comply not later than April 14, 2003.

(5) On August 14, 2002, the Department of Health and Human Services issued modifications to the December 2000 medical privacy rule that significantly weakened privacy protections.

(6) These modifications eliminated the requirement that health care providers, health plans, and health care clearinghouses obtain patient consent before using or disclosing patient health information for treatment, payment, or health care operations. This change means that patients' medical information can be used or disclosed without their permission for a wide range of purposes, including business activities that have nothing to do with patient care, such as the sale or merger of a health maintenance

organization (HMO). This change also permits the use and disclosure of information in existing medical records even though patients disclosed the information with the understanding and expectation that it would not be used or disclosed without their consent. The elimination of consent compromises the confidentiality that is the heart of physician-patient relationships and is indispensable for the delivery of high-quality health care.

(7) The August 2002 modifications also undermined medical privacy protections by expanding the circumstances under which patients' information can be shared without their knowledge or consent to include activities that consumers typically consider marketing. This change permits pharmacies and other providers to use consumers' medical information without their permission to mail them unsolicited drug product recommendations. Furthermore, providers are not required to disclose fees paid to them by drug companies for sending such communications nor provide consumers with the choice to opt out of such future communications.

(8) The August 2002 modifications further undermined medical privacy protections by changing the section of the rule governing public health. The

change allows providers to disclose medical information without patient permission to entities regulated by the Food and Drug Administration, such as pharmaceutical companies and medical device manufacturers, for a broad range of purposes including marketing campaigns. In contrast, the December 2000 rule allowed nonconsensual disclosure of patient health information for a limited list of public health-related activities, such as reporting serious side effects from a prescription drug to the Food and Drug Administration.

(9) Reversal of the August 2002 modifications to the medical privacy rule is integral to any effort to ensure privacy protections for consumers' personal health information and preserve access to high-quality health care in the United States.

(10) Congress should restore core medical privacy protections of the December 2000 medical privacy rule by—

(A) reinstating the patient consent requirement for treatment, payment, and health care operations, while ensuring that the requirement does not impede important health care activities such as filling pharmaceutical prescriptions and making physician referrals;

(B) returning to the December 2000 definition of ''marketing'' and thus ensuring that activities typically considered ''marketing,'' such as drug companies paying pharmacies to send product recommendations to patients, fall under the rule's privacy protections governing marketing activities; and

(C) eliminating the broad ''public health'' loophole created by the August 2002 rule.

SEC. 3. PURPOSE.

The purpose of this Act is to restore patient privacy protections essential for high-quality health care that were undermined by the August 2002 modifications of the December 2000 medical privacy rule.

SEC. 4. RESTORATION OF PRIVACY PROTECTIONS.

(a) CONSENT FOR USES OR DISCLOSURES TO CARRY OUT TREATMENT, PAYMENT, OR HEALTH CARE OPERATIONS.—

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

(2) CLARIFICATION REGARDING INSTANCES WHEN CONSENT IS NOT REQUIRED.— In addition to the circumstances described in the December 2000

medical privacy rule, and notwithstanding any provision to the contrary, such section 164.506 shall be construed and applied so as to permit a health care provider to use or disclose an individual's protected health information without obtaining the prior consent of the individual in the following circumstances:

(A) A health care provider may use or disclose an individual's protected health information to fill or dispense a prescription, search for drug interactions related to that prescription, and determine eligibility and obtain authorization for payment regarding that prescription, if the health care provider obtains written consent from the individual as soon as practicable.

(B) A health care provider may use or disclose an individual's protected health information to carry out treatment of that individual if—

(i) the individual and the health care provider have not had in-person communication regarding such treatment;

(ii) obtaining consent would be impracticable;

(iii) the health care provider determines, in the exercise of professional judg-

ment, that the individual's consent is clearly inferred from the circumstances, such as an order or referral from another health care provider; and

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

(b) MARKETING.—

(1) IN GENERAL.—The modifications made by the August 2002 medical privacy rule to the definition of the term ''marketing'' in section 164.501 of title 45, Code of Federal Regulations, shall have no force or effect.

(2) TREATMENT OF CERTAIN COMMUNICATIONS.—The exception for oral communications in paragraph (2)(i) of the definition of the term ''marketing'' in section 164.501 of title 45, Code of Federal Regulations, as contained in the December 2000 medical privacy rule, shall have no force or effect.

(3) AUTHORIZATIONS FOR MARKETING.—Section 164.508 of title 45, Code of Federal Regulations, shall be construed and applied so as to require that, if an authorization is required for a use or disclosure for marketing, the authorization shall be considered invalid unless it—

(A) uses the term ''marketing'';

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

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

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

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

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

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

(c) PUBLIC HEALTH.—The modifications made to section 164.512(b)(1)(iii) of title 45, Code of Federal Regulations, by the August 2002 medical privacy rule shall have no force or effect.

SEC. 5. DEFINITIONS; EFFECTIVE DATE.

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

(1) DECEMBER 2000 MEDICAL PRIVACY RULE.—The term ''December 2000 medical privacy rule'' means the final rule on standards for privacy of individually identifiable health information published on December 28, 2000, in the Federal Register (65 Fed. Reg. 82462), including the provisions of title 45, Code of Federal Regulations, revised or added by such rule.

(2) AUGUST 2002 MEDICAL PRIVACY RULE.—The term ''August 2002 medical privacy rule'' means the final rule, published on August 14, 2002, in the Federal Register (67 Fed. Reg. 53182), that modified the December 2000 medical privacy rule.

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

(1) BUSINESS ASSOCIATE; COVERED ENTITY; HEALTH CARE PROVIDER.—The terms ''business associate'', ''covered entity'', and ''health care provider'' shall have the meaning given such terms in section 160.103 of title 45, Code of Federal Regulations, as contained in the December 2000 medical privacy rule.

(2) DISCLOSURE; INDIVIDUAL, PROTECTED HEALTH INFORMATION; TREATMENT; USE.—The

terms ''disclosure'', ''individual'', ''protected health information'', ''treatment'', and ''use'' shall have the meaning given such terms in section 164.501 of title 45, Code of Federal Regulations, as contained in the December 2000 medical privacy rule.

(c) EFFECTIVE DATE; NO REGULATIONS REQUIRED.—This Act shall take effect on the date of the enactment of this Act and does not require the issuance of regulations.

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