AMENDMENT NO. ____ Calendar No. ____

Purpose: To provide for a complete substitute.

IN THE SENATE OF THE UNITED STATES—106th Cong., 1st Sess.

S.____

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

Referred to the Committee on _____
and ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT IN THE NATURE OF A SUBSTITUTE intended to be proposed by Mr. JEFFORDS

Viz:

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the "Health Information Confidentiality Act of 1999".

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

SEC. 2. FINDINGS.

The Congress finds that—

(1) individuals have a right of confidentiality with respect to their personal health information and records;

(2) with respect to information about medical care and health status, the traditional right of confidentiality is at risk;

(3) an erosion of the right of confidentiality may reduce the willingness of patients to confide in physicians and other practitioners, thus jeopardizing quality health care;

(4) an individual's confidentiality right means that an individual's authorization or informed consent is needed to disclose his or her protected health information, except in rare and limited circumstances required by the public interest;

(5) any disclosure of protected health information should be limited to that information or portion of the medical record necessary to fulfill the purpose of the disclosure;

(6) incentives need to be created to use nonidentifiable health information where appropriate;

(7) the availability of timely and accurate personal health data for the delivery of health care services throughout the Nation is needed;

(8) personal health care data may be essential for selected types of medical research;

(9) public health uses of personal health data are critical to both personal health as well as public health;

(10) confidentiality of an individual's health information must be assured without jeopardizing the pursuit of clinical and epidemiological research undertaken to improve health care and health outcomes and to assure the quality and efficiency of health care;

(11) there is an imperative need for confidence and trust between a psychotherapist and a patient and that such trust can only be established by an assurance of confidentiality; and

(12) the assurance described in paragraph (11) serves the public interest by facilitating the provision of appropriate treatment for individuals.

SEC. 3. PURPOSES.

The purpose of this Act is to—

(1) establish strong and effective mechanisms to protect against the unauthorized and inappropriate use of protected health information that is created or maintained as part of health care treatment,

diagnosis, enrollment, payment, plan administration, testing, or research processes;

(2) promote the efficiency and security of the health information infrastructure so that members of the health care community may more effectively exchange and transfer health information in a manner that will ensure the confidentiality of protected health information without impeding the delivery of high quality health care;

(3) create incentives to turn personal health information into nonidentifiable health information for oversight, health research, public health, law enforcement, judicial, and administrative purposes, where appropriate; and

(4) establish strong and effective remedies for violations of this Act.

SEC. 4. DEFINITIONS.

As used in this Act:

(1) ACCREDITING BODY.—The term "accrediting body" means a national body, committee, organization, or institution (such as the Joint Commission on Accreditation of Health Care Organizations or the National Committee for Quality Assurance) that has been authorized by law or is recognized by a health care regulating authority as an accrediting

entity or any other entity that has been similarly authorized or recognized by law to perform specific accreditation, licensing or credentialing activities.

(2) AGENT.—The term "agent" means a person, including a contractor, who represents and acts for another under the contract or relation of agency, or whose function is to bring about, modify, affect, accept performance of, or terminate contractual obligations between the principal and a third person.

(3) COMMON RULE.—The term "common rule" means the Federal policy for the protection of human subjects from research risks originally published as 56 Federal Register 28.012 (et seq.) (June 18, 1991) as adopted and implemented by a Federal department or agency.

(4) DISCLOSE AND DISCLOSURE.—

(A) DISCLOSE.—The term "disclose" means to release, publish, transfer, provide access to, or otherwise divulge protected health information to any person other than the individual who is the subject of such information.

(B) DISCLOSURE.—

(i) IN GENERAL.—The term "disclosure" refers to a release, publication, transfer, provision for access to, or com-

munication of information described in subparagraph (A).

(ii) USE.—The use of protected health information by an authorized person and its agents shall not be considered a disclosure for purposes of this Act if the use is for the purposes for which the information was lawfully obtained. Using or providing access to health information in the form of nonidentifiable health information shall not be construed as a disclosure of protected health information.

(5) EMPLOYER.—The term "employer" has the meaning given such term under section 3(5) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1002(5)), except that such term shall include only employers of 2 or more employees.

(6) HEALTH CARE.—The term "health care" means—

(A) preventive, diagnostic, therapeutic, rehabilitative, maintenance, or palliative care, including appropriate assistance with disability, disease or symptom management and health maintenance, counseling, service, or procedure—

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

(ii) affecting the structure or function of the human body or any part of the human body, including the banking of blood, sperm, organs, or any other tissue; or

(B) pursuant to a prescription or medical order any sale or dispensing of a drug, device, equipment, or other health care related item to an individual, or for the use of an individual.

(7) HEALTH CARE OPERATIONS.—The term "health care operations" means, with respect to a health plan, health care provider, or life insurer, services provided by or on behalf of such health plan, health care provider, or life insurer for the purpose of carrying out the management functions of such health plan, health care provider, or life insurer, or carrying out the delivery of health benefits by such health plan, health care provider, or life insurer under the terms of a contract for health plan or life insurance benefits. Such term means only the following:

(A) Conducting quality assessment and improvement activities, including outcomes evalua-

tion, and clinical guideline development and improvement.

(B) Reviewing the competence or qualifications of health care professionals, evaluating provider performance, health plan performance, and conducting professional or clinical health care education, accreditation, certification, licensing, or credentialing activities.

(C) Rating and insurance activities, including underwriting, experience rating, and reinsurance.

(D) Conducting or arranging for auditing services, including fraud and abuse detection and compliance programs.

(E) Such other services as the Secretary determines appropriate through regulations (after notice and comment).

(8) HEALTH CARE PROVIDER.—The term "health care provider" means (for purposes of this Act only) a person, who with respect to a specific item of protected health information, receives, creates, uses, maintains, or discloses the information while acting in whole or in part in the capacity of—

(A) a person who is licensed, certified, registered, or otherwise authorized by Federal or

State law to provide an item or service that constitutes health care in the ordinary course of business, or practice of a profession, or an officer, employee, or agent of a person described in this subparagraph that is engaged in the provision of health care; or

(B) a Federal, State, or employer sponsored program, or a health plan that provides, or facilitates the provision of items or services that constitute health care to beneficiaries.

(9) HEALTH OVERSIGHT AGENCY.—The term "health oversight agency" means a person who, with respect to a specific item of protected health information, receives, creates, uses, maintains, or discloses the information while acting in whole or in part in the capacity of—

(A) a person who performs or oversees the performance of an assessment, evaluation, determination, or investigation, relating to the licensing, accreditation, or credentialing of health care providers; or

(B) a person who—

(i) performs or oversees the performance of an audit, assessment, evaluation, determination, or investigation, or the ini-

tiation of administrative, civil or criminal proceedings, relating to the effectiveness of, compliance with, applicability of, or enforcement of laws or regulations, or legal, fiscal, medical, or scientific standards, requirements or aspects of performance related to the delivery of, or payment for, health care or related to the use of health information in the business of insurance, including complaints, claims, investigations, underwriting, sales, and managed care; and

(ii) is a public agency, acting on behalf of a public agency, or a law enforcement agency carrying out activities under a law or regulation governing the audit, assessment, evaluation, determination, investigation, or activities related to the initiation of administrative, civil or criminal proceedings described in clause (i).

(10) HEALTH PLAN.—

(A) IN GENERAL.—The term "health plan" means any health insurance issuer (as such term is defined in section 2791(b)(2) of the Public Health Service Act (42 U.S.C. 300gg-

91(b)(2))) including any provider-sponsored organization, and any group health plan that provides medical care as defined in section 733(a) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1191b(a)).

(B) BENEFITS.—For purposes of subparagraph (A), the term "health plan" includes any benefit for which the delivery of the benefit requires the use or disclosure of protected health information, including benefits for disability, dental, vision, long-term care, nursing home care, and community-based care, and any benefit that involves medical care.

(11) HEALTH RESEARCHER.—The term "health researcher" means a person, or an officer, employee or independent contractor of a person, who creates or receives protected health information as part of a systematic investigation, including research development, testing and evaluation designed to develop or contribute to generalizable knowledge.

(12) INFORMATION PROTECTION OFFICER.—The term "information protection officer" means an individual (or individuals), designated by a person under this Act who has the authority to establish

and maintain safeguards to protect the confidentiality of protected health information.

(13) INDIVIDUAL REPRESENTATIVE.—The term "individual representative" means a person who is designated by the individual, authorized by law (based on grounds other than the individual being a minor), or by an instrument recognized under law, to act as an agent, attorney, proxy, or other representative of a protected individual. Such term includes a health care power of attorney.

(14) INSTITUTIONAL REVIEW BOARD.—The term "institutional review board" means a review panel that is responsible for implementing Federal human subject protection requirements as stipulated under the common rule.

(15) KEY.—The term "key" means a method or procedure used to transform nonidentifiable health information that is in a coded or encrypted form into protected health information.

(16) LAW ENFORCEMENT INQUIRY AND PROCEEDING.—The term "law enforcement inquiry" or "law enforcement proceeding" means—

(A) an investigation or official proceeding inquiring into a violation of, or failure to com-

ply with, any statute, regulation, rule or order; or

(B) a criminal, civil or administrative proceeding, arising from a violation of, or failure to comply with, any statute, regulation, rule or order.

(17) LAW ENFORCEMENT OFFICIAL.—The term "law enforcement official" means any officer of the United States or of a State or political subdivision thereof, who is empowered by law to conduct—

(A) an investigation or official proceeding inquiring into a violation of, or failure to comply with, any statute, regulation, rule or order; or

(B) a criminal, civil or administrative proceeding, arising from a violation of, or failure to comply with, any statute, regulation, rule or order.

For purposes of section 210(e), such term includes officers or persons engaged in corrections, probation, pardon, or parole functions.

(18) LIFE INSURER.—The term "life insurer" means a life insurance company as defined in section 816 of the Internal Revenue Code of 1986.

(19) NONIDENTIFIABLE HEALTH INFORMATION.—The term "nonidentifiable health information" means protected health information from which personal identifiers, that either reveal the identity of the individual who is the subject of such information or provide a means of identifying the individual (such as name, address, and social security number), have been removed, encrypted, or replaced with a code, such that the identity of the individual is not revealed without (in the case of encrypted or coded information) the use of a key.

(20) ORIGINATING PROVIDER.—The term "originating provider" means a health care provider who creates or originates medical information that is or that becomes protected health information.

(21) PAYMENT.—The term "payment" means—

(A) the activities undertaken by—

(i) or on behalf of a health plan or a life insurer to obtain payment or to determine its responsibility for coverage under the health plan or life insurance policy and the actual payment under such health plan or life insurance policy;

(ii) a health care provider to obtain payment for items or services; or

(iii) or on behalf of the Health Care Financing Administration in determining payment for the medicare program under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.) or the appropriate State authority in determining payment for the medicaid program under title XIX of such Act (42 U.S.C. 1396 et seq.) or payment for the State children's health insurance program under title XXI of such Act (42 U.S.C. 1397aa et seq.); and

(B) activities undertaken as described in subparagraph (A) including—

(i) billing, claims management, medical data processing or other administrative services;

(ii) determinations of coverage, or improving payment methodology or coverage policies or adjudication or subrogation of health benefit claims;

(iii) review of health care services with respect to medical necessity, coverage

under a health plan, appropriateness of care, or justification of charges;

(iv) utilization review activities, including precertification and preauthorization of services; and

(v) risk adjusting payments based on enrollee health status and demographic characteristics.

(22) PERSON.—The term "person" means a government, governmental subdivision, agency or authority; corporation; company; association; firm; partnership; society; estate; trust; joint venture; individual; individual representative; tribal government; and any other legal entity.

(23) PROTECTED HEALTH INFORMATION.—The term "protected health information" with respect to the individual who is the subject of the information, means any information, whether oral or recorded in any form or medium, that—

(A) is created or received by a health care provider, health plan, health researcher, health oversight agency, public health authority, employer, law enforcement official, life insurer, school or university;

(B) relates to, or is derived from, the past, present or future—

(i) physical or mental health or condition of the individual (including individual cells or their components);

(ii) the provision of health care to the individual; or

(iii) payment for the provision of health care to the individual; and

(C) that is not nonidentifiable health information.

(24) PUBLIC HEALTH AUTHORITY.—The term "public health authority" means an authority or instrumentality of the United States, a tribal government, a State, or a political subdivision of a State that is—

(A) responsible for public health matters; and

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

(25) SCHOOL OR UNIVERSITY.—The term "school or university" means an institution or place for instruction or education, including an elementary school, secondary school, or institution of higher

learning, a college, or an assemblage of colleges united under one corporate organization or government.

(26) SECRETARY.—The term "Secretary" means the Secretary of Health and Human Services.

(27) SIGNED.—The term "signed" refers to documentation of assent in any medium, whether ink, digital, or biometric signatures, or tape recorded oral authorizations.

(28) STATE.—The term "State" includes the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands.

(29) TREATMENT.—The term "treatment" means the provision of health care by, or the coordination of health care (including health care management of the individual through risk assessment, case management and disease management) among, health care providers, or the referral of a patient from one provider to another, or coordination of health care or other services among health care providers and third parties authorized by the health plan or the individual.

(30) WRITING.—The term "writing" means any form of documentation whether paper, electronic, digital, biometric, or tape recorded.

TITLE I—INDIVIDUAL'S RIGHTS

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

SEC. 101. INSPECTION AND COPYING OF PROTECTED HEALTH INFORMATION.

(a) IN GENERAL.—At the request of an individual and except as provided in subsection (b), a health care provider, health plan, employer, life insurer, school, or university shall permit an individual who is the subject of protected health information or the individual's designee, to inspect and copy protected health information concerning the individual, including records created under sections 102 and 112, that such person maintains. The person may set forth appropriate procedures to be followed for such inspection or copying and may require an individual to pay reasonable costs associated with such inspection or copying. Such fees may not be assessed where such an assessment would have the effect of inhibiting an individual from gaining access to the information described in this section.

(b) EXCEPTIONS.—Unless ordered by a court of competent jurisdiction, a person described in subsection (a) is not required to permit the inspection or copying of protected health information if any of the following conditions are met:

(1) ENDANGERMENT TO LIFE OR SAFETY.—The person determines that the disclosure of the information could reasonably be expected to endanger the life or safety of the individual who is the subject of the record.

(2) CONFIDENTIAL SOURCE.—The information identifies, or could reasonably lead to the identification of, a person who provided information under a promise of confidentiality concerning the individual who is the subject of the information.

(3) INFORMATION COMPILED IN ANTICIPATION OF LITIGATION.—The information is compiled principally—

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

(B) for use in such action or proceeding.

(4) RESEARCH PURPOSES.—The information was collected or created solely for a research project. When protected health information is collected as part of a clinical trial, or other interventional or interactive research, inspection and copying of such information shall be governed by the terms of the informed consent agreement of the individual with the researcher.

(c) INSPECTION AND COPYING OF SEGREGABLE PORTION.—A person described in subsection (a) shall permit the inspection and copying under subsection (a) of any reasonably segregable portion of a record after deletion of any portion that is exempt under subsection (b).

(d) DENIAL OF A REQUEST FOR INSPECTION OR COPYING.—If a person described in subsection (a) denies a request for inspection or copying pursuant to subsection (b), the person shall inform the individual in writing of—

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

(2) any procedures for further review of the denial; and

(3) the individual's right to file with the person a concise statement setting forth the request for inspection or copying.

(e) STATEMENT REGARDING REQUEST.—If an individual has filed a statement under subsection (d)(3), the person in any subsequent disclosure of the portion of the information shall include—

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

(2) a concise statement of the reasons for denying the request for inspection or copying.

(f) DEADLINE.—

(1) IN GENERAL.—Except as provided in paragraph (2), a person described in subsection (a) shall comply with or deny, in accordance with subsection (d), a request for inspection or copying of protected health information under this section not later than 30 days after the date on which the person receives the request.

(2) OFF PREMISES.—In the case of a request described in paragraph (1), if the information involved is in paper form, film or fiche, located off the premises of the person involved, and not readily available, the person shall have 60 days to comply with or deny such request.

(g) RULES GOVERNING AGENTS.—An agent of a person described in subsection (a) shall not be required to provide for the inspection and copying of protected health information, except where—

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

(2) the agent has received in writing a request from the person involved to fulfill the requirements of this section;

at which time such information shall be provided to the requesting person. Such requesting person shall comply with subsection (f) with respect to any such information.

(h) RULE OF CONSTRUCTION.—This section shall not be construed to require a person described in subsection (a) to conduct a formal, informal, or other hearing or proceeding concerning a request for inspection or copying of protected health information.

SEC. 102. AMENDMENT OF PROTECTED HEALTH INFORMATION.

(a) REQUIREMENTS.—

(1) IN GENERAL.—Except as provided in subsections (c) and (f), not later than 45 days after the date on which a health care provider, health plan, employer, life insurer, school, or university receives from an individual a request in writing to amend information that meets the requirements of paragraph (2), such person shall—

(A) make the amendment requested;

(B) inform the individual of the amendment that has been made; and

(C) make reasonable efforts to inform any person to whom the unamended portion of the information was previously disclosed, of any nontechnical amendment that has been made.

(2) INFORMATION.—The requirements of this paragraph are that—

(A) the information that is the subject of the request is in fact inaccurate; and

(B) the person receiving the request created the information that is at issue.

(b) REQUEST OF ORIGINATING PROVIDER.—

(1) IN GENERAL.—Protected health information that is created or received by a health plan or health care provider as part of treatment or payment shall be subject to amendment as provided for in this section upon a written request made to the originating provider.

(2) SPECIAL CIRCUMSTANCES.—If an originating provider, its agents, or contractors no longer maintains the protected health information sought to be amended by an individual pursuant to paragraph (1), a health plan or another health care provider that maintains such information shall arrange for amendment consistent with this section.

(c) REFUSAL TO AMEND.—If a person described in subsection (a) refuses to make the amendment requested under such subsection, the person shall inform the individual in writing of—

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

(2) any procedures for further review of the refusal; and

(3) the individual's right to file with the person a concise statement setting forth the requested amendment and the individual's reasons for disagreeing with the refusal.

(d) STATEMENT OF DISAGREEMENT.—If an individual has filed a statement of disagreement under subsection (c)(3), the person involved, in any subsequent disclosure of the disputed portion of the information—

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

(2) may include a concise statement of the reasons for not making the requested amendment.

(e) RULES GOVERNING AGENTS.—The agent of a person described in subsection (a) shall not be required to make amendments to protected health information, except where—

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

(2) the agent has been asked, in writing, by such person to fulfill the requirements of this section.

If the agent is required to comply with this section as provided for in paragraph (2), such agent shall be subject to the 45-day deadline described in subsection (a).

(f) EXTENSION FOR RECORDS OFF PREMISES.—In the case of a request described in subsection (a), if the information involved is in paper, film, or fiche form, located off the premises of the person involved, and not readily available, the person shall have 60 days to comply with or deny such request.

(g) REPEATED REQUESTS FOR AMENDMENTS.—If a person described in subsection (a) receives a request for an amendment of information as provided for in such subsection and a statement of disagreement has been filed pursuant to subsection (d), the person shall inform the individual of such filing and shall not be required to carry out the procedures required under this section.

(h) RULES OF CONSTRUCTION.—This section shall not be construed to—

(1) require that a person described in subsection (a) conduct a formal, informal, or other hearing or proceeding concerning a request for an amendment to protected health information;

(2) require a provider to amend an individual's record as to the type, duration, or quality of treat-

ment the individual believes he or she should have been provided; or

(3) require any deletion or alteration of the original information.

SEC. 103. NOTICE OF CONFIDENTIALITY PRACTICES.

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

(1) a description of the individual's rights with respect to protected health information, including the right to inspect and copy protected health information pertaining to the individual;

(2) the types of uses and disclosures of protected health information authorized under this Act that the person providing the notice will make and the categories of persons who will receive protected health information through such uses and disclosures;

(3) the types of persons authorized to receive protected health information without authorization or informed consent as stipulated under this Act;

(4) the procedures for authorizing disclosures of protected health information and for revoking such authorizations;

(5) an explanation of the safeguards that a person uses to maintain the confidentiality of protected health information;

(6) the procedures established by the person for the exercise of the individual's rights;

(7) a description of who the individual may contact to obtain more detailed information about the uses and disclosures of protected health information;

(8) an explanation of the individual's right to limit disclosure by choosing to assume financial responsibility for treatment, as provided for in section 201(h) and the procedures for exercising that right; and

(9) the right to obtain a copy of the notice of the confidentiality practices required under this Act.

(b) MODEL NOTICE.—The Secretary, after notice and opportunity for public comment, shall develop and disseminate model notices of confidentiality practices, using the advice of the National Committee on Vital Health Statistics, for use under this section. Use of the model notice shall serve as an absolute defense against claims of receiving inappropriate notice.

Subtitle B—Establishment of Safeguards

SEC. 111. ESTABLISHMENT OF SAFEGUARDS.

(a) IN GENERAL.—A health care provider, health plan, health oversight agency, public health authority, employer, life insurer, health researcher, law enforcement official, school, or university shall establish and maintain appropriate administrative, technical, and physical safeguards to protect the confidentiality, security, accuracy, and integrity of protected health information created, received, obtained, maintained, used, transmitted, or disposed of by such person.

(b) DESIGNATION OF INFORMATION PROTECTION OFFICER.—

(1) IN GENERAL.—Subject to paragraph (2), each person to which this section applies shall designate an information protection officer to establish and maintain safeguards described in subsection (c) to—

(A) protect against threats or hazards to the security and integrity of protected health information;

(B) protect against the unauthorized use or disclosure of protected health information; and

(C) otherwise ensure compliance with this Act by the officers and employees of the person.

(2) HEALTH CARE ENTITIES.—With respect to a health care provider that is part of a health care entity, the entity will be responsible for designating the information protection officer for the entity.

(c) SAFEGUARDS.—The safeguards described in this subsection shall address the following factors:

(1) The purposes for which protected health information is needed and whether such purposes can be accomplished with nonidentifiable health information.

(2) Appropriate procedures for maintaining the physical security of protected health information and assuring the appropriate use of any key used in creating nonidentifiable health information.

(3) The categories of personnel who will have access to protected health information and appropriate limitations on access to individual identifiers.

(4) A process for documenting the use of protected health information.

(5) Appropriate training, supervision and sanctioning of personnel who will have access to protected health information with respect to their use of

protected health information and adherence to established safeguards.

(6) Appropriate mechanisms for limiting disclosures of protected health information to the information necessary to respond to the request for disclosure.

(7) Procedures for handling requests for protected health information by persons other than the individual who is the subject of such information, including relatives and affiliates of such individual, law enforcement officials, parties in civil litigation, health researchers, health care providers, and health plans.

(d) REGULATIONS.—The Secretary shall issue regulations to coordinate the requirements under this section with regulations establishing requirements relating to safeguards that are in effect on the effective date of this Act.

SEC. 112. ACCOUNTING FOR DISCLOSURES.

(a) IN GENERAL.—

(1) HEALTH RELATED ENTITIES.—Except as provided in paragraph (3), a health care provider, health plan, health oversight agency, public health authority, employer, life insurer, health researcher, law enforcement official, school, or university shall

establish and maintain, with respect to any protected health information disclosure, a record of such disclosure in accordance with regulations issued by the Secretary.

(2) AGENT.—Except as provided in paragraph (3), an agent shall maintain a record of its disclosures made pursuant to sections 205 through 212.

(3) EXCEPTION.—A record of disclosures under this subsection is not required with respect to disclosures made to officers or employees of the person who maintains the record involved and who, in the performance of their duties, consistent with section 201(c), have a need for the protected health information.

(b) RECORD OF DISCLOSURE.—A record established under subsection (a) shall be maintained for not less than 7 years.

TITLE II—RESTRICTIONS ON USE AND DISCLOSURE

SEC. 201. GENERAL RULES REGARDING USE AND DISCLOSURE.

(a) PROHIBITION.—

(1) GENERAL RULE.—A health care provider, health plan, health oversight agency, public health authority, employer, life insurer, health researcher,

law enforcement official, school, or university, or any agents of such a person, may not use or disclose protected health information except as authorized under this Act or as authorized by the individual who is the subject of such information, or as otherwise determined under State law to be necessary to comply with a State law with respect to benefits described in section 401(d).

(2) RULE OF CONSTRUCTION.—Use or disclosure of nonidentifiable health information shall not be construed as a use or disclosure of protected health information.

(b) USE AND DISCLOSURE BY AGENTS.—An agent who receives protected health information from a person described in subsection (a) shall be subject to all rules of use and disclosure and safeguard requirements under this Act.

(c) SCOPE OF DISCLOSURE.—Use or disclosure of protected health information by a person under this title shall be limited to the information and individual (or individuals) necessary to accomplish the purpose for which the information is disclosed.

(d) DISCLOSURE FOR PURPOSE ONLY.—A recipient of information pursuant to an authorization under this title may use or disclose such information solely to carry

out the purpose for which the information was authorized for release.

(e) NO GENERAL REQUIREMENT TO DISCLOSE.—Nothing in this title permitting the disclosure of protected health information shall be construed to require such disclosure unless such disclosure is otherwise required by a Federal or State law requiring the reporting of specific protected health information (including to law enforcement officials).

(f) CREATION OF NONIDENTIFIABLE INFORMATION.—A person described in subsection (a)(1) may disclose protected health information to an employee or agent of the person for purposes of creating nonidentifiable information, if the person prohibits the employee or agent of the person from using or disclosing the protected health information for purposes other than the sole purpose of creating nonidentifiable information as specified by the person.

(g) DEEMED DISCLOSURE OF PROTECTED HEALTH INFORMATION.—Any person who, without authorization—

(1) creates protected health information through the manipulation of nonidentifiable information;

(2) discloses nonidentifiable information to an individual with actual knowledge that such individual

intended to manipulate the nonidentifiable information in order to create protected health information;

(3) receives protected health information with actual knowledge that such information has been unlawfully created through the manipulation of nonidentifiable information; or

(4) releases, publishes, transfers, provides access to, or otherwise divulges a key;

shall be deemed to be in violation of this title and to have disclosed protected health information in violation of section 2801 of title 18, United States Code.

(h) SELF-PAY EXEMPTION.—An individual who receives treatment, and assumes financial responsibility for such treatment with a health care provider, may limit or prohibit the disclosure of protected health information related to such episode.

(i) INDIVIDUAL AUTHORIZATION.—To be valid, an authorization to use or disclose protected health information under this title shall—

(1) identify the individual who is the subject of the protected health information;

(2) describe the nature of the information to be disclosed;

(3) identify the types of persons to whom the information is to be disclosed;

(4) describe the types of uses and disclosures of protected health information that the person will make;

(5) be subject to revocation by the individual and indicate that the authorization is valid until revocation by the individual;

(6) be in writing, dated, and signed by the individual, family member, or other authorized representative;

(7) a description of the individual's rights with respect to protected health information; and

(8) indicate whether or not coverage under the plan or treatment by the provider is conditioned upon the individual signing the authorization.

(j) MODEL AUTHORIZATIONS.—The Secretary, after notice and opportunity for public comment, shall develop and disseminate model written authorizations of the type described in subsection (a) that meet the requirements of sections 202 and 203. The Secretary shall consult with the National Committee on Vital and Health Statistics in developing such authorizations. An authorization obtained on a model authorization form developed by the Secretary pursuant to the preceding sentence shall be deemed to meet the authorization requirements of this section.

SEC. 202. PROCUREMENT OF AUTHORIZATIONS FOR DISCLOSURE OF PROTECTED HEALTH INFORMATION FOR TREATMENT, PAYMENT, AND HEALTH CARE OPERATIONS.

(a) REQUIREMENTS RELATING TO EMPLOYERS, HEALTH PLANS, AND UNINSURED INDIVIDUALS.—

(1) IN GENERAL.—To meet the requirements relating to the authorized use or disclosure of protected health information under section 201, an authorization form must be secured for each individual in connection with treatment, payment and health care operations.

(2) CONSOLIDATED AUTHORIZATION.—A single authorization may be secured for each individual in connection with treatment, payment, and health care operations.

(3) EMPLOYERS.—Every employer offering a health plan to its employees shall, at the time of, and as a condition of enrollment in the health plan, obtain a signed, written authorization that is a legal, informed authorization concerning the use and disclosure of protected health information for treatment, payment, and health care operations with respect to each individual who is eligible to receive care under the health plan.

(4) HEALTH PLANS.—Every health plan offering enrollment to individuals or non-employer groups shall, at the time of, and as a condition of enrollment in the health plan, obtain a signed, written authorization that is a legal, informed authorization concerning the use and disclosure of protected health information for treatment, payment, and health care operations, with respect to each individual who is eligible to receive care under the plan.

(5) OTHERS.—A provider providing health care to an individual not seeking services pursuant to an authorization obtained under paragraphs (3) and (4), shall obtain a signed, written authorization that is a legal, informed authorization concerning the use and disclosure of protected health information with respect to such individual for treatment, payment and health care operations of such provider, and in arranging for treatment and payment from other providers.

(6) TRANSITION RULE FOR ENROLLEES ON EFFECTIVE DATE.—

(A) IN GENERAL.—With respect to any individual who is enrolled in a health plan on the effective date of this Act, the employer or health plan responsible for obtaining an author-

ization for treatment, payment, or health care operations, may deem such individual to have furnished the authorization required under paragraph (3) or (4) if the employer or health plan provides notice to the individual that meets the requirements of this paragraph.

(B) CONTENTS.—An authorization notice under this paragraph shall contain—

(i) a disclosure of the confidentiality practices required under section 103;

(ii) an authorization form that meets the requirements of section 202(i); and

(iii) a statement of the need of the employer or health plan to obtain a written authorization from the individual in order to continue their enrollment in the health plan.

(C) METHOD OF DELIVERY.—A notice under this paragraph shall be provided not later than 30 days after the effective date of this Act and shall be delivered in a manner that is reasonably determined to ensure actual receipt by the individual. If the individual is a participant or beneficiary of an employee welfare benefit plan, such notice may be provided pursuant to

the same methods used to provide information under section 104(b) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1024(b)).

(D) SECOND NOTICE.—If an individual fails to respond to a notice provided under subparagraph (A), the employer or health plan shall, not later than 6 months after the date on which the initial notice was delivered, provide a second notice to the individual that meets the requirements of this paragraph.

(E) RECORDKEEPING.—With respect to an individual to which this paragraph applies, a person maintaining records as provided for in subsection (c) shall, in lieu of maintaining a record of a signed authorization, maintain a record that documents the provision of notice to the individual as provided for in this paragraph.

(F) EFFECT OF FAILURE TO RESPOND.—During the 2-year period beginning on the effective date of this Act, an individual who fails to respond to a notice provided under this paragraph may be deemed by the employer or health plan to have provided the authorization required under paragraph (3) or (4) for purposes

of treatment, payment, or health care operations, so long as such individual is continuously enrolled in the health plan.

(G) FINDING BY SECRETARY.—Not later than 18 months after the effective date of this Act, the Secretary shall make a finding as to whether it is in the public interest to permit employers or health plans to continue to rely on the authorization process described in this paragraph for purposes of treatment, payment, or health care operations for an indefinite period so long as the individuals involved are continuously enrolled (from the effective date of this Act) in a health plan during such period.

(b) REVOCATION OF AUTHORIZATION.—

(1) IN GENERAL.—An individual may revoke in writing an authorization under this section at any time, unless the use or disclosure that is the subject of the authorization is required to complete a course of treatment, effectuate payment, or conduct health care operations for health care that has been provided to the individual.

(2) HEALTH PLANS.—With respect to a health plan, the authorization of an individual is deemed to be revoked at the time of the cancellation or non-re-

newal of enrollment in the health plan, except as may be necessary to complete health care operations and payment requirements related to the individual's period of enrollment.

(3) TERMINATION OF PLAN.—With respect to the revocation of an authorization under this section by an enrollee in a health plan, the health plan may, upon notice to the enrollee and an opportunity to rescind the revocation, terminate the coverage of such enrollee under such plan if the health plan determines that the revocation has resulted in the inability of the plan to provide care for the enrollee or conduct health care operations.

(c) RECORD OF INDIVIDUAL'S AUTHORIZATIONS AND REVOCATIONS.—

(1) IN GENERAL.—Each person collecting or storing protected health information shall maintain a record for a period of 7 years of each authorization of an individual and revocation thereof.

(2) RULE OF CONSTRUCTION.—Records of authorizations and revocations maintained under paragraph (1) shall not be construed to be protected health information under this Act.

(d) NO WAIVER.— Except as provided for in this Act, an authorization to disclose protected health information

by an individual shall not be construed as a waiver of any rights that the individual has under other Federal or State laws, the rules of evidence, or common law.

(e) RULES OF CONSTRUCTION.—

(1) SINGLE AUTHORIZATIONS.—An employer or health plan shall be deemed to meet the requirements of subsection (a) with respect to a spouse, child, or other eligible dependent if, at the time of enrollment, a single authorization under subsection (a) is obtained from the employee or other individual who accepts responsibility for health plan enrollment.

(2) SEPARATE AUTHORIZATIONS.—Authorizations for the use or disclosure of protected health information for treatment, payment, and health care operations shall not authorize the use or disclosure of such information by an individual with the intent to sell or transfer protected health information for the purpose of marketing a product or service. For such disclosures a separate authorization is required under section 203.

(3) LIFE INSURERS.—For purposes of this section, a life insurer shall be treated as a health plan.

SEC. 203. AUTHORIZATIONS FOR DISCLOSURE OF PROTECTED HEALTH INFORMATION OTHER THAN FOR TREATMENT, PAYMENT, OR HEALTH CARE OPERATIONS.

(a) WRITTEN AUTHORIZATIONS.—A health care provider, health plan, health oversight agency, public health authority, law enforcement official, employer, life insurer, school, or university may use or disclose protected health information, for purposes other than those authorized under section 202, pursuant to an authorization executed by the individual who is the subject of the information that meets the requirements of section 201(i). Such an authorization shall be separate from an authorization provided under section 202.

(b) LIMITATION ON AUTHORIZATIONS.—A person described in section 202 may not condition the delivery of treatment or payment for services on the receipt of an authorization described in this section.

(c) REVOCATION OR AMENDMENT OF AUTHORIZATION.—

(1) IN GENERAL.—An individual may in writing revoke or amend an authorization described in subsection (a).

(2) NOTICE OF REVOCATION.—A person described in subsection (a) that discloses protected health information pursuant to an authorization that

has been revoked under paragraph (1) shall not be subject to any liability or penalty under this title if that person had no actual or constructive notice of the revocation.

SEC. 204. NEXT OF KIN AND DIRECTORY INFORMATION.

(a) NEXT OF KIN.—A health care provider, or a person who receives protected health information under section 205, may disclose protected health information regarding an individual to the individual's next of kin, an individual's representative, or to another person whom the individual has identified, if—

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

(A) has been notified of the individual's right to object to such disclosure and the individual has not objected to the disclosure; or

(B) is in a physical or mental condition such that the individual is not capable of objecting, and there are no prior indications that the individual would object;

(2) the information disclosed relates to health care currently being provided to that individual; and

(3) the disclosure of the protected health information is consistent with good medical or professional practice.

(b) DIRECTORY INFORMATION.—

(1) DISCLOSURE.—

(A) IN GENERAL.—Except as provided in paragraph (2), an entity described in subsection (a) may disclose the information described in subparagraph (B) to any person if the individual who is the subject of the information—

(i) has been notified of the individual's right to object and the individual has not objected to the disclosure; or

(ii) is in a physical or mental condition such that the individual is not capable of objecting, the individual's next of kin has not objected, and there are no prior indications that the individual would object.

(B) INFORMATION.—Information described in this subparagraph is information that consists only of 1 or more of the following items:

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

(ii) The general health status of the individual, described as critical, poor, fair, stable, or satisfactory or in terms denoting similar conditions.

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

(2) EXCEPTION.—

(A) LOCATION.—Paragraph (1)(B)(iii) shall not apply if disclosure of the location of the individual would reveal specific information about the physical or mental condition of the individual, unless the individual expressly authorizes such disclosure.

(B) DIRECTORY OR NEXT OF KIN INFORMATION.—A disclosure may not be made under this section if the health care provider involved has reason to believe that the disclosure of directory or next of kin information could lead to the physical or mental harm of the individual, unless the individual expressly authorizes such disclosure.

(c) IDENTIFICATION OF DECEASED INDIVIDUAL.—An entity described in subsection (a) may disclose protected health information if such disclosure is necessary to assist in the identification or safe handling of a deceased individual.

(d) RIGHTS OF MINORS.—The rights of minors under this Act shall be exercised by a parent, the minor, or other person, as provided for under applicable State law.

SEC. 205. EMERGENCY CIRCUMSTANCES.

(a) GENERAL RULE.—In the event of a threat of imminent physical or mental harm to the subject of protected health information, any person may, in order to allay or remedy such threat, disclose protected health information about such subject to a health care practitioner, health care facility, law enforcement official, public health authority, or emergency medical personnel.

(b) HARM TO OTHERS.—Any person may disclose protected health information about the subject of the information where—

(1) such subject has made a direct or indirect threat of serious injury or death with respect to an individual or group of individuals;

(2) the subject has the ability to carry out such threat, or is engaged in carrying out the threat; and

(3) the release of such information is necessary to prevent or significantly reduce the possibility of such threat being carried out.

(c) GOOD FAITH BELIEF.—No disclosure made in the good faith belief that the disclosure was necessary to protect the health or safety of an individual or others from serious, imminent harm shall be a violation of, or punishable under, this Act.

(d) EXIGENT CIRCUMSTANCES.—

(1) IN GENERAL.—When exigent circumstances exist, any person may disclose protected health information upon the request of a law enforcement official that is in hot pursuit of, or is attempting to locate and identify, a fugitive, suspect, or material witness.

(2) GOOD FAITH BELIEF.—No disclosure made in the good faith belief or in reliance on a law enforcement official's representation that exigent circumstances exist, as described in paragraph (1), shall be a violation of, or punishable under, this Act.

SEC. 206. OVERSIGHT.

(a) DISCLOSURE.—

(1) IN GENERAL.—A health care provider, health plan, health researcher, employer, life insurer, law enforcement official, public health authority, health oversight agency, school, or university may disclose protected health information to a health oversight agency for purposes of, or in compliance with, an oversight function authorized by law.

(2) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to permit a person to refuse to disclose information if required or obligated to do so by other statutory, regulatory, or compulsory processes.

(b) USE IN ACTION AGAINST INDIVIDUALS.—

(1) IN GENERAL.—Protected health information about an individual that is disclosed under this section may not be used in, or disclosed to any person for use in, an administrative, civil, or criminal action or investigation directed against the individual—

(A) unless the action or investigation arises out of and is directly related to—

(i) the receipt of health care or payment for health care;

(ii) an action involving a fraudulent claim related to health; or

(iii) qualification for, or receipt of benefits, payments or services based on a fraudulent statement or material misrepresentation of the health of the patient; or

(B) unless authorized by an appropriate order of a court of competent jurisdiction which is granted after application showing good cause therefore.

(2) PROVISIONS RELATING TO ORDER OF THE COURT.—For purposes of paragraph (1)(B):

(A) GOOD CAUSE.—In assessing good cause, the court shall weigh the public interest and the need for disclosure against the injury

to the patient, to the physician-patient relationship, and to the treatment services involved.

(B) SAFEGUARDS.—Upon the granting of an order, the court, in determining the extent to which any disclosure of all or any part of any record is necessary, shall impose appropriate safeguards against unauthorized disclosure.

SEC. 207. PUBLIC HEALTH.

(a) IN GENERAL.—A health care provider, health plan, health researcher, public health authority, employer, life insurer, law enforcement official, school, or university may disclose protected health information to a public health authority or other person authorized by law for use in a legally authorized—

(1) disease or injury report;

(2) public health surveillance;

(3) public health investigation or intervention;

(4) vital statistics report, such as birth or death information;

(5) report of abuse or neglect information about any individual; or

(6) report of information concerning a communicable disease status.

(b) ADVERSE EVENT REPORTING.—

(1) IN GENERAL.—An adverse event report shall not be prohibited under this Act so long as the adverse event report—

(A) is pursuant to, or necessary for, any regulation or program authorized by the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) or other program administered or relied upon by the Food and Drug Administration to discover adverse events, whether voluntary or required by law;

(B) relates to any Food and Drug Administration regulated articles; and

(C) is to, or by, any person manufacturing, distributing, researching, dispensing, prescribing, using, or regulating articles described in subparagraph (B).

(2) NO IDENTIFICATION OF PATIENTS.—Any person required by law or regulation to report adverse events to the Food and Drug Administration shall not identify patients by name, address, or social security number in such reports. Such person shall assign a code for each patient in each such report referred to in paragraph (1). Nothing in this subsection shall be construed to prohibit the Food and Drug Administration from obtaining identifiable

health information in order to implement or administer any program.

(c) REQUIREMENT TO RELEASE PROTECTED HEALTH INFORMATION TO CORONERS AND MEDICAL EXAMINERS.—

(1) IN GENERAL.—When a Coroner or Medical Examiner or their duly appointed deputies seek protected health information for the purpose of inquiry into and determination of, the cause, manner, and circumstances of a death, the health care provider, health plan, health oversight agency, public health authority, employer, life insurer, health researcher, law enforcement official, school, or university involved shall provide the protected health information to the Coroner or Medical Examiner or to the duly appointed deputies without undue delay.

(2) PRODUCTION OF ADDITIONAL INFORMATION.—If a Coroner or Medical Examiner or their duly appointed deputies receives health information from an entity referred to in paragraph (1), such health information shall remain as protected health information unless the health information is attached to or otherwise made a part of a Coroner's or Medical Examiner's official report, in which case it shall no longer be protected.

(3) EXEMPTION.—Health information attached to or otherwise made a part of a Coroner's or Medical Examiner's official report, shall be exempt from the provisions of this Act except as provided for in this subsection.

(4) REIMBURSEMENT.—A Coroner or Medical Examiner may require a person to reimburse their Office for the reasonable costs associated with such inspection or copying.

SEC. 208. HEALTH RESEARCH.

(a) RESEARCH SUBJECT TO THE COMMON RULE.—A health care provider, health plan, health researcher, public health authority, employer, life insurer, school, or university may use or disclose protected health information to a health researcher if the research involves human subjects or involves individually identifiable information as defined under the common rule and the researcher complies with the common rule.

(b) REVIEW OF THE COMMON RULE BY THE SECRETARY.—

(1) IN GENERAL.—The Secretary shall review the requirements of the common rule with respect to the confidentiality of protected health information and shall consider any necessary amendments to the common rule to ensure the confidentiality of infor-

mation that is subject to the rule. In conducting such review the Secretary shall consider—

(A) the extent to which the confidentiality of information is addressed under the common rule and during the institutional review board process; and

(B) the risks and benefits of the informed consent process (including waivers of informed consent) with respect to the confidentiality of protected health information.

(2) CONSULTATION.—In determining the adequacy of the common rule regulations with respect to the confidentiality of protected health information, the Secretary shall consult with individuals in the private sector with appropriate expertise and with other Federal agencies.

(c) RESEARCH NOT SUBJECT TO THE COMMON RULE.—A health care provider, health plan, health researcher, public health authority, employer, life insurer, school, or university may use or disclose protected health information to a health researcher if—

(1) the individual who is the subject of the protected health information, or the individual's representative, provides informed consent;

(2) the research proposal is reviewed and approved by an institutional review board; or

(3) the requirements of subsection (d) are met.

(d) USE OR DISCLOSURE OF PROTECTED HEALTH INFORMATION WITHOUT INFORMED CONSENT.—

(1) IN GENERAL.—A health care provider, health plan, health researcher, public health authority, employer, life insurer, school, or university shall formally designate an information protection officer pursuant to section 111 to review proposals that request the use or disclosure of protected health information for health research. Nothing in this subsection shall be construed as authorizing research involving intervention or interaction with a human subject without the explicit informed consent of such individual or the representative of the individual.

(2) INFORMATION PROTECTION OFFICER FUNCTIONS.—

(A) IN GENERAL.—An information protection officer shall review research proposals in accordance with paragraphs (3), (4) and (5) to determine—

(i) the need for protected health information; and

(ii) whether the waiver of informed consent to use protected health information is appropriate.

(B) WAIVER.—Informed consent may be waived under subparagraph (A)(ii) only if—

(i) the research involves no more than a minimal risk to the research subject with respect to the confidentiality of protected health information;

(ii) the waiver will not adversely affect the rights and welfare of the subject; and

(iii) the research could not practicably be carried out without the waiver.

(C) FAILURE TO MEET CRITERIA FOR WAIVER OF INFORMED CONSENT.—If the information protection officer determines that any of the criteria for a waiver of information consent under subparagraph (B) is not met, the information protection officer shall not permit the use or disclosure of protected health information without informed consent by the individual or review and approval of the research proposal by an institutional review board.

(D) AVOIDANCE OF BIASED REVIEWS.—Any compensation received by the information

protection officer shall not influence, bias, or be contingent on the information protection officer's determination with respect to the review.

(3) USE OF PROTECTED HEALTH INFORMATION FOR HEALTH RESEARCH WITHIN AN ENTITY.—

(A) IN GENERAL.—When the person in possession of protected health information and the researcher requesting protected health information are within the same entity, the information protection officer of such entity shall conduct a review of the research proposal pursuant to paragraph (2).

(B) INFORMATION IN POSSESSION OF RESEARCHER.—Except with respect to minor changes in previously approved research proposals, additional research uses of protected health information already in the possession of a researcher described in subparagraph (A) shall undergo review pursuant to paragraph (2).

(4) DISCLOSURE OF PROTECTED HEALTH INFORMATION FOR HEALTH RESEARCH BETWEEN ENTITIES.—When the person in possession of protected health information and the researcher requesting protected health information are not within the same entity, the information protection officer of each en-

tity shall each conduct a review of the research proposal pursuant to paragraph (2). If either of the information protection officers determines that any of the criteria for a waiver of informed consent under paragraph (2)(B) is not met, the disclosure of the protected health information shall be prohibited without informed consent by the individual or review and approval of the research proposal by an institutional review board.

(5) INFORMATION PROTECTION OFFICER DUTIES.—In additional to the duties required under section 111, an information protection officer shall—

(A) prepare and maintain adequate documentation of all research proposals reviewed, actions taken and the need for protected health information, and the basis for waiving or requiring informed consent; and

(B) maintain the confidentiality of any proprietary information, trade secrets, programmatic research investments, and other non-public research plans reviewed.

Nothing in subparagraph (B) shall be construed as prohibiting the review of information maintained under subparagraph (A).

SEC. 209. DISCLOSURE IN CIVIL, JUDICIAL, AND ADMINISTRATIVE PROCEDURES.

(a) IN GENERAL.—A health care provider, health plan, public health authority, employer, life insurer, law enforcement official, school, or university may disclose protected health information pursuant to a discovery request or subpoena in a civil action brought in a Federal or State court or a request or subpoena related to a Federal or State administrative proceeding, but only if the disclosure is made pursuant to a court order as provided for in subsection (b).

(b) COURT ORDERS.—

(1) STANDARD FOR ISSUANCE.—In considering a request for a court order regarding the disclosure of protected health information under subsection (a), the court shall issue such order if the court determines that without the disclosure of such information, the person requesting the order would be impaired from establishing a claim or defense.

(2) REQUIREMENTS.—An order issued under paragraph (1) shall—

(A) provide that the protected health information involved is subject to court protection;

(B) specify to whom the information may be disclosed;

(C) specify that such information may not otherwise be disclosed or used; and

(D) meet any other requirements that the court determines are needed to protect the confidentiality of the information.

(c) APPLICABILITY.—This section shall not apply in a case in which the protected health information sought under such discovery request or subpoena—

(1) is nonidentifiable health information;

(2) is related to a party to the litigation whose medical condition is at issue; or

(3) could be disclosed under any of sections 202 through 208, 210, and 211.

(d) EFFECT OF SECTION.—This section shall not be construed to supersede any grounds that may apply under Federal or State law for objecting to turning over the protected health information.

SEC. 210. DISCLOSURE FOR LAW ENFORCEMENT PURPOSES.

(a) IN GENERAL.—A health care provider, health plan, health oversight agency, employer, life insurer, law enforcement official, school, university, or person who receives protected health information pursuant to sections 203 through 208 (except if section 502(c) of the Controlled Substances Act (21 U.S.C. 872(c)) or section

301(d) of the Public Health Service Act (42 U.S.C. 241(d)) applies), may disclose protected health information under this section to a law enforcement official conducting or supervising a law enforcement inquiry pursuant to—

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

(2) an administrative subpoena or summons pursuant to Federal or State law, or judicial subpoena;

(3) a civil investigative demand pursuant to Federal or State law as issued by the Attorney General or a State official as authorized by State law;

(4) a warrant issued on a showing of probable cause;

(5) a law requiring the reporting of protected health information to law enforcement officials, including laws requiring the reporting of wounds, rape, or abuse or neglect;

(6) a request otherwise authorized under Federal or State law for the conduct of lawful intelligence activities conducted pursuant to the National Security Act of 1947 (50 U.S.C. 401 et seq.);

(7) a request made in connection with providing protective services to the President or other individ-

uals pursuant to section 3056 of title 18, United States Code; or

(8) any other court order.

Nothing in this section shall be construed to permit a person to refuse to disclose protected health information if required or obligated to do so by other statutory, regulatory, or compulsory processes. Nothing in this section shall be construed as affecting or altering the provisions of section 502(c) of the Controlled Substances Act (21 U.S.C. 872(c)) or section 301(d) of the Public Health Service Act (42 U.S.C. 241(d)). Nothing in this section shall be construed to prevent an audit or lawful investigation, pursuant to the authority of a governmental department or agency, of a research project conducted, supported, or subject to regulation by such department or agency.

(b) DESTRUCTION OR RETURN OF INFORMATION.—When the law enforcement need, investigation or proceeding for which protected health information was disclosed, including matters before a grand jury, has concluded, including any derivative matters which may have arisen from the original need, investigation or proceeding, the law enforcement agency or grand jury shall either destroy the protected health information, or return it to the person from whom it was obtained unless another applicable law

requires that the protected health information be retained by the law enforcement agency, including DNA database entries for sexual offenders. This subsection shall not apply to protected health information disclosed to an entity as provided for under paragraph (6) or (7) of subsection (a).

(c) REDACTIONS.—A law enforcement agency shall, when necessary to disclose protected health information in public forums (such as court filings or trials, or administrative proceedings, where the individual who is the subject of the protected health information has either not consented to the disclosure, or not put their health condition at issue)—

(1) redact the personally identifiable information to the extent practicable; or

(2) if not practicable, otherwise minimize, in a reasonable and appropriate manner, the public disclosure of protected health information.

(d) USE OF INFORMATION.—Protected health information obtained by a law enforcement agency pursuant to this section may only be used for purposes of a legitimate law enforcement inquiry.

(e) PRISON AND DETENTION FACILITIES.—Any person or detention or correctional facility that provides health care services to detainees, prisoners or inmates, or

a law enforcement official performing functions related to detention or correction, shall not be subject to the provisions of this Act with respect to the protected health information that is created through the provision of such health care services, so long as such information is used or disclosed only for the purposes of security, safety, corrections, probation, pardon, and parole or as otherwise authorized by Federal or State law or in order to provide health care services for that detainee, prisoner, or inmate.

(f) LIMITATION ON USE AND DISCLOSURE FOR LAW ENFORCEMENT INQUIRIES.—Protected health information about an individual that is disclosed under this section may not be used in any administrative, civil, or criminal action or investigation directed against the individual, unless the information is relevant to a legitimate law enforcement inquiry or as permitted under subsection (e).

(g) IDENTIFICATION OF INDIVIDUALS.—Notwithstanding subsections (a) and (b), a health care provider may, in response to a law enforcement inquiry, provide the name, address, social security number, date of birth, place of birth, type of injury, and date and time of treatment of an individual who received medical services from the health care provider if obtaining the identity of such individual is necessary for an official law enforcement inquiry.

(h) EXCEPTIONS.—Nothing in this section shall be construed to limit the provisions of section 206 that govern disclosures to a law enforcement official performing an official oversight function that is subject to such section.

SEC. 211. PAYMENT CARD AND ELECTRONIC PAYMENT TRANSACTION.

(a) PAYMENT FOR HEALTH CARE THROUGH CARD OR ELECTRONIC MEANS.—If an individual pays for health care by presenting a debit, credit, or other payment card or account number, or by any other electronic payment means, the entity receiving payment may disclose to a person described in subsection (b) only such protected health information about the individual as is necessary for the processing of the payment transaction or the billing or collection of amounts charged to, debited from, or otherwise paid by, the individual using the card, number, or other electronic means.

(b) TRANSACTION PROCESSING.—A person who is a debit, credit, or other payment card issuer, or is otherwise directly involved in the processing of payment transactions involving such cards or other electronic payment transactions, or is otherwise directly involved in the billing or collection of amounts paid through such means, may use or disclose protected health information about an individ-

ual that has been disclosed in accordance with subsection (a) only when necessary for—

(1) the authorization, settlement, billing or collection of amounts charged to, debited from, or otherwise paid by the individual using a debit, credit, or other payment card or account number, or by other electronic payment means;

(2) the transfer of receivables, accounts, or interest therein;

(3) the audit of the debit, credit, or other payment card account information;

(4) compliance with Federal, State, or local law, or

(5) compliance with a properly authorized civil, criminal, or regulatory investigation by Federal, State, or local authorities as governed by the requirements of this section.

SEC. 212. STANDARDS FOR ELECTRONIC DISCLOSURES.

The Secretary shall promulgate standards for disclosing, authorizing, and authenticating, protected health information in electronic form consistent with this title.

SEC. 213. INDIVIDUAL REPRESENTATIVES.

(a) IN GENERAL.—Except as provided in subsections (b) and (c), a person who is designated by the individual, authorized by law (based on grounds other than the indi-

vidual being a minor), or by an instrument recognized under law, to act as an agent, attorney, proxy, or other representative of a protected individual, may, to the extent so authorized, exercise and discharge the rights of the individual under this Act.

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

(c) NO COURT DECLARATION.—If a health care provider determines that an individual, who has not been declared to be legally incompetent, suffers from a medical condition that prevents the individual from acting knowingly or effectively on the individual's own behalf, the right of the individual to authorize disclosure under this Act may be exercised and discharged in the best interest of the individual by—

(1) a person described in subsection (b) with respect to the individual;

(2) a person described in subsection (a) with respect to the individual, but only if a person de-

scribed in paragraph (1) cannot be contacted after a reasonable effort;

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

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

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

(e) EXERCISE OF RIGHTS ON BEHALF OF A DECEASED INDIVIDUAL.—

(1) IN GENERAL.—A person who is authorized by law or by an instrument recognized under law, to act as an executor of the estate of a deceased individual, or otherwise to exercise the rights of the deceased individual, may, to the extent so authorized, exercise and discharge the rights of such deceased individual under this Act for a period of 2-years following the death of that individual. If no such designee has been authorized, the rights of the deceased individual may be exercised as provided for in subsection (c).

(2) INSURED INDIVIDUALS.—In the case of an individual who is deceased and who was the insured under an insurance policy or policies, the right to authorize disclosure of protected health information may be exercised by the beneficiary or beneficiaries of such insurance policy or policies.

SEC. 214. LIMITED LIABILITY FOR LAW ENFORCEMENT OFFICIALS.

Law enforcement officials when performing oversight functions or law enforcement inquiries shall not be personally liable for violations of this Act unless it is shown that the violation was committed with the intent to sell, transfer, or use protected health information for commercial advantage, personal gain or purpose, or malicious harm.

SEC. 215. NO LIABILITY FOR PERMISSIBLE DISCLOSURES.

A health care provider, health plan, health oversight agency, health researcher, public health authority, law enforcement official, prosecutor, employer, life insurer, school, or university, or an agent of such person, who makes a disclosure of protected health information about an individual that is permitted by this Act shall not be liable to the individual for such disclosure under common law.

SEC. 216. IMMUNITY.

Nothing in this Act shall be construed to waive or affect the defense of sovereign immunity of the United States. This Act shall not be construed to limit or supersede any immunity of a Federal or State employee except to the extent expressly provided in this Act. Nothing in this Act shall be construed to supplant the Equal Access to Justice Act (28 U.S.C. 2412 et seq.).

TITLE III—SANCTIONS

Subtitle A—Criminal Provisions

SEC. 301. WRONGFUL DISCLOSURE OF PROTECTED HEALTH INFORMATION.

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

"CHAPTER 124—WRONGFUL DISCLOSURE OF PROTECTED HEALTH INFORMATION

"Sec.
"2801. Wrongful disclosure of protected health information.

"§ 2801. Wrongful disclosure of protected health information

"(a) OFFENSE.—The penalties described in subsection (b) shall apply to a person that knowingly and intentionally—

"(1) obtains protected health information relating to an individual in violation of title II of the Health Information Confidentiality Act of 1999;

"(2) discloses protected health information to another person in violation of title II of the Health Information Confidentiality Act of 1999; or

"(3) uses protected health information in violation of title II of the Health Information Confidentiality Act of 1999.

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

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

"(2) if the offense is committed under false pretenses, be fined not more than $250,000, imprisoned not more than 5 years, or any combination of such penalties;

"(3) if the offense is committed with the intent to sell, transfer, or use protected health information for commercial advantage, personal gain, or malicious harm, be fined not more than $500,000, imprisoned not more than 10 years, excluded from participation in any federally funded health care programs, or any combination of such penalties.

"(c) SUBSEQUENT OFFENSES.—In the case of a person described in subsection (a), the maximum penalties described in subsection (b) shall be doubled for every subsequent conviction for an offense arising out of a violation

or violations related to a set of circumstances that are different from those involved in the previous violation or set of related violations described in such subsection (a).".

(b) CLERICAL AMENDMENT.—The table of chapters for part I of title 18, United States Code, is amended by inserting after the item relating to chapter 123 the following new item:

"124. Wrongful disclosure of protected health information ..... 2801".

Subtitle B—Civil Sanctions

SEC. 311. CIVIL PENALTY.

(a) VIOLATION.—A health care provider, health researcher, health plan, health oversight agency, public health agency, law enforcement agency, employer, life insurer, school, or university, or the agent of any such individual or entity, who the Secretary, in consultation with the Attorney General, determines has substantially and materially failed to comply with this Act shall be subject, in addition to any other penalties that may be prescribed by law—

(1) in a case in which the violation relates to title I, to a civil penalty of not more than $500 for each such violation, but not to exceed $5,000 in the aggregate for multiple violations;

(2) in a case in which the violation relates to title II, to a civil penalty of not more than $10,000

for each such violation, but not to exceed $50,000 in the aggregate for multiple violations; or

(3) in a case in which the Secretary finds that such violations have occurred with such frequency as to constitute a general business practice, to a civil penalty of not more than $100,000.

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

SEC. 312. PROCEDURES FOR IMPOSITION OF PENALTIES.

(a) INITIATION OF PROCEEDINGS.—

(1) IN GENERAL.—The Secretary may initiate a proceeding to determine whether to impose a civil money penalty under section 311 only as authorized by the Attorney General pursuant to procedures agreed upon by the Secretary and the Attorney General. The Secretary may not initiate an action under this section with respect to any violation described in section 311 after the expiration of the 6-year period beginning on the date on which such violation was alleged to have occurred. The Secretary may initiate

an action under this section by serving notice of the action in any manner authorized by Rule 4 of the Federal Rules of Civil Procedure.

(2) NOTICE AND OPPORTUNITY FOR HEARING.—The Secretary shall not make a determination adverse to any person under paragraph (1) until the person has been given written notice and an opportunity for the determination to be made on the record after a hearing at which the person is entitled to be represented by counsel, to present witnesses, and to cross-examine witnesses against the person.

(3) ESTOPPEL.—In a proceeding under paragraph (1) that—

(A) is against a person who has been convicted (whether upon a verdict after trial or upon a plea of guilty or nolo contendere) of a crime under section 2801 of title 18, United States Code; and

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

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

(4) SANCTIONS FOR FAILURE TO COMPLY.—The official conducting a hearing under this section may sanction a person, including any party or attor-

ney, for failing to comply with an order or procedure, failing to defend an action, or other misconduct as would interfere with the speedy, orderly, or fair conduct of the hearing. Such sanction shall reasonably relate to the severity and nature of the failure or misconduct. Such sanction may include—

(A) in the case of refusal to provide or permit discovery, drawing negative factual inferences or treating such refusal as an admission by deeming the matter, or certain facts, to be established;

(B) prohibiting a party from introducing certain evidence or otherwise supporting a particular claim or defense;

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

(D) staying the proceedings;

(E) dismissal of the action;

(F) entering a default judgment;

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

(H) refusing to consider any motion or other action which is not filed in a timely manner.

(b) SCOPE OF PENALTY.—In determining the amount or scope of any penalty imposed pursuant to section 311, the Secretary shall take into account—

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

(2) the degree of culpability, history of prior offenses, and financial condition of the person presenting the claims; and

(3) such other matters as justice may require.

(c) REVIEW OF DETERMINATION.—

(1) IN GENERAL.—Any person adversely affected by a determination of the Secretary under this section may obtain a review of such determination in the United States Court of Appeals for the circuit in which the person resides, or in which the claim was presented, by filing in such court (within 60 days following the date the person is notified of the determination of the Secretary) a written petition requesting that the determination be modified or set aside.

(2) FILING OF RECORD.—A copy of the petition filed under paragraph (1) shall be forthwith transmitted by the clerk of the court to the Secretary, and thereupon the Secretary shall file in the Court the record in the proceeding as provided in section

2112 of title 28, United States Code. Upon such filing, the court shall have jurisdiction of the proceeding and of the question determined therein, and shall have the power to make and enter upon the pleadings, testimony, and proceedings set forth in such record a decree affirming, modifying, remanding for further consideration, or setting aside, in whole or in part, the determination of the Secretary and enforcing the same to the extent that such order is affirmed or modified.

(3) CONSIDERATION OF OBJECTIONS.—No objection that has not been raised before the Secretary with respect to a determination described in paragraph (1) shall be considered by the court, unless the failure or neglect to raise such objection shall be excused because of extraordinary circumstances.

(4) FINDINGS.—The findings of the Secretary with respect to questions of fact in an action under this subsection, if supported by substantial evidence on the record considered as a whole, shall be conclusive. If any party shall apply to the court for leave to adduce additional evidence and shall show to the satisfaction of the court that such additional evidence is material and that there were reasonable grounds for the failure to adduce such evidence in

the hearing before the Secretary, the court may order such additional evidence to be taken before the Secretary and to be made a part of the record. The Secretary may modify findings as to the facts, or make new findings, by reason of additional evidence so taken and filed, and shall file with the court such modified or new findings, and such findings with respect to questions of fact, if supported by substantial evidence on the record considered as a whole, and the recommendations of the Secretary, if any, for the modification or setting aside of the original order, shall be conclusive.

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

(d) RECOVERY OF PENALTIES.—

(1) IN GENERAL.—Civil money penalties imposed under this subtitle may be compromised by the Secretary and may be recovered in a civil action in the name of the United States brought in United States district court for the district where the claim

was presented, or where the claimant resides, as determined by the Secretary. Amounts recovered under this section shall be paid to the Secretary and deposited as miscellaneous receipts of the Treasury of the United States.

(2) DEDUCTION FROM AMOUNTS OWING.—The amount of any penalty, when finally determined under this section, or the amount agreed upon in compromise under paragraph (1), may be deducted from any sum then or later owing by the United States or a State to the person against whom the penalty has been assessed.

(e) DETERMINATION FINAL.—A determination by the Secretary to impose a penalty under section 312 shall be final upon the expiration of the 60-day period referred to in subsection (c)(1). Matters that were raised or that could have been raised in a hearing before the Secretary or in an appeal pursuant to subsection (c) may not be raised as a defense to a civil action by the United States to collect a penalty under section 311.

(f) SUBPOENA AUTHORITY.—

(1) IN GENERAL.—For the purpose of any hearing, investigation, or other proceeding authorized or directed under this section, the Secretary shall have the power to issue subpoenas requiring

the attendance and testimony of witnesses and the production of any evidence that relates to any matter under investigation or in question before the Secretary. Such attendance of witnesses and production of evidence at the designated place of such hearing, investigation, or other proceeding may be required from any place in the United States or in any Territory or possession thereof.

(2) SERVICE.—Subpoenas of the Secretary under paragraph (1) shall be served by anyone authorized by the Secretary by delivering a copy thereof to the individual named therein, by registered mail or by certified mail addressed to such individual at his or her last dwelling place or principal place of business.

(3) PROOF OF SERVICE.—A verified return by the individual serving the subpoena under this subsection setting forth the manner of service, or in the case of service by registered mail or by certified mail, the return post-office receipt therefore signed by the individual so served, shall be proof of service.

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

(5) REFUSAL TO OBEY.—In case of contumacy by, or refusal to obey a duly served upon, any person, any district court of the United States for the judicial district in which such person charged with contumacy or refusal to obey is found or resides or transacts business, upon application by the Secretary, shall have jurisdiction to issue an order requiring such person to appear and give testimony, or to appear and produce evidence, or both. Any failure to obey such order of the court may be punished by the court as contempt thereof.

(g) INJUNCTIVE RELIEF.—Whenever the Secretary has reason to believe that any person has engaged, is engaging, or is about to engage in any activity which makes the person subject to a civil monetary penalty under section 311, the Secretary shall request the Attorney General bring an action in an appropriate district court of the United States (or, if applicable, a United States court of any territory) to enjoin such activity, or to enjoin the person from concealing, removing, encumbering, or disposing of assets which may be required in order to pay a civil monetary penalty if any such penalty were to be imposed or to seek other appropriate relief.

(h) AGENCY.—A principal is liable for penalties under section 311 for the actions of the principal's agent acting within the scope of the agency.

SEC. 313. REPORT ON USE OF EXISTING ENFORCEMENT MECHANISMS.

In addition to the criminal and civil penalties that may be applied under this title, the Secretary shall prepare and submit to Congress a report regarding the use of existing Federal, State and other licensure, certification and regulatory mechanisms, including State insurance regulations, for the imposition of sanctions or penalties for the wrongful disclosure of protected health information.

SEC. 314. CIVIL ACTION BY INDIVIDUALS.

(a) LIABILITY.—Any health care provider, health researcher, health plan, health oversight agency, public health agency, employer, life insurer, school, or university, or the agent of any such individual or entity who willfully and intentionally discloses protected health information in violation of this Act shall be liable to the individual to whom such information relates for—

(1) any economic losses sustained by the individual as a result of the disclosure;

(2) any non-economic damages sustained by the individual as a result of the disclosure, but in no

event shall an award of such damages exceed $50,000; and

(3) such preliminary and equitable relief as the court determines to be appropriate.

(b) LIMITATIONS.—No action may be commenced under subsection (a) with respect to the disclosure of protected health information concerning an individual after the expiration of the 2-year period beginning on the date on which the disclosure was or should have reasonably been discovered by the individual.

(c) EXCLUSIVE REMEDIES.—The remedies and sanctions described in this Act (and the amendments made by this Act) shall be the only authorized judicial remedies and sanctions for violations of this Act.

TITLE IV—MISCELLANEOUS

SEC. 401. RELATIONSHIP TO OTHER LAWS.

(a) STATE AND FEDERAL LAW.—

(1) STATE LAW ENACTED PRIOR TO DATE OF ENACTMENT.—

(A) IN GENERAL.—Except as provided in this section, the provisions of this Act shall preempt State laws enacted prior to the date of enactment of this Act to the following extent:

(i) COPYING, INSPECTION, AND AMENDMENT.—The provisions of title I re-

lating to the copying or inspection and amendment of protected health information shall preempt any such State law to the extent that such law relates to the right of an individual to inspect or copy protected health information pertaining to the individual, or the right of an individual with respect to the amendment of protected health information pertaining to the individual.

(ii) USE AND DISCLOSURE FOR TREATMENT, PAYMENT, AND HEALTH CARE OPERATIONS.—Section 202 shall preempt any such State law to the extent that such law relates to the use and disclosure of protected health information for purposes of treatment, payment or health care operations.

(iii) USE AND DISCLOSURE FOR RESEARCH.—Section 208 shall preempt any such State law to the extent that such law relates to the use and disclosure of protected health information for purposes of research.

(B) LIMITATION.—

(i) IN GENERAL.—Nothing in this Act shall be construed to preempt any provision of State law relating to the confidentiality of protected health information if such provision of State law is not a law of the type described in subparagraph (A).

(ii) MORE PROTECTIVE STATE LAWS.—No provision of this Act described in subparagraph (A) shall be construed to preempt any State law enacted prior to the date of enactment of this Act if such State law is more protective of the confidentiality rights of individuals than such provision.

(2) STATE LAW ENACTED AFTER DATE OF ENACTMENT.—Except as provided in subsections (b) and (c), the provisions of this Act described in paragraph (1)(A) shall preempt any related provisions of a State law pertaining to the confidentiality of protected health information if such law is enacted after the date of enactment of this Act.

(3) CONSISTENCY WITH OTHER FEDERAL LAWS.—

(A) IN GENERAL.—Nothing in this Act shall be construed as altering, amending, modifying, invalidating, impairing or superseding,

explicitly or implicitly, other Federal laws or regulations relating to protected health information or relating to an individual's access to protected health information or health care services.

(B) OTHER LAWS.—Nothing in this Act shall be construed to prevent an employer or its agent from using or disclosing protected health information necessary to comply with or consistent with exercising its rights and responsibilities under—

(i) the Americans with Disabilities Act of 1990 (29 U.S.C. 12101 et seq.) or any State or local law relating to discrimination on the basis of disability;

(ii) the Family and Medical Leave Act of 1993 (29 U.S.C. 2601 et seq.) or any State or local law relating to family and medical leave; or

(iii) the Occupational Safety and Health Act of 1970 (29 U.S.C. 651 et seq.), the Federal Mine Safety and Health Act of 1977 (30 U.S.C. 801 et seq.), or any State or local law relating to workplace safety and health.

It shall not be considered a violation of this Act if an employer or its agents use or disclosure of its protected health information is limited to the purpose of exercising its rights and responsibilities under the laws described in this subparagraph.

(4) MINORS.—Nothing in this Act shall be construed to preempt, modify, repeal or affect the interpretation of a provision of Federal or State law that relates to the disclosure of protected health information or any other information about a minor to a parent or guardian of such minor.

(b) PRIVILEGES.—Nothing in this section shall be construed to preempt or modify any provision of State statutory or common law to the extent that such law concerns a privilege of a witness or person in a court of that State. This title shall not be construed to supersede or modify any provision of Federal statutory or common law to the extent such law concerns a privilege of a witness or person in a court of the United States. Authorizations pursuant to sections 202 shall not be construed as a waiver of any such privilege.

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

(1) the use and disclosure of information pertaining to mental health; or

(2) the use and disclosure of information pertaining to public health consistent with section 207; to the extent that such State law prevents or otherwise restricts the use and disclosure of protected health information otherwise permissible under this Act.

(d) STATE FLEXIBILITY IN LAWS PROTECTING HEALTH INFORMATION RELATED TO PROPERTY-CASUALTY INSURANCE.—

(1) FLEXIBILITY IN GENERAL.—

(A) NONAPPLICATION.—The requirements of this Act shall not apply to any person in connection with providing, administering, supporting, or coordinating benefits excepted under any of subparagraphs (B) through (F) and (H) of section 2791(c)(1) of the Public Health Service Act (42 U.S.C. 300gg-91(c)(1)(B)-(F) and (H)).

(B) PREEMPTION.—State laws that protect the confidentiality of health information used or disclosed in connection with any of the benefits described in subparagraph (A), shall not be preempted with respect to the application of such laws to such benefits.

(2) REVIEW OF STATE LAWS.—It is the sense of the Senate that—

(A) each State should review its laws to ensure that the confidentiality of protected health information used or disclosed in connection with any of the benefits described in paragraph (1)(A) is consistent with the purposes of this Act;

(B) the review under subparagraph (A) should examine—

(i) the purposes for which such information is collected and used;

(ii) the extent to which beneficiaries are informed of such uses;

(iii) the feasibility of an authorization process; and

(iv) the impact of confidentiality restrictions on the administration of these benefits;

(C) the review under subparagraph (A) should examine the use and disclosures of protected health information pursuant to State public records and freedom of information laws.

(3) REPORT.—Not later than 24 months after the date of enactment of this Act, the General Ac-

counting Office, in consultation with the National Association of Insurance Commissioners and other interested parties, shall submit a report to Congress concerning the adequacy of State laws in providing the protections for protected health information described in paragraph (2).

(e) FEDERAL PRIVACY ACT.—

(1) MEDICAL EXEMPTIONS.—Sections 552a of title 5, United States code, is amended by adding at the end thereof the following: "The head of an agency that is an entity described in section 311 (a) of the Health Information Confidentiality Act of 1999 shall promulgate rules, in accordance with the requirements (including general notice) of subsections (b)(1), (b)(2), (b)(3), (c), and (e) of section 553 of this title, to exempt a system of records within an agency, to the extent that the system of records contains protected health information (as defined in section 4(23) of such Act), from all provisions of this section except subsections (b)(6), (d), (e)(1), (e)(2), subparagraphs (A) and (C) and (E) through (I) of subsection (e)(4), and subsections (e)(5), (e)(6), (e)(9), (e)(12), (l), (n), (o), (p), (r), and (u).".

(2) TECHNICAL AMENDMENT.—Section 552a(f)(3) of title 5, United States Code, is amend-

ed by striking "pertaining to him." and all that follows through the semicolon and inserting "pertaining to the individual."

(f) APPLICATION TO CERTAIN FEDERAL AGENCIES.—

(1) DEPARTMENT OF DEFENSE.—

(A) EXCEPTIONS.—The Secretary of Defense may, by regulation, establish exceptions to the disclosure requirements of this Act to the extent such Secretary determines that disclosure of protected health information relating to members of the armed forces from systems of records operated by the Department of Defense is necessary under circumstances different from those permitted under this Act for the proper conduct of national defense functions by members of the armed forces.

(B) APPLICATION TO CIVILIAN EMPLOYEES.—The Secretary of Defense may, by regulation, establish for civilian employees of the Department of Defense and employees of Department of Defense contractors, limitations on the right of such persons to revoke or amend authorizations for disclosures under section 203 when such authorizations were provided by such

employees as a condition of employment and the disclosure is determined necessary by the Secretary of Defense to the proper conduct of national defense functions by such employees.

(2) DEPARTMENT OF TRANSPORTATION.—

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

(B) APPLICATION TO CIVILIAN EMPLOYEES.—The Secretary of Transportation may, with respect to civilian employees of the Coast Guard and Coast Guard contractors, exercise the same powers as the Secretary of Defense may exercise under paragraph (1)(B).

(3) DEPARTMENT OF VETERANS AFFAIRS.—The limitations on use and disclosure of protected health information under this Act shall not be construed to prevent any exchange of such information within and among components of the Department of Veterans Affairs that determine eligibility for or entitlement to, or that provide, benefits under laws administered by the Secretary of Veteran Affairs.

(4) CENTRAL INTELLIGENCE AGENCY.—

(A) EXCEPTIONS.—The Director of the Central Intelligence Agency may, by regulation, establish exceptions to the disclosure requirements of this Act to the extent that the Director determines that disclosure of protected health information, relating to officers and employees of the Central Intelligence Agency and contractors of such Agency, is necessary to the conduct of lawful intelligence activities conducted pursuant to the National Security Act of 1947 (50 U.S.C. 401 et seq.).

(B) APPLICATION TO OFFICERS, EMPLOYEES AND CONTRACTORS.—The Director of the Central Intelligence Agency may, by regulation, establish, for officers, employees and contractors of the Central Intelligence Agency, limitations on the rights of such persons to revoke or amend authorizations for disclosures under section 203 when such authorizations were provided by such officers, employees and contractors as a condition of employment or contract and the disclosure is determined necessary by the Director to the conduct of lawful intelligence activities conducted pursuant to the Na-

tional Security Act of 1947 (50 U.S.C. 401 et seq.).

(g) NO INTERFERENCE WITH STATE AUTHORITY TO REGULATE INSURANCE.—Except as specifically provided for in this Act, nothing in this Act, including sections 301, 311, and 312, shall be construed as interfering with the exclusive authority of a State insurance commissioner (or similar State official) to regulate an entity engaged in the business of insurance in the State of such commissioner (or official) with respect to the business of insurance of such insurance company.

SEC. 402. RESULTS OF DRUG TESTS.

For purposes of this Act, the results of a test required by an employer or its agent to determine the illegal use of drugs shall not be considered protected health information but such results may only be used as otherwise permitted under Federal or State law.

SEC. 403. STUDY BY INSTITUTE OF MEDICINE.

Not later than 2 years after the date of enactment of this Act, the Institute of Medicine of the National Academy of Sciences shall conduct a study to examine health care operation activities relating to protected health information, such as the need for protected health information to carry out the functions of the health plan or provider and the relationship between providing treatment and con-

ducting internal business functions, as well as current and proposed protection of health information in relation to the legitimate needs of health care providers and health plans. The Institute of Medicine shall prepare and submit to Congress a report concerning the results of such study.

SEC. 404. EFFECTIVE DATE.

(a) EFFECTIVE DATE.—Except as provided in subsection (b), this Act shall take effect on the date that is 24 months after the date of enactment of this Act.

(b) REGULATIONS.—The Secretary, in consultation with other agencies, as appropriate, shall promulgate regulations implementing this Act not later than 12 months after the date of enactment of this Act.

OPTIONAL FORM 99 (7-90)

FAX TRANSMITTAL # of pages ▶ 4

To Chris Jennings	From 6-5557
Dept./Agency Exec Office	Phone # 5-7245
Fax #	Fax #

NSN 7540-01-317-7368 5099-101 GENERAL SERVICES ADMINISTRATION

June 8, 1999

URGENT

Note for:

L. Sierra, OMB

From: Greg Jones DOJ

Re: Treasury letter

I received this after the deadline. It's hard to provide views on this, since Treasury basically doesn't identify the provisions on which they are commenting. Given timing, a disclaimer should be added to the effect that time did not permit a thorough interagency review.

NB: The language re: protection of health information should be struck. The provision in this bill (if that's what they are talking about) that concerns the protection of health information appears to amount to a new restriction on law enforcement on access to medical information. We are opposing this kind of thing in a much larger context involving DOJ, HHS, the White House, and OMB. (In fact medical records privacy legislation is to be marked up in the Senate on 6/15.) Treasury has not (I think) been a player in that debate and should not be opining on it here. Bob Pellicci is the LRD person on this and can fill you in. In any event, HHS would want to be included in the circulation of any letter on this matter.

I will let you know if I hear from anyone else this afternoon.

Also, we may have comments on other financial privacy aspects of this legislation. For example, sec. 179 includes a new criminal provision. We would want to be sure the FTC doesn't think it's going to enforce it.

U.S. Department of Justice
Office of Legislative Affairs

Office of the Assistant Attorney General Washington, D.C. 20530

May 28, 1999

The Honorable James M. Jeffords
Chairman
Committee on Health, Education, Labor and Pensions
United States Senate
Washington, D.C. 20510

Dear Mr. Chairman:

Thank you for the opportunity to present the views of the Department of Justice on behalf of the law enforcement community on pending legislation to protect the confidentiality of personal medical information. We look forward to working with the Committee to protect the privacy of confidential health information, while preserving the ability of Federal, state and local law enforcement agencies to enforce the laws within their jurisdictions and to oversee the integrity of the health care payment system.

The Department recognizes that additional safeguards are necessary to prevent future abuses of medical records privacy, particularly in response to the growing use of computers to store, analyze, and distribute confidential health information. Morever, the Department believes it would be appropriate to establish reasonable restrictions on law enforcement access to, and use of, confidential health information that reflect current law and practice. The Department offers the following specific suggestions on how to strike the appropriate balance between the need to protect confidential health information and the need to protect public health and safety and investigate and punish illegal activity.

At a minimum, medical records privacy legislation should prohibit Federal, state and local law enforcement agencies and employees from obtaining or using such information except for official law enforcement activities. In addition, as a general principle, we believe it would be appropriate to codify current practice by requiring law enforcement to use lawful compulsory process, such as a search warrant, grand jury subpoena, summons, warrant, judicial subpoena, administrative subpoena or a civil investigative demand in order to obtain protected health information; provided, that the legislation include limited but important exceptions, discussed below, that are necessary to protect public health and safety.

The Department supports legislation that requires law enforcement agencies to take appropriate and reasonable steps to minimize the public disclosure of identifiable health

information, consistent with the requirements of due process and the needs of law enforcement to present a complete case. Law enforcement also should be required to destroy or return medical records to the original record holder when the official law enforcement activity requiring the retention of those records has concluded, and no other applicable law or regulation requires that the medical records be retained.

We support reasonable restrictions on law enforcement access to and use of confidential health information. We also believe medical records privacy legislation should not unduly hinder the ability of Federal, state and local law enforcement to investigate and prosecute illegal activity and to protect the integrity of the health care payment system. Thus, we believe the requirement for law enforcement to use compulsory process, discussed above, should not apply in four circumstances: (1) when law enforcement is performing a health oversight function authorized by law (subject to the derivative use limitations discussed below); (2) pursuant to Federal, state or local mandatory reporting laws (including laws requiring the reporting of gunshot wounds, rapes, abuse of children or the elderly, or diversion of controlled substances); (3) in time-sensitive circumstances to prevent threatened or imminent physical harm to any person; and (4) to obtain limited name or other essential identifying information, but not the entire medical file, to enable law enforcement to locate and identify a patient who is a fugitive, suspect, or material witness.

With respect to the issue of derivative use, there are special concerns that may arise when law enforcement obtains access to large numbers of health records during health oversight activities. Therefore, we recommend that law enforcement should not be permitted to use information discovered during the oversight function against a patient for an unrelated, non-health care matter, unless authorized by a court under procedures similar to those in 18 U.S.C. 3486(e). However, because these concerns are not replicated when law enforcement obtains health records in non-health oversight law enforcement activities pursuant to compulsory process, any legislation should reflect current law which provides no restriction on the derivative use of confidential health information obtained by a law enforcement agency in the discharge of its general (i.e., non-health oversight) enforcement responsibilities.

Finally, we believe jails, prisons and detention facilities present unique situations with respect to medical records privacy. While the Department supports legislation that prohibits correctional facilities and employees from disclosing, using or obtaining medical information for non-official purposes, we believe such institutions should be exempted from the general obligations and duties imposed by medical record privacy legislation. These facilities also should be permitted to exchange prisoner or detainee health records without patient authorization with community health care providers providing health care services to the prisoners or detainees.

There are other technical drafting issues on which we would like to work with the Committee, including issues relating to certain definitions, the procedures for the imposition of penalties for violations, and government legal department access to health records from governmental departments and agencies while representing these bodies in civil matters prior to the initiation of legal proceedings.

Thank you for your attention to this matter. If we may be of additional assistance we trust that you will not hesitate to call upon us. The Office of Management and Budget has advised that there is no objection from the standpoint of the Administration's program to the presentation of this report.

Sincerely,

Jon P. Jennings

Jon P. Jennings
Acting Assistant Attorney General

cc: The Honorable Edward M. Kennedy
Ranking Minority Member

THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

JUN 15 1999

The Honorable James M. Jeffords
Chairman
Committee on Health, Education, Labor, and Pensions
United States Senate
Washington, D.C. 20510

Dear Chairman Jeffords:

On behalf of the Administration, I want to thank you and the other members of the Committee for working in a cooperative, bipartisan manner to bring the "Health Information Confidentiality Act of 1999" to markup. While we are unable to support this legislation in its current form, we hope to continue working with you and your colleagues to resolve our remaining concerns prior to final Committee action. With further improvements, this legislation has the potential to help us to achieve the goal of so many Americans – the right to privacy for medical and health information.

The President has indicated his strong desire to see the Congress enact a comprehensive medical privacy bill this year. At the same time, we are working hard to make sure the Department is prepared to go forward with the regulations specified under HIPAA, if Congress is unable to pass such a bill. As the President said in his State of the Union Address:

> "As more of our medical records are stored electronically, the threats to all our privacy increase. Because Congress has given me the authority to act if it does not do so by August, one way or another, we can all say to the American people, we will protect the privacy of medical records and we will do it this year."

As you know, the Committee has made progress in a number of areas, including: limits on the use and disclosure of health information; providing notice to individuals about how their information may be used and restricting its use; adding a new standard for how private sector researchers use identifiable health information; and restricting the use of information beyond the entity that originally collected it. However, we continue to have serious concerns about the following provisions: meaningful enforcement provisions, State preemption, privileges, and the ability of entities to use personal information for underwriting.

With regard to areas of progress, we are pleased to see that the Chairman's mark places important limits on the ways that health plans, providers and other health care-related organizations and individuals, as well as employers, use and disclose personal health information. The mark incorporates changes clarifying that these limits apply both to disclosures between health care organizations as well as to disclosures and uses within such organizations, and requiring that protected health care information be provided to and used by only those individuals necessary to accomplish the purpose for which the information was obtained.

For example, an employer generally could not disclose protected information gathered for the purpose of health care treatment and payment by the employer's group health plan to managers charged with job performance or job placement functions. These limits are vital if Americans are to have confidence that they can seek treatment under their health insurance without fear that their personal information could be used against them in the workplace.

Similarly, we are very encouraged to see the Committee recognize that it should be unlawful for someone to disclose information that is not identifiable with the knowledge that the recipient of the information will wrongly reidentify it. We could not support a bill that includes loopholes that allow disclosure of information from which identifiers have been stripped or encoded to people who intend to reidentify that information.

We are also encouraged that the notice and authorization provisions together will provide consumers with the crucial information they need to understand how their health information will be used and their rights and responsibilities with respect to that information. While the notice provisions are vastly improved, we continue to have concerns regarding a provision that would make use of a model notice an "absolute defense" to a claim of inadequate notice, even if the information contained in the notice was not accurate for the circumstances in which it was used. While use of the model should provide some special legal protection, it should only do so if it accurately reflects the health plan's actual information practices. We remain concerned that, as a practical matter, the mark's framework for obtaining authorizations and revocations could prove unworkable. In particular, it is not clear how important information about a patient's authorization and revocation is communicated among the plans and providers who need that information in order to make the bill's protections real.

With respect to non-federally funded health research, we are pleased that the Committee has included a review mechanism for researchers who wish to use medical records without obtaining a patient's prior authorization. We believe this section would be strengthened to provide greater protection for the public if some form of independent oversight were incorporated into this new process.

We are also pleased that the bill now makes clear that the allowable uses of protected health care information for health care operations apply only within the health plan or provider (and their agents) that originally obtains the information. Any sharing beyond that entity requires a separate authorization. Even within the entity, the allowable uses could not be expanded beyond those for the purpose of the delivery of health benefits.

In today's ever expanding, technology-based environment, it is becoming easier and easier to identify individuals with only tidbits of either demographic or personal information. Because the Chairman's mark has a loose definition of "non-identifiable information", it is imperative that it be a crime for anyone to transmit the 'key' that allows such information to become identifiable.

Disclosing the key to reidentify such information is no different than disclosing the identified information itself, and should be just as unlawful. The bill to be considered today reflects your concern for this issue and we appreciate recognition of this important prohibition.

While the improvements to your legislation have been significant, we have serious concerns and believe changes are necessary in important areas of the bill. First, we believe that the strength of any law conveying rights to individuals is their ability to enforce such rights. Our medical records hold the most intimate information about us. Yet the framework in the Chairman's mark through which individuals could enforce their rights is significantly weaker than the Video Privacy Protection Act. That statute, passed just one month after introduction and signed by President Reagan in 1988, includes a better standard of proof for individuals, a wider array of uncapped damages, as well as attorneys' fees. I think we would all agree that an individual's rights to medical records privacy should be at least as strong as the privacy protections governing his or her video rentals.

The current standard in the Chairman's mark for civil remedies – "willful and intentional"-- is unprecedented as a condition for liability in a private right of action under any federal statute. This standard places the bar for a plaintiff so high as to make the right of action meaningless. When information about our video rentals is wrongfully disclosed, federal law allows recovery of damages if that disclosure was "knowing." Medical records, which hold our most personal information, should be subject to at least this level of protection.

In addition, the limited remedies available under the bill could severely impair an individual's ability to find counsel to assist them in enforcing their rights. Restricting the award of noneconomic damages to $50,000 is unreasonable, and would have a disproportionate effect on those who have been subjected to the greatest harm. Further, not all harms stemming from wrongful disclosure of private health information are easily quantifiable. Wrongful disclosure of medical information can have dramatic effects on a person's reputation and standing in the community.

We also have serious concerns with the effect of language included in the Chairman's mark on state laws that pertain to minors and their rights to either permit or prevent access to their health information. We urge that the bill strike a balance and not disrupt any state law currently in effect.

Mr. Chairman, as you know, the Administration's general view is that federal statutes that establish new health protections for individuals should set a floor upon which states can build to address their unique circumstances. While we appreciate your inclusion of provisions to protect existing and future State laws governing public and mental health, we are concerned, in general, about a statutory design that preempts State laws. We intend to consider this issue carefully as we work with you to further strengthen the federal protections included in this legislation.

Finally, we are extremely concerned that this bill would allow unfettered access to and use of genetic information, under the guise of underwriting, in a way that undermines laws prohibiting such discrimination. Given the Committee's past interest in addressing such discrimination, we urge that the language be dropped from the bill, so that no one can misconstrue the intent of the bill.

In closing, let me reiterate that we appreciate the bipartisan progress that has been made, but regret that we cannot support the bill moving forward in Committee at this time. We look forward to working with you and the other Committee members to address the Administration's remaining concerns.

Sincerely,

Donna E. Shalala

cc: Senator Edward Kennedy

NACDS

National Association of Chain Drug Stores

Facsimile Cover Sheet

To: CHRIS JENNINGS

Company: DOMESTIC POLICY COUNCIL
Fax: 202-456-5557
Phone:

From: Rob Hartwell
Fax: (703) 549-0772
Phone: (703) 549-3001
Date: Thursday, May 27, 1999 07:13AM

Total Pages: 14

Message:

Just wanted to get an advanced copy of our Commerce Health Subcommittee testimony to you.

Hope all is well and that you have a great recess.

Best wishes,

Rob Hartwell

413 North Lee Street, P.O. Box 1417-D49, Alexandria Virginia 22313-1480 Phone: 703-549-3001 Fax: 703-836-4869

Medical Records Confidentiality in the Modern Delivery of Health Care

Testimony submitted by

Mr. Daniel L. Krinsky, RPh, MS
Director, Patient Services and Pharmacy Practice

Ritzman Pharmacies, Inc.

on behalf of

NACDS

National Association of Chain Drug Stores

to the

House Commerce Committee
Subcommittee on Health and Environment

on

May 27, 1999

Mr. Chairman and Members of the Subcommittee, The National Association of Chain Drug Stores (NACDS) appreciates the opportunity to present testimony today regarding the important issue of protecting the confidentiality of patient medical records in today's modern health care delivery system.

Founded in 1933 and based in Alexandria, Virginia, the NACDS membership consists of over 130 retail chain community pharmacy companies. Collectively, chain community pharmacy comprises the largest component of pharmacy practice with over 93,000 pharmacists. The chain community pharmacy industry is comprised of over 19,000 traditional chain drug stores, 7,000 supermarket pharmacies and nearly 5,000 mass merchant pharmacies. NACDS members operate more than 31,000 retail community pharmacies with annual sales totaling over $135 billion including prescription drugs, over-the-counter (OTC) medications and health and beauty aids (HBA). Chain operated community retail pharmacies fill over 60% of the more than 2.73 billion prescriptions

dispensed annually in the United States. Additionally, NACDS membership includes more than 1,400 suppliers of goods and services to chain community pharmacies and 96 international members from 26 foreign countries.

Executive Summary: NACDS Supports a Strong National Law

Let me begin by stating that NACDS supports enactment of a strong Federal confidentiality law that will preempt the patchwork of existing state laws and protect patient privacy. We want our patients to have confidence that their personal information is secure, while allowing chain pharmacies to appropriately utilize medical information as health care providers to maintain and improve patient

care.

On this note, I'd like to point out that NACDS has endorsed S. 881, "*The Medical Information Protection Act of 1999,*" introduced by Senator Robert Bennett (R-UT). Senator Bennett has been working to perfect his legislation for over five years and the resulting "Bennett bill" is the most comprehensive and thoughtful medical records privacy legislation introduced in Congress to date. While the legislation rightfully imposes tough penalties for the misuse of confidential patient information, it is carefully balanced to allow providers sufficient flexibility to appropriately utilize patient information to optimize patient care. It would also protect patient data without the inconvenience of burdensome paperwork on patients and providers.

NACDS also has worked for years to take a leading role on protecting patient privacy. Attached to my statement are ten "*Principles to Protect the Confidentiality of Consumer Medical Records*" that our industry created and continually updates to ensure chain pharmacies operate with protecting

patient privacy as a top priority.

Key Pharmacy Confidentiality Legislative Issues

Because retail pharmacies process about fifty percent of all health care payment claims, it is important that new Federal requirements for patient confidentiality not have a disproportionate effect on the ability of retail pharmacies to operate efficiently or provide integrated, comprehensive patient-oriented prescription services. NACDS supports Federal standardization of patient confidentiality safeguards that includes:

- **Federal Pre-emption of State Laws:** There are approximately 31,000 chain community pharmacies, many of which operate across state lines. However, more and more states have been enacting their own new (and differing) privacy laws and regulations, making it increasingly difficult for multi-state pharmacies to understand and comply with these laws in an efficient manner. Adding another Federal law on top of this or trying to determine which law is stronger, as some bills calls for, would create even more challenges for multi-state pharmacy operations.

Conflicts between Federal and state law could be virtually impossible for health care providers to identify and resolve on a patient-specific basis. Moreover, does the law in the state in which the patient resides prevail, or does the law in the state in which the product or service is being provided govern the transaction? This question is particularly important for pharmacies located near state borders.

Without Federal preemption, patients will be required to wait longer to obtain their prescription medications because pharmacies will be required to take additional time to determine whether to follow a specific provision of state or Federal law. For each patient, the pharmacist must first identify any conflicts between provisions of Federal and state law and then compare those provisions to determine which is the most restrictive. The pharmacist must make these two legal decisions while patients, or their designees, are waiting for their medications.

Making legal decisions is a job for attorneys, NOT for health care providers who are trying to

provide medication as efficiently and expeditiously as possible to sick patients. The impact on our patients is our most paramount concern, and, therefore, NACDS supports a comprehensive Federal standard that preempts state confidentiality laws.

- **A Single Consolidated Authorization for the Use and Disclosure of Personally-Identifiable Health Information (PHI):** NACDS supports the use of a single consolidated authorization for the purpose of obtaining patient authorization to use and disclose PHI for payment, treatment and health care operations. Such authorization is provided at the time that the patient enrolls in a health plan, or when an uninsured patient provides an authorization for these purposes to an "originating provider" of a prescription. Under this approach, the patient's prescription will be sufficient to use PHI for the purpose of practicing pharmacy as defined in state practice laws and by regulatory boards. This approach also limits the recordkeeping and reporting burdens of the patient or the provider.

To maximize patient convenience, any Federal confidentiality law must require employers, health plans, and originating providers to obtain from the patient a single consolidated authorization to use and disclose that patient's personally identifiable health care information for the purposes of treatment, payment, and health care operations.

Down-stream health care providers MUST be able to legally assume that the single consolidated authorization has been obtained, otherwise these providers will be forced to require patients to

take the time to fill out an additional separate authorization form to protect themselves from litigation alleging a breach of the patient's confidentiality.

Since up to 40% of patients have others pick up or deliver both new and refill prescriptions, obtaining the additional separate authorization from all patients would be next to impossible. Imposing a requirement that the patient personally pick up a prescription would inconvenience the patient and could jeopardize the health of the elderly, children, or the infirm who can't otherwise physically get to the drug store. Under some legislation already introduced, prescriptions could not be refilled until patients have signed the necessary multi-point authorization form, causing yet another patient inconvenience.

- **Recognition of Pharmacy Practice Activities as a "Continuum of Care":** In 1990, Congress passed the Omnibus Budget Reconciliation Act (OBRA 90), which recognized that

delivering pharmacy services involves more than just filling an original prescription. The role of the pharmacist, which continues to evolve, includes enhancing outcomes from medication use. Pharmacy providers engage in a wide range of activities that use PHI. These include refill reminder programs, prospective and retrospective drug use review, disease management, physician-pharmacy collaborative practice agreements, and formulary management.

Moreover, given that over 70 percent of all prescriptions are "managed" by pharmacy providers for PBMs and third party payors, pharmacies are often contractually obligated to provide some of these services, to a range private and public plans, including Medicare + Choice plans, Medicaid and some Federal Employee Health Benefit (FEHBP) plans. NACDS believes that any new

Federal law should recognize that pharmacy is an evolving health profession whose role is to enhance appropriate outcomes from medication use through a continuum of care approach.

The definitions of health care and treatment in any confidentiality legislation should include compliance programs, refill reminder programs and pharmacy programs recognized by Federal and state agencies as disease management programs. Any Federal confidentiality law must recognize and provide flexibility for the evolving role of community pharmacy in the health care system. Most recently, the Health Care Financing Administration issued regulations reimbursing diabetes education management programs in pharmacies and many states recognize the value of pharmacy professionals providing educational and counseling services.

Implementation Issues for Retail Pharmacies

There are several important issues for chain community pharmacy relating to the implementation of

new Federal privacy laws. Some of the more important considerations include:

Originating Providers: NACDS supports the rights of patients to inspect, copy and amend their medical records, and that the originating provider is the appropriate place for these operations to occur. Originating providers are those that initially prescribe a course of treatment and create the historical medical record, such as health plans, physicians or emergency rooms.

The originating provider of the prescription must be the primary source for patients to access,

copy, and amend their health care information.

Audit Trail Related to Disclosures: Some proposals would require pharmacies to maintain records for seven years and document each and every case in which PHI was disclosed - such as the date, purpose, and description of information disclosure - even when PHI is used for treatment or obtaining payment.

Such requirements would create tremendous time and work burdens on pharmacy providers, given that PHI is used for multiple operations each day to assure that the patient receives the appropriate therapy, the pharmacy meets operational guidelines of third party payors, and the pharmacy is reimbursed for providing the service. Such a proposal would result in enormous if not impossible workload requirements on our pharmacists and disclosure records would number in the multiple billions. The benefit of an audit trail and how often it is used must be weighed

against the increased costs to the health care delivery system.

Sufficient Time to Modify Computer Systems: Like most health care providers, chain pharmacies have invested in expensive and sophisticated computer software systems to help process claims and help deliver pharmacy services. NACDS believes that a realistic time frame is needed to implement new uniform confidentiality standards, including time to develop software and hardware, test and distribute new products, and train employees in their use. Retail pharmacy estimates a minimum of 18 months would be needed to implement a new confidentiality law, once a law is passed or regulations are finalized.

Use of NCPDP Standards: The entire pharmaceutical industry relies on the National Council for Prescription Drug Programs (NCPDP) to establish standards for electronic transmission of prescription payment claims. Any new Federal confidentiality law must recognize the important role that NCPDP has and should continue to have as a standard-setting organization for the billions of retail pharmacy payment claims.

Other Key Issues

Other issues not specific to pharmacies are also extremely important to the entire health care continuum. Expanding or creating new Federal regulatory oversight of health provider operations must be examined carefully. Patient care must not be compromised in the name of added paperwork; consumer costs must not be driven up by excessive regulation; and basic common sense protections for privacy must take precedence.

For instance, creating an entire new right of private action specific to privacy should not be necessary. Consumers currently have legal recourse to sue if their medical records are used inappropriately.

In addition, especially when it comes to prescription drugs, falsely obtaining a prescription drug or controlled substance without a valid script from a physician can result in severe penalties and prosecution under Federal and state law. The penalties included in legislation introduced to date are severe, and would certainly deter any effort by a business or entity to illegally use or disclose patient identifiable information.

Let me reiterate that the use of electronic records and technology, if carefully coordinated and protected, results in a much safer and secure system that protects patient confidentiality, while providing for optimum care. Avoiding millions of pieces of paperwork that must be filed and maintained increases the protection of health care records.

Because this issue is so complex and so dependent upon the use of technology, detailed attention must be given to the coordination of technology and health care systems. It is critical that legislators and regulators "get it right." As was seen earlier this year in the state of Maine, a law that may sound good to consumers, but is not perfected before implementation, can disrupt the entire health care system. The Maine law was suspended by the legislature after being in effect for just two weeks and is currently under a two-year review.

In conclusion, we applaud you for holding this hearing on this complex but critical issue. With my

testimony, I have also attached a list of key implementation issues and questions for persons to think about when drafting provisions with a potential impact on pharmacy. Thank you for providing me with the opportunity to testify today on behalf of Ritzman Pharmacies and NACDS. I'll be glad to answer any questions you may have.

Attachment 1

NACDS Principles to Protect the Confidentiality of Consumer Medical Records

1) **Patients Have the Right to Know Who May Access, Use, Share, or Further Disclose, Patient Identifiable Health Care Information.** Insured patients' informed consent must be in writing, signed, and obtained by either the employer or the health plan. Uninsured patients' informed consent must be in writing, signed, and obtained by the originating provider who prescribes or orders the health care services.

2) **A Patient's Informed Consent Should Authorize...** health care providers to access, use, and share or further disclose patient identifiable health care information, to: 1) Provide treatment; 2) Seek payment; 3) Manage programs which improve outcomes and health care quality or result in reduced costs to consumers; and, 4) Undertake health care operations and utilize sufficient administrative information to support all of the above.

3) **One National Law...** must be the product of a national debate to assure confidentiality of patient medical records, while at the same time promoting quality of care and not unnecessarily increasing health care costs. It will be much easier for both patient and health care provider to understand and comply with one national law rather than 51 laws... a national law plus 50 different state laws.

4) **Employers Must be Prohibited from Accessing Patient Identifiable Health Care Information...** unless the patient signs a separate informed consent form.

5) **Non-Patient Care or Marketing Activities...** must be authorized by a separate patient consent for programs that are outside of the scope of treatment, payment, management of programs which improve outcomes and health care quality or result in reduced costs to consumers, and health care operations/administrative information

6) **"Treatment"...** is defined as everything that state boards of pharmacy allow pharmacists to do within the definition of the practice of pharmacy, including compliance, disease management, outcomes, and other quality assurance programs, from which patients may freely choose to withdraw or opt-out.

7) **Patients Must have the Right to Inspect, Copy, and Amend (but not change) their Medical Records...** at the originating provider, for a fee to cover copying and administrative costs.

8) **Computer Security Must...** safeguard patient identifiable health care information that is maintained or transmitted for any purpose.

9) **The National Law Must Go into Effect Within a Reasonable Timeframe...** to provide patient confidentiality protection as soon as possible, but also to allow health care providers reasonable time to develop, test, distribute, and to be trained to use new software to help them comply with this lengthy and complex legislation.

10) **Those With Legitimate Access to Patient Identifiable Data Must Commit to Maintain and Abide by Confidentiality Laws.** Penalties and fines should be imposed if individuals or entities knowingly and intentionally break the law.

Attachment 2

Key Pharmacy Issues with Medical Records Confidentiality Legislation

May 27, 1999

KEY ISSUES

- Full Federal preemption of the patchwork of state privacy laws, with an allowance for exceptions for communicable disease reporting, essential health data and vital statistics collection, is critical. Precedent exists in the financial institution sector. Without Federal preemption... pharmacies and pharmacists will NOT be able to comply with laws that cannot be readily found or quickly compared for conflicts between Federal and state law.

- Written authorizations should be obtained by originating providers, such as health plans and physicians, but not be required for downstream treatment authorized by those providers. Pharmacies account for about 50% of all consumer health care payment claims and patients and pharmacies could not handle additional form requirements for each prescription or initial visit.

- Consolidated authorizations for treatment and payment must create a "legal presumption" that allows pharmacies and other downstream health care providers to rely upon: that individuals, presenting health insurance cards or a valid prescription, have provided the necessary authorization for treatment and payment from their employer or health plan. **The same assumption must be recognized for the non-insured... the originating provider obtained the necessary authorization.**

- The definition of health care or treatment should include pharmacy compliance and disease management programs that are often required by Federal laws and rules and are a continuation of dispensing the prescription.

- Electronic data collection and data transmission provisions dealing with payment must not limit our ability to perform drug utilization review (DUR) and other quality enhancement measures, often required by Federal and state law.

- Pharmacists should not be required to obtain authorizations for counseling patients on OTC drugs.

- The definition of "individual representative" or next of kin should not interfere in allowing family members, friends, caregivers or neighbors to pick up prescriptions for patients.

Attachment 2 Continued

- Pharmacy benefit cards must NOT be included in payment and electronic payment transaction limitations. If so, pharmacies which would no longer be allowed to transmit the NCPDP

payment claim for payment because its information is MUCH broader than that required for payment. As a result, pharmacy benefit managers and health plans would no longer have access to the clinical information contained on the NCPDP payment claim necessary for DUR.

- Assurances should be made that Federal agencies will not use new penalty authority as they have under the False Claims Act or Controlled Substance Act to pursue providers for innocent and technical errors. If there is no harm to the patient and mistakes are innocent, providers should not be unduly punished for employee error.

KEY QUESTIONS IN DRAFTING CONFIDENTIALITY LEGISLATION

- Does the definition of health care include over-the-counter (OTC) drugs and medically "related items"? It should not, as the workload, confusion and consumer inconvenience would be prohibitive.

- Will bill language interfere in the common tradition of allowing relatives, friends, caregivers and neighbors pick up prescriptions for patients?

- Is it the intent of legislation to require separate, written authorizations for each pharmacy customer, despite the fact that patients have their choice in deciding where to deliver prescriptions to pharmacists directly, asking for treatment and granting permission for pharmacists to dispense and be paid?

- Have members and staff contemplated the impact of "Administrative Billing Information" and payment provisions and their possible impact on the use of the NCPDP prescription payment

claim forms and PBM clinical data collection used for utilization review?

- Is it clear that pharmacy benefit cards are not considered a "payment card"?

- Do lawmakers know that software experts have told industry that 18 months is the minimum time needed to create, test, and train pharmacists in using new software for pharmacy compliance with a new Federal privacy law and that it is unlikely that software can be developed and implemented for a bill that does not substantially preempt state laws?

- Is it the intent of legislators to limit the use of prescription information to issue discount coupons for over-the-counter drugs and products related to the treatment or prescription by requiring a written authorization?

THE WHITE HOUSE

WASHINGTON

6/14/99

TO: Bruce Reed
Elena Kagan
Chris Jennings
Bill White

FROM: Mickey Ibarra

FOR YOUR INFORMATION.

SOUTHERN GOVERNORS' ASSOCIATION

M —
Copy to:
– Bruce
– Eleanor
– Chris
– Bill
Mickey
6-11-99

June 8, 1999

Mr. Mickey Ibarra
Assistant to the President
Office of Intergovernmental Affairs
The White House
Washington, DC 20500

Dear Mr. Ibarra:

As chair of the Southern Governors' Association (SGA), I am pleased to present to you the SGA policy statement on healthcare confidentiality. This statement was developed by our Task Force on Medical Technology and approved by the Southern Governors' Association. I commend you for your leadership in this area and respectfully submit our recommendations for your use during your deliberations in Congress on this most important matter.

As I am sure you would agree, the confidentiality of a patient's healthcare record is a fundamental right. It is a right that patients believe exists when they visit their physician in hope of receiving medical treatment that will improve their daily lives. But due to the surge in the field of information technology, that right may not exist for everyone. The answer to protecting this right is not to craft laws that ignore a state's role in the healthcare system but to create federal standards that allow a state to develop laws that address the needs of their diverse constituencies.

We understand that pursuant to the August 21 deadline enacted by the Health Insurance Portability and Accountability Act (HIPAA) of 1996, Congress is required to pass legislation establishing a federal baseline for healthcare confidentiality or forfeit its authority to the Secretary of the Department of Health and Human Services to implement safeguards through federal regulations. However, many states in the South and nationwide have already developed strong, effective laws relating to healthcare confidentiality and we want to ensure that these and future state laws will not be preempted by this federal baseline. Therefore, we urge you to consider these recommendations as you draft federal legislation and to recognize the need for each state to be able to construct laws designed to meet the needs of their populations.

Again, thank you for your valuable leadership on this important issue and consideration of our recommendations. If you have any questions about this statement or wish to discuss it further, please contact SGA Policy Analyst Catherine Finley at (202) 624-5897.

Sincerely,

Governor Don Sundquist

HALL OF THE STATES 444 NORTH CAPITOL STREET, NW SUITE 200 WASHINGTON, DC 20001
202/624-5897 FAX 202/624-7797 WWW.SOUTHERNGOVERNORS.ORG

The Southern Governors' Association's Policy Statement on Healthcare Confidentiality

The members of the Southern Governors' Association (SGA) believe that confidentiality is one of the most important health care issues that Congress will debate this year. The decisions that Congress makes will affect consumers, healthcare providers and medical related industries in every state. Therefore, we believe that the role of states as regulators of healthcare and consumer advocates should be built upon and strengthened, not diminished. Additionally, a sound balance must be found that will protect the rights of consumers, while allowing vital healthcare research to move forward. As southern governors, we ask that the following principles be incorporated into any federal legislation:

- that states retain the prerogative to enact state safeguards that are stronger than a federal legislative floor, including those that are established as a part of regional compacts. Further, this prerogative shall not be subject to a time limit;
- that healthcare consumers be allowed to inspect, copy and, when inaccurate, correct their own protected health information through the appropriate procedure;
- that confidentiality practices be clearly and concisely provided in writing to consumers;
- that very strong administrative, technical and physical safeguards be required to protect the confidentiality, security, accuracy and integrity of protected health information, especially with regard to user authentication and audit trails;
- that healthcare providers be permitted to disclose protected health information when necessary in emergency circumstances, to the appropriate individual, to protect the health or safety of the patient;
- that strong measures are taken to prohibit protected health information disclosure to healthcare marketing companies and other related businesses without the specific written consent of a consumer, and that such consent shall not be "bundled" into other consents for treatment or payment;
- that healthcare providers be permitted to disclose nonidentifiable protected healthcare information for the purpose of private healthcare research. Further, that healthcare providers be permitted to disclose protected healthcare information to public health authorities and researchers to enable states to continue to have access to healthcare data for traditional state uses; and
- that strong civil and criminal penalties be established to punish those individuals and institutions who knowingly and willfully disclose protected healthcare information.

May 18, 1999

DRAFT DRAFT

Reserve minor agreement to look in if we are OK

NOTE: Italicized language reflects issues that may be resolved before markup tomorrow.

Dear Chairman Jeffords,

On behalf of the Administration, I want to commend you and the other Committee members for working in a cooperative, bipartisan manner to bring the "Health Information Confidentiality Act of 1999" to markup. While we continue to have significant concerns that would need to be addressed before we could support passage of this legislation by the full Senate, we are encouraged by the bipartisan progress made to date. This is an important piece of legislation that has the potential to help us to achieve the goal of so many Americans – the right to privacy for medical and health information.

The President has indicated his strong desire to see the Congress enact a comprehensive medical privacy bill this year. At the same time, we are working hard to make sure the Department is prepared to go forward with the regulations specified under HIPAA, if Congress is unable to pass such a bill. As the President said in his State of the Union Address:

> "As more of our medical records are stored electronically, the threats to all our privacy increase. Because Congress has given me the authority to act if it does not do so by August, one way or another, we can all say to the American people, we will protect the privacy of medical records and we will do it this year."

In this regard, we are pleased to see that the Chairman's mark places important limits on the ways that health plans, providers and other health care-related organizations and individuals use and disclose personal health information. The mark incorporates changes that clarify that these limits apply both to disclosures between health care organizations as well as to disclosures within such organizations, requiring that protected health care information be provided to and used by only those individuals necessary to accomplish the purpose for which the information was

obtained. For example, an employer generally could not disclose protected information gathered for the purpose of health care treatment and payment by the employer's group health plan to ~~employees~~ many charged with job performance or job placement functions. These limits are vital if Americans are to have confidence that they can seek treatment under their health insurance without fear that their personal information could be used against them in the workplace.

Similarly, we are very encouraged to see the Committee recognize that it should be unlawful for ~~someone~~ the disclosure of information to disclose information that is not identifiable with the knowledge that the recipient will re-identify ~~that information~~ it. We could not support a bill that includes loopholes that allow disclosure of information from which identifiers have been stripped or encoded to people who intend to re-identify that information. ~~Fetus~~ Emphasize / Give sense of security

We are also encouraged that the notice and authorization provisions together will provide consumers with the crucial information they need to understand how their health information will be used and their rights and responsibilities with respect to that information. While the notice provisions are vastly improved, we continue to have concerns regarding a provision that would make use of a model notice an "absolute defense" to a claim of inadequate notice, even if the information contained in the notice was not accurate for the circumstances in which it was used. While use of the model should provide some special legal protection, it should only do so if it accurately reflects use of the model.

With respect to non-federally funded health research, we are pleased that the Committee has included a review mechanism for researchers who wish to use medical records without obtaining a patient's prior authorization. We believe this section would be strengthened ~~to provide greater protection for the public~~ if some form of independent oversight were incorporated into this new process.

We are also pleased that the bill now makes clear that the allowable uses of protected health care information for health care operations apply only within the health plan or provider (and their agents) that originally obtains the information. Any sharing beyond that entity requires a separate authorization. Even within the entity, the allowable uses could not be expanded by contract beyond those for the purpose of the delivery of health benefits.

Underwriting w/out disclosure authorization

While the improvements to your legislation have been significant, there are other areas that we believe require changes. The strength of any law conveying rights to individuals is their ability to enforce such rights. The standard in the bill under which an individual could bring a private action is too high.

In the ever expanding, technology-based environment we live in, it is becoming easier and easier to identify individuals with only tidbits of either demographic or personal information. Because the Chairman's mark has a loose definition of "non-identifiable information", it is imperative that it be a crime for anyone to transmit the 'key' that allows such information to become identifiable. Absent such a prohibition, the bill would contain a significant loophole through which protected health information could be available to numerous parties for marketing or other purposes, all of which would be legal. Disclosing the key to re-identifying such information is no different than disclosing the identified information itself, and should be just as unlawful.

We understand that there is a general consensus that this legislation should not affect state laws that pertain to minors and their rights to either permit or prevent access to their health information. Unfortunately, it appears that the provision currently in the bill may not achieve this purpose. The language should be changed to ensure it is consistent with this original purpose.

As you know, the Administration's general view is that federal statutes that establish new health protections for individuals should set a floor upon which states can build to address their unique circumstances. We are concerned, therefore, about a statutory design that preempts State laws, and are still analyzing the particular approach taken in your bill. We intend to consider this issue carefully as we work with you to further strengthen the federal protections included in this legislation.

Finally, we agree that an insurer or health plan has a right to request certain personal information for underwriting purposes *before* an individual enrolls in the plan. After enrollment, the insurer or the plan should not be permitted to use that information to conduct ongoing internal plan operations. Allowing access to such information may undermine State laws prohibiting genetic

discrimination. Given the Committee's past interest in addressing such discrimination, we urge that the language be dropped from the bill, so that no one can misconstrue the intent of the bill.

In closing, let me reiterate that we believe that this bipartisan effort represents a positive step toward meaningful privacy legislation, and we are very pleased with the progress you have made in working with us on various issues. We look forward to working with you to strengthen the bill further prior to Senate floor consideration.

Sincerely,

Donna E. Shalala