U.S. Department of Justice
Office of Legislative Affairs

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

The Honorable James M. Jeffords
Chairman
Committee on Health, Education, Labor and Pensions
United States Senate
Washington, D.C. 20510-6300

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. As Mr. John Bentivoglio, Special Counsel for Health Care Fraud, testified before the Committee on April 27, we look forward to working with the you to support this important goal, while preserving the ability of the Department of Justice to enforce the laws within its jurisdiction, and also to oversee the integrity of the health care payment system. We believe that the Department can and should play a constructive role in this effort.

Subsequent to the hearing, we have reviewed the three primary medical record proposals pending in the Senate, S. 578, S. 573 and S. 881, with an eye toward addressing the concerns voiced by members during our testimony. In addition, the Department has met several times with the Staff of the Committee, to further explore these issues. We believe that the Department can support a number of important principles governing law enforcement access to and use of personal medical records, which would advance the protection of medical record privacy in a manner that would at the same time preserve the ability of law enforcement to obtain important evidence when necessary:

- Law enforcement agencies and employees should be permitted to obtain and use medical records only for official law enforcement activities.

- Law enforcement agencies and employees when pursuing an official oversight investigation, or related criminal or civil proceeding, should be permitted to obtain individually identifiable medical records for that purpose.

- When law enforcement obtains medical records in the course of administrative, civil or criminal health care fraud oversight activities, law enforcement should be restricted from using those records against an individual patient whose record is obtained, except: 1) where the medical record is relevant to an investigation of the patient relating to billing for health care; or 2) where the law enforcement agency makes an application for, and obtains, a judicial disclosure order in an ex-parte proceeding analogous to the provisions of 18 U.S.C. § 3486(e).

- As a general matter, law enforcement should continue to be permitted to obtain medical records of a patient pursuant to lawful compulsory process, including a grand jury subpoena, a warrant, a judicial subpoena, an administrative subpoena, an authorized investigative demand, or a civil investigative demand.

- In exigent circumstances, in order to prevent threatened or imminent harm to a patient or another person, law enforcement should be permitted to obtain the medical records of that patient, without compulsory process. In other exigent circumstances, not involving threatened or imminent harm, law enforcement should be permitted to obtain without compulsory process, limited information contained in medical records, to locate and identify a patient who is a fugitive, a suspect, or a material witness.

- Medical record privacy legislation should not preempt federal or state mandatory reporting laws which require the disclosure of limited medical information to law enforcement agencies, including the Drug Enforcement Agency. Such laws include, but are not limited to, mandatory reporting of gunshot wounds, abuse and neglect of children, elders, spouses; rape; and diversion of scheduled pharmaceuticals.

- Whistleblowers should be permitted to disclose medical records to law enforcement either directly or in the course of False Claims Act proceedings, when the disclosure of the medical records is related to the reporting potential false claims or fraud, or relevant to an official law enforcement activity;

- Law enforcement should be required when it is necessary to disclose medical information in public forums, such as court filings or trials, either to redact the medical records to the extent practicable, or to take other appropriate and reasonable steps to minimize the public disclosure of identifiable health information, consistent with the requirements of due process and the direction of the appropriate judicial or administrative hearing officer.

- The provisions governing the procedures for imposing and appealing civil penalties should make clear that they envision an administrative proceeding to review civil monetary penalties imposed by the Secretary of Health and Human Services, and do not contemplate a civil court proceeding by the Secretary in the United States District Courts. If a new cause of action in federal District Court for a civil fine is created, the Attorney General should be responsible for enforcing such a provision.

- Any provision that provides for injunctive relief to prevent or terminate violations of the statute, should be enforceable by the Attorney General.

- Law enforcement 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 by law enforcement.

- References to law enforcement should include federal, state and local law enforcement.

- Special concerns govern the operation of jails, prisons and detention facilities. These institutions perform hybrid functions that run from law enforcement to actually providing medical care to prisoners and

detainees. These special concerns should be addressed by generally exempting these institutions from the obligations and duties imposed by medical record privacy legislation. However, these institutions should be restricted from disclosing, using or obtaining medical information, except for an official activity. Also, the final language legislative language governing these facilities, must insure that they are permitted to exchange prisoner or detainee health records, without patient authorization, with community health care providers who provide health care services to the prisoners or detainees.

We believe that medical record privacy legislation that incorporates these principles would substantially enhance the protection of medical record privacy, while preserving the ability of law enforcement to perform its important duties. Many of these principles are already incorporated in one or more of the bills. The Department looks forward to continuing to work with you, the Committee and the staff on this important legislation.

Thank you for the opportunity to present our views on 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,
Acting Assistant Attorney General

cc. The Honorable Edward M. Kennedy,
Ranking Minority Member

O:\BAI\BAI98.H71

same as H70, but also includes financial incentives
- see p. 11
- does not prohibit transfer of indemnification

AMENDMENT NO. ____ Calendar No. ____

Purpose: To prohibit interference with communications between health care providers and their patients and provide for certain patient advocacy protections.

IN THE SENATE OF THE UNITED STATES—105th Cong., 2d Sess.

S. 2330

To improve the access and choice of patients to quality, affordable health care.

Referred to the Committee on _____
and ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT intended to be proposed by _____

Viz:

Beginning on page 17, strike line 9 and all that follows through line 1 on page 18, and insert the following:

"SEC. 726. PROHIBITION OF INTERFERENCE WITH CERTAIN MEDICAL COMMUNICATIONS.

"(a) PROHIBITION.—

"(1) GENERAL RULE.—The provisions of any contract or agreement, or the operation of any contract or agreement, between a group health plan (including any partnership, association, or other organization that enters into or administers such a con-

tract or agreement) and a health care provider (or group of health care providers) shall not prohibit or restrict the provider from engaging in medical communications with the provider's patient.

"(2) NULLIFICATION.—Any contract provision or agreement described in paragraph (1) shall be null and void.

"(b) RULES OF CONSTRUCTION.—Nothing in this section shall be construed—

"(1) to prohibit the enforcement, as part of a contract or agreement to which a health care provider is a party, of any mutually agreed upon terms and conditions, including terms and conditions requiring a health care provider to participate in, and cooperate with, all programs, policies, and procedures developed or operated by a group health plan to assure, review, or improve the quality and effective utilization of health care services (if such utilization is according to guidelines or protocols that are based on clinical or scientific evidence and the professional judgment of the provider) but only if the guidelines or protocols under such utilization do not prohibit or restrict medical communications between providers and their patients; or

"(2) to permit a health care provider to misrepresent the scope of benefits covered under the group health plan or to otherwise require a group health plan to reimburse providers for benefits not covered under the plan.

"(c) MEDICAL COMMUNICATION DEFINED.—In this section:

"(1) IN GENERAL.—The term 'medical communication' means any communication made by a health care provider with a patient of the health care provider (or the guardian or legal representative of such patient) with respect to—

"(A) the patient's health status, medical care, or treatment options;

"(B) any utilization review requirements that may affect treatment options for the patient; or

"(C) any financial incentives that may affect the treatment of the patient.

"(2) MISREPRESENTATION.—The term 'medical communication' does not include a communication by a health care provider with a patient of the health care provider (or the guardian or legal representative of such patient) if the communication in-

volves a knowing or willful misrepresentation by such provider.

"SEC. 727. ADDITIONAL RULES REGARDING PARTICIPATION OF HEALTH CARE PROFESSIONALS.

"(a) PROCEDURES.—Insofar as a group health plan provides benefits through participating health care professionals, the plan shall establish reasonable procedures relating to the participation (under an agreement between a professional and the plan) of such professionals under the plan or coverage. Such procedures shall include—

"(1) providing notice of the rules regarding participation;

"(2) providing written notice of participation decisions that are adverse to professionals; and

"(3) providing a process within the plan for appealing such adverse decisions, including the presentation of information and views of the professional regarding such decision.

"(b) CONSULTATION IN MEDICAL POLICIES.—A group health plan shall consult with participating physicians (if any) regarding the plan's medical policy, quality, and medical management procedures.

"SEC. 728. PROTECTION FOR PATIENT ADVOCACY.

"(a) PROTECTION FOR USE OF UTILIZATION REVIEW AND GRIEVANCE PROCESS.—A group health plan may not

retaliate against a participant or beneficiary, or health care provider based on the participant's or beneficiary's, or provider's use of, or participation in, a utilization review process or a grievance process of the plan (including an internal or external review or appeal process).

"(b) PROTECTION FOR QUALITY ADVOCACY BY HEALTH CARE PROFESSIONALS.—

"(1) IN GENERAL.—A group health plan may not retaliate or discriminate against a protected health care professional because the professional in good faith—

"(A) discloses information relating to the care, services, or conditions affecting one or more participants or beneficiaries of the plan to an appropriate public regulatory agency, an appropriate private accreditation body, or appropriate management personnel of the plan; or

"(B) initiates, cooperates, or otherwise participates in an investigation or proceeding by such an agency with respect to such care, services, or conditions.

If an institutional health care provider is a participating provider with such a plan or otherwise receives payments for benefits provided by such a plan, the provisions of the previous sentence shall

apply to the provider in relation to care, services, or conditions affecting one or more patients within an institutional health care provider in the same manner as they apply to the plan in relation to care, services, or conditions provided to one or more participants or beneficiaries; and for purposes of applying this sentence, any reference to a plan is deemed a reference to the institutional health care provider.

"(2) GOOD FAITH ACTION.—For purposes of paragraph (1), a protected health care professional is considered to be acting in good faith with respect to disclosure of information or participation if, with respect to the information disclosed as part of the action—

"(A) the disclosure is made on the basis of personal knowledge and is consistent with that degree of learning and skill ordinarily possessed by health care professionals with the same licensure or certification and the same experience;

"(B) the professional reasonably believes the information to be true;

"(C) the information evidences either a violation of a law, rule, or regulation, of an applicable accreditation standard, or of a gen-

erally recognized professional or clinical standard or that a patient is in imminent hazard of loss of life or serious injury; and

"(D) subject to subparagraphs (B) and (C) of paragraph (3), the professional has followed reasonable internal procedures of the plan or institutional health care provider established or the purpose of addressing quality concerns before making the disclosure.

"(3) EXCEPTION AND SPECIAL RULE.—

"(A) GENERAL EXCEPTION.—Paragraph (1) does not protect disclosures that would violate Federal or State law or diminish or impair the rights of any person to the continued protection of confidentiality of communications provided by such law.

"(B) NOTICE OF INTERNAL PROCEDURES.—Subparagraph (D) of paragraph (2) shall not apply unless the internal procedures involved are reasonably expected to be known to the health care professional involved. For purposes of this subparagraph, a health care professional is reasonably expected to know of internal procedures if those procedures have been

made available to the professional through distribution or posting.

"(C) INTERNAL PROCEDURE EXCEPTION.—Subparagraph (D) of paragraph (2) also shall not apply if—

"(i) the disclosure relates to an imminent hazard of loss of life or serious injury to a patient;

"(ii) the disclosure is made to an appropriate private accreditation body pursuant to disclosure procedures established by the body; or

"(iii) the disclosure is in response to an inquiry made in an investigation or proceeding of an appropriate public regulatory agency and the information disclosed is limited to the scope of the investigation or proceeding.

"(4) ADDITIONAL CONSIDERATIONS.—It shall not be a violation of paragraph (1) to take an adverse action against a protected health care professional if the plan or provider taking the adverse action involved demonstrates that it would have taken the same adverse action even in the absence of the activities protected under such paragraph.

"(5) NOTICE.—A group health plan and institutional health care provider shall post a notice, to be provided or approved by the Secretary of Labor, setting forth excerpts from, or summaries of, the pertinent provisions of this subsection and information pertaining to enforcement of such provisions.

"(6) CONSTRUCTIONS.—

"(A) DETERMINATIONS OF COVERAGE.—Nothing in this subsection shall be construed to prohibit a plan from making a determination not to pay for a particular medical treatment or service or the services of a type of health care professional.

"(B) ENFORCEMENT OF PEER REVIEW PROTOCOLS AND INTERNAL PROCEDURES.—Nothing in this subsection shall be construed to prohibit a plan or provider from establishing and enforcing reasonable peer review or utilization review protocols or determining whether a protected health care professional has complied with those protocols or from establishing and enforcing internal procedures for the purpose of addressing quality concerns.

"(C) RELATION TO OTHER RIGHTS.—Nothing in this subsection shall be construed to

abridge rights of participants, beneficiaries, and protected health care professionals under other applicable Federal or State laws.

"(7) PROTECTED HEALTH CARE PROFESSIONAL DEFINED.—For purposes of this subsection, the term 'protected health care professional' means an individual who is a licensed or certified health care professional and who—

"(A) with respect to a group health plan is an employee of the plan or has a contract with the plan for provision of services for which benefits are available under the plan; or

"(B) with respect to an institutional health care provider, is an employee of the provider or has a contract or other arrangement with the provider respecting the provision of health care services.

"SEC. 729. PROHIBITION AGAINST IMPROPER INCENTIVE ARRANGEMENTS.

"(a) PROHIBITION OF IMPROPER PHYSICIAN INCENTIVE PLANS.—

"(1) IN GENERAL.—A group health plan may not operate any physician incentive plan (as defined in subparagraph (B) of section 1876(i)(8) of the Social Security Act) unless the requirements described

in subparagraph (A) of such section are met with respect to such a plan.

"(2) APPLICATION.—For purposes of carrying out paragraph (1), any reference in section 1876(i)(8) of the Social Security Act to the Secretary, an eligible organization, or an individual enrolled with the organization shall be treated as a reference to the applicable authority or a group health plan, respectively, and a participant or beneficiary with the plan respectively.

"(b) PROHIBITION OF CONTINGENT COMPENSATION ARRANGEMENTS IN UTILIZATION REVIEW PROGRAMS.—A utilization review program maintained by a group health plan shall not, with respect to utilization review activities, permit or provide compensation or anything of value to its employees, agents, or contractors in a manner that—

"(1) provides incentives, direct or indirect, for such persons to make inappropriate review decisions, or

"(2) is based, directly or indirectly, on the quantity or type of [adverse] determinations rendered.

"(c) PROHIBITION OF CONFLICTS.—A program described in subsection (b) shall not permit a health care professional who provides health care services to an individual to perform utilization review activities in connection

with the health care services being provided to the individual.

"SEC. 730. APPLICABILITY AND OTHER PROVISIONS.

"(a) APPLICABILITY.—Notwithstanding section 730A(a), the provisions of sections 726, 727, 728, and 729 shall apply to group health plans and health insurance issuers as if included in—

"(1) subpart 2 of part A of title XXVII of the Public Health Service Act;

"(2) the first subpart 3 of part B of title XXVII of the Public Health Service Act (relating to other requirements); and

"(3) subchapter B of chapter 100 of the Internal Revenue Code of 1986.

"(b) NO IMPACT ON SOCIAL SECURITY TRUST FUND.—

"(1) IN GENERAL.—Nothing in sections 726, 727, 728 and 729 shall be construed to alter or amend the Social Security Act (or any regulation promulgated under that Act).

"(2) TRANSFERS.—

"(A) ESTIMATE OF SECRETARY.—The Secretary of the Treasury shall annually estimate the impact that the enactment of the sections referred to in paragraph (1) has on the income

and balances of the trust funds established under section 201 of the Social Security Act (42 U.S.C. 401).

"(B) TRANSFER OF FUNDS.—If, under subparagraph (A), the Secretary of the Treasury estimates that the enactment of the sections referred to in paragraph (1) has a negative impact on the income and balances of the trust funds established under section 201 of the Social Security Act (42 U.S.C. 401), the Secretary shall transfer, not less frequently than quarterly, from the general revenues of the Federal Government an amount sufficient so as to ensure that the income and balances of such trust funds are not reduced as a result of the enactment of such sections.

"(c) NONAPPLICATION OF CERTAIN PROVISION.—Section 2721(b)(2) of the Public Health Service Act shall not apply to the provisions of this section.

"SEC. 730A. GENERALLY APPLICABLE PROVISIONS.

Changes on p. 2

AMENDMENT NO. ____ Calendar No. ____

Purpose: To provide for coverage of emergency medical care.

IN THE SENATE OF THE UNITED STATES—105th Cong., 2d Sess.

S. 2330

To improve the access and choice of patients to quality, affordable health care.

Referred to the Committee on _____
and ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT intended to be proposed by _____

Viz:

Beginning on page 5, strike line 6 and all that follows through line 19 on page 7, and insert the following:

"SEC. 721. ACCESS TO EMERGENCY CARE.

"(a) COVERAGE OF EMERGENCY SERVICES.—

"(1) IN GENERAL.—If a group health plan provides any benefits with respect to emergency services (as defined in paragraph (2)(B)), the plan shall cover emergency services furnished under the plan—

"(A) without the need for any prior authorization determination;

"(B) whether or not the health care provider furnishing such services is a participating provider with respect to such services;

"(C) in a manner so that, if such services are provided to a participant or beneficiary by a nonparticipating health care provider without prior authorization by the plan—

"(i) the participant or beneficiary is not liable for amounts that exceed the amounts of liability that would be incurred if the services were provided by a participating health care provider ~~without~~ prior authorization by the plan, and

"(ii) the plan pays an amount that is not less than the amount paid to a participating health care provider for the same services; and

"(D) without regard to any other term or condition of such plan (other than exclusion or coordination of benefits, or an affiliation or waiting period, permitted under section 701 of this Act, section 2701 of the Public Health Service Act, or section 9801 of the Internal Revenue Code of 1986, and other than applicable cost-sharing).

"(2) DEFINITIONS.—In this section:

"(A) EMERGENCY MEDICAL CONDITION BASED ON PRUDENT LAYPERSON STANDARD.—The term 'emergency medical condition' means a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that a prudent layperson, who possesses an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in a condition described in clause (i), (ii), or (iii) of section 1867(e)(1)(A) of the Social Security Act.

"(B) EMERGENCY SERVICES.—The term 'emergency services' means—

"(i) a medical screening examination (as required under section 1867 of the Social Security Act) that is within the capability of the emergency department of a hospital, including ancillary services routinely available to the emergency department to evaluate an emergency medical condition (as defined in subparagraph (A)), and

"(ii) within the capabilities of the staff and facilities available at the hospital, such further medical examination and treatment as are required under section 1867 of such Act to stabilize the patient.

"(b) REIMBURSEMENT FOR MAINTENANCE CARE AND POST-STABILIZATION CARE.—In the case of services (other than emergency services) for which benefits are available under a group health plan, the plan shall provide for reimbursement with respect to such services provided to a participant or beneficiary other than through a participating health care provider in a manner consistent with subsection (a)(1)(C) ~~if the services are~~ maintenance care or post-stabilization care covered under the guidelines established under section 1852(d)(2) of the Social Security Act (relating to promoting efficient and timely coordination of appropriate maintenance and post-stabilization care of a participant or beneficiary after the participant or beneficiary has been determined to be stable), or, in the absence of guidelines under such section, such guidelines as the Secretary shall establish to carry out this subsection.

"(c) APPLICABILITY.—Notwithstanding section 727(a), the provisions of this section shall apply to group

health plans and health insurance issuers as if included in—

"(1) subpart 2 of part A of title XXVII of the Public Health Service Act;

"(2) the first subpart 3 of part B of title XXVII of the Public Health Service Act (relating to other requirements); and

"(3) subchapter B of chapter 100 of the Internal Revenue Code of 1986.

"(d) NO IMPACT ON SOCIAL SECURITY TRUST FUND.—

"(1) IN GENERAL.—Nothing in this section shall be construed to alter or amend the Social Security Act (or any regulation promulgated under that Act).

"(2) TRANSFERS.—

"(A) ESTIMATE OF SECRETARY.—The Secretary of the Treasury shall annually estimate the impact that the enactment of this section has on the income and balances of the trust funds established under section 201 of the Social Security Act (42 U.S.C. 401).

"(B) TRANSFER OF FUNDS.—If, under subparagraph (A), the Secretary of the Treasury estimates that the enactment of this section

has a negative impact on the income and balances of the trust funds established under section 201 of the Social Security Act (42 U.S.C. 401), the Secretary shall transfer, not less frequently than quarterly, from the general revenues of the Federal Government an amount sufficient so as to ensure that the income and balances of such trust funds are not reduced as a result of the enactment of such section.

"(e) NONAPPLICATION OF CERTAIN PROVISION.—Section 2721(b)(2) of the Public Health Service Act shall not apply to the provisions of this section.

Access to specialists

. Uses similar access language already in 2330.

AMENDMENT NO. ____ Calendar No. ____

Purpose: To guarantee access to certain specialists.

IN THE SENATE OF THE UNITED STATES—105th Cong., 2d Sess.

S. 2330

To improve the access and choice of patients to quality, affordable health care.

Referred to the Committee on _____
and ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT intended to be proposed by _____

Viz:

On page 11, between lines 17 and 18, insert the following:

SEC. 723A. ACCESS TO SPECIALTY CARE.

"(a) SPECIALTY CARE.—

"(1) SPECIALTY CARE FOR COVERED SERVICES.—

"(A) IN GENERAL.—If—

"(i) an individual is a participant or beneficiary under a group health plan,

"(ii) the individual has a condition or disease of sufficient seriousness and com-

plexity to require treatment by a specialist, and

"(iii) benefits for such treatment are provided under the plan,

the plan shall make or provide for a referral to a specialist who is available and accessible to provide the treatment for such condition or disease.

"(B) SPECIALIST DEFINED.—For purposes of this subsection, the term 'specialist' means, with respect to a condition, a health care practitioner, facility, or center (such as a center of excellence) that has adequate expertise through appropriate training and experience (including, in the case of a child, appropriate pediatric expertise) to provide high quality care in treating the condition.

"(C) CARE UNDER REFERRAL.—A group health plan may require that the care provided to an individual pursuant to such referral under subparagraph (A) be—

"(i) pursuant to a treatment plan, only if the treatment plan is developed by the specialist and approved by the plan, in consultation with the designated primary

care provider or specialist and the individual (or the individual's designee), and

"(ii) in accordance with applicable quality assurance and utilization review standards of the plan.

Nothing in this subsection shall be construed as preventing such a treatment plan for an individual from requiring a specialist to provide the primary care provider with regular updates on the specialty care provided, as well as all necessary medical information.

"(D) REFERRALS TO PARTICIPATING PROVIDERS.—A group health plan is not required under subparagraph (A) to provide for a referral to a specialist that is not a participating provider, unless the plan does not have an appropriate specialist that is available and accessible to treat the individual's condition and that is a participating provider with respect to such treatment.

"(E) TREATMENT OF NONPARTICIPATING PROVIDERS.—If a plan refers an individual to a nonparticipating specialist pursuant to subparagraph (A), services provided pursuant to the approved treatment plan ~~(if any)~~ shall be pro-

vided at no additional cost to the individual beyond what the individual would otherwise pay for services received by such a specialist that is a participating provider.

"(2) SPECIALISTS AS PRIMARY CARE PROVIDERS.—

"(A) IN GENERAL.—A group health plan shall have a procedure by which an individual who is a participant or beneficiary and who has an ongoing special condition (as defined in subparagraph (C)) may receive a referral to a specialist for such condition who shall be responsible for and capable of providing and coordinating the individual's primary and specialty care. If such an individual's care would most appropriately be coordinated by such a specialist, such plan shall refer the individual to such specialist.

"(B) TREATMENT AS PRIMARY CARE PROVIDER.—Such specialist shall be permitted to treat the individual without a referral from the individual's primary care provider and may authorize such referrals, procedures, tests, and other medical services as the individual's primary care provider would otherwise be per-

mitted to provide or authorize, subject to the terms of the treatment plan (referred to in paragraph (1)(C)(i)).

"(C) ONGOING SPECIAL CONDITION DEFINED.—In this paragraph, the term "special condition" means a condition or disease that—

"(i) is life-threatening, degenerative, or disabling, and

"(ii) requires specialized medical care over a prolonged period of time.

"(D) TERMS OF REFERRAL.—The provisions of subparagraphs (C) through (E) of paragraph (1) apply with respect to referrals under subparagraph (A) of this paragraph in the same manner as they apply to referrals under paragraph (1)(A).

"(3) STANDING REFERRALS.—

"(A) IN GENERAL.—A group health plan shall have a procedure by which an individual who is a participant or beneficiary and who has a condition that requires ongoing care from a specialist may receive a standing referral to such specialist for treatment of such condition. If the plan, or if the primary care provider in consultation with the medical director of the

plan and the specialist (if any), determines that such a standing referral is appropriate, the plan shall make such a referral to such a specialist.

"(B) TERMS OF REFERRAL.—The provisions of subparagraphs (C) through (E) of paragraph (1) apply with respect to referrals under subparagraph (A) of this paragraph in the same manner as they apply to referrals under paragraph (1)(A).

"(b) OBSTETRICAL AND GYNECOLOGICAL CARE.—If a group health plan requires or provides for a participant or beneficiary to designate a participating primary care provider the plan shall permit such an individual who is a female to designate a participating physician who specializes in obstetrics and gynecology as the individual's primary care provider.

"(c) APPLICABILITY.—Notwithstanding section 727(a), the provisions of this section shall apply to group health plans and health insurance issuers as if included in—

"(1) subpart 2 of part A of title XXVII of the Public Health Service Act;

"(2) the first subpart 3 of part B of title XXVII of the Public Health Service Act (relating to other requirements); and

"(3) subchapter B of chapter 100 of the Internal Revenue Code of 1986.

"(d) NO IMPACT ON SOCIAL SECURITY TRUST FUND.—

"(1) IN GENERAL.—Nothing in this section shall be construed to alter or amend the Social Security Act (or any regulation promulgated under that Act).

"(2) TRANSFERS.—

"(A) ESTIMATE OF SECRETARY.—The Secretary of the Treasury shall annually estimate the impact that the enactment of this section has on the income and balances of the trust funds established under section 201 of the Social Security Act (42 U.S.C. 401).

"(B) TRANSFER OF FUNDS.—If, under subparagraph (A), the Secretary of the Treasury estimates that the enactment of this section has a negative impact on the income and balances of the trust funds established under section 201 of the Social Security Act (42 U.S.C. 401), the Secretary shall transfer, not less frequently than quarterly, from the general revenues of the Federal Government an amount sufficient so as to ensure that the income and

balances of such trust funds are not reduced as a result of the enactment of such section.

"(e) NONAPPLICATION OF CERTAIN PROVISION.—Section 2721(b)(2) of the Public Health Service Act shall not apply to the provisions of this section.

AMENDMENT NO. ____ Calendar No. ____

Purpose: To modify provisions relating to continuity of care.

IN THE SENATE OF THE UNITED STATES—105th Cong., 2d Sess.

S. 2330

To improve the access and choice of patients to quality, affordable health care.

Referred to the Committee on _____
and ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT intended to be proposed by _____

Viz:

Beginning on page 12, strike line 21 and all that follows through line 8 on page 17, and insert the following:

"SEC. 725. CONTINUITY OF CARE.

"(a) IN GENERAL.—

"(1) TERMINATION OF PROVIDER.—If a contract between a group health plan and a health care provider is terminated (as defined in paragraph (2)), or benefits or coverage provided by a health care provider are terminated because of a change in the terms of provider participation in a group health plan, and an individual who is a participant or bene-

ficiary in the plan is undergoing a course of treatment from the provider at the time of such termination, the plan shall—

"(A) notify the individual on a timely basis of such termination, and

"(B) subject to subsection (c), permit the individual to continue or be covered with respect to the course of treatment with the provider's consent during a transitional period (as provided under subsection (b)).

"(2) TREATMENT OF TERMINATION OF CONTRACT WITH HEALTH INSURANCE ISSUER.—If a contract for the provision of health insurance coverage between a group health plan and a health insurance issuer is terminated and, as a result of such termination, coverage of services of a health care provider is terminated with respect to an individual, the provisions of paragraph (1) (and the succeeding provisions of this section) shall apply under the plan in the same manner as if there had been a contract between the plan and the provider that had been terminated, but only with respect to benefits that are covered under the plan after the contract termination.

"(3) TERMINATION.—In this section, the term 'terminated' includes, with respect to a contract, the expiration or nonrenewal of the contract by the group health plan, but does not include a termination of the contract by the plan for failure to meet applicable quality standards or for fraud.

"(b) TRANSITIONAL PERIOD.—

"(1) GENERAL RULE.—Except as provided in paragraphs (2) through (4), the transitional period under this subsection shall extend for at least 90 days from the date of the notice described in subsection (a)(1)(A) of the provider's termination.

"(2) INSTITUTIONAL CARE.—The transitional period under this subsection for institutional or inpatient care from a provider shall extend until the discharge or termination of the period of institutionalization and also shall include institutional care provided within a reasonable time of the date of termination of the provider status if the care was scheduled before the date of the announcement of the termination of the provider status under subsection (a)(1)(A) or if the individual on such date was on an established waiting list or otherwise scheduled to have such care.

"(3) PREGNANCY.—Notwithstanding paragraph (1), if—

"(A) a participant or beneficiary has entered the second trimester of pregnancy at the time of a provider's termination of participation; and

"(B) the provider was treating the pregnancy before the date of the termination;

the transitional period under this subsection with respect to provider's treatment of the pregnancy shall extend through the provision of post-partum care directly related to the delivery.

"(4) TERMINAL ILLNESS.—If—

"(A) a participant or beneficiary was determined to be terminally ill (as determined under section 1861(dd)(3)(A) of the Social Security Act) at the time of a provider's termination of participation; and

"(B) the provider was treating the terminal illness before the date of termination;

the transitional period under this subsection shall extend for the remainder of the individual's life for care directly related to the treatment of the terminal illness.

"(c) PERMISSIBLE TERMS AND CONDITIONS.—A group health plan may condition coverage of continued treatment by a provider under subsection (a)(1)(B) upon the provider agreeing to the following terms and conditions:

"(1) The provider agrees to accept reimbursement from the plan and individual involved (with respect to cost-sharing) at the rates applicable prior to the start of the transitional period as payment in full (or, in the case described in subsection (a)(2), at the rates applicable under the replacement plan after the date of the termination of the contract with the group health plan) and not to impose cost-sharing with respect to the individual in an amount that would exceed the cost-sharing that could have been imposed if the contract referred to in subsection (a)(1) had not been terminated.

"(2) The provider agrees to adhere to the quality assurance standards of the plan responsible for payment under paragraph (1) and to provide to such plan necessary medical information related to the care provided.

"(3) The provider agrees otherwise to adhere to such plan's policies and procedures, including procedures regarding referrals and obtaining prior au-

thorization and providing services pursuant to a treatment plan (if any) approved by the plan.

"(d) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to require the coverage of benefits which would not have been covered if the provider involved remained a participating provider.

"(e) DEFINITION.—In this section, the term 'health care provider' or 'provider' means—

"(1) any individual who is engaged in the delivery of health care services in a State and who is required by State law or regulation to be licensed or certified by the State to engage in the delivery of such services in the State; and

"(2) any entity that is engaged in the delivery of health care services in a State and that, if it is required by State law or regulation to be licensed or certified by the State to engage in the delivery of such services in the State, is so licensed.

"(f) NO IMPACT ON SOCIAL SECURITY TRUST FUND.—

"(1) IN GENERAL.—Nothing in this section shall be construed to alter or amend the Social Security Act (or any regulation promulgated under that Act).

"(2) TRANSFERS.—

"(A) ESTIMATE OF SECRETARY.—The Secretary of the Treasury shall annually estimate the impact that the enactment of this section has on the income and balances of the trust funds established under section 201 of the Social Security Act (42 U.S.C. 401).

"(B) TRANSFER OF FUNDS.—If, under subparagraph (A), the Secretary of the Treasury estimates that the enactment of this section has a negative impact on the income and balances of the trust funds established under section 201 of the Social Security Act (42 U.S.C. 401), the Secretary shall transfer, not less frequently than quarterly, from the general revenues of the Federal Government an amount sufficient so as to ensure that the income and balances of such trust funds are not reduced as a result of the enactment of this section.

"(g) NONAPPLICATION OF CERTAIN PROVISION.—Section 2721(b)(2) of the Public Health Service Act shall not apply to the provisions of this section.

AMENDMENT NO. ____ Calendar No. ____

Purpose: To expand provisions relating to continuity of care.

IN THE SENATE OF THE UNITED STATES—105th Cong., 2d Sess.

S. 2330

To improve the access and choice of patients to quality, affordable health care.

Referred to the Committee on _____
and ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT intended to be proposed by _____

Viz:

On page 13, between lines 16 and 17, insert the following:

"(2) TREATMENT OF TERMINATION OF CONTRACT WITH HEALTH INSURANCE ISSUER.—If a contract for the provision of health insurance coverage between a group health plan and a health insurance issuer is terminated and, as a result of such termination, coverage of services of a health care provider is terminated with respect to an individual, the provisions of paragraph (1) (and the succeeding provisions of this section) shall apply under the plan

in the same manner as if there had been a contract between the plan and the provider that had been terminated, but only with respect to benefits that are covered under the plan after the contract termination.

AMENDMENT NO. ____ Calendar No. ____

Purpose: To provide for the coverage of certain prescription drugs.

IN THE SENATE OF THE UNITED STATES—105th Cong., 2d Sess.

S. 2330

To improve the access and choice of patients to quality, affordable health care.

Referred to the Committee on _____
and ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT intended to be proposed by _____

Viz:

On page 18, strike line 1, and insert the following:

"SEC. 727. ACCESS TO NEEDED PRESCRIPTION DRUGS.

"(a) IN GENERAL.—If a group health plan provides benefits with respect to prescription drugs but the plan limits such benefits to drugs included in a formulary, the plan shall—

"(1) ensure participation of participating physicians and pharmacists in the development of the formulary;

"(2) disclose to providers and, disclose upon request under section 713, to participants and beneficiaries, the nature of the formulary restrictions; and

"(3) consistent with the standards for a utilization review program of the plan, provide for exceptions from the formulary limitation when a non-formulary alternative is medically indicated.

"(b) APPLICABILITY.—Notwithstanding section 728(a), the provisions of this section shall apply to group health plans and health insurance issuers as if included in—

"(1) subpart 2 of part A of title XXVII of the Public Health Service Act;

"(2) the first subpart 3 of part B of title XXVII of the Public Health Service Act (relating to other requirements); and

"(3) subchapter B of chapter 100 of the Internal Revenue Code of 1986.

"(c) NO IMPACT ON SOCIAL SECURITY TRUST FUND.—

"(1) IN GENERAL.—Nothing in this section shall be construed to alter or amend the Social Security Act (or any regulation promulgated under that Act).

"(2) TRANSFERS.—

"(A) ESTIMATE OF SECRETARY.—The Secretary of the Treasury shall annually estimate the impact that the enactment of this section has on the income and balances of the trust funds established under section 201 of the Social Security Act (42 U.S.C. 401).

"(B) TRANSFER OF FUNDS.—If, under subparagraph (A), the Secretary of the Treasury estimates that the enactment of this section has a negative impact on the income and balances of the trust funds established under section 201 of the Social Security Act (42 U.S.C. 401), the Secretary shall transfer, not less frequently than quarterly, from the general revenues of the Federal Government an amount sufficient so as to ensure that the income and balances of such trust funds are not reduced as a result of the enactment of such section.

"(d) NONAPPLICATION OF CERTAIN PROVISION.—Section 2721(b)(2) of the Public Health Service Act shall not apply to the provisions of this section.

"SEC. 728. GENERALLY APPLICABLE PROVISIONS.

O:\BAI\BAI98.H68

S.L.C.

-add ability to go ontside network at no extra cost if no one is available and qualified in network
- list social security transfer only one

AMENDMENT NO. ____ Calendar No. ____

Purpose: To ensure the adequacy of provider networks and that individuals have a choice of health care providers.

IN THE SENATE OF THE UNITED STATES—105th Cong., 2d Sess.

S. 2330

To improve the access and choice of patients to quality, affordable health care.

Referred to the Committee on _____
and ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT intended to be proposed by _____

Viz:

On page 18, strike line 1, and insert the following:

"SEC. 727. ADEQUACY OF PROVIDER NETWORK.

"(a) IN GENERAL.—Each group health plan that provides benefits, in whole or in part, through participating health care providers shall have (in relation to the coverage) a sufficient number, distribution, and variety of qualified participating health care providers to ensure that all covered health care services, including specialty services, will be available and accessible in a timely manner to all participants and beneficiaries under the plan.

"(b) TREATMENT OF CERTAIN PROVIDERS.—The qualified health care providers under subsection (a) may include Federally qualified health centers, rural health clinics, migrant health centers, and other essential community providers located in the service area of the plan and shall include such providers if necessary to meet the standards established to carry out such subsection.

"(c) APPLICABILITY.—Notwithstanding section 727(a), the provisions of this section shall apply to group health plans and health insurance issuers as if included in—

"(1) subpart 2 of part A of title XXVII of the Public Health Service Act;

"(2) the first subpart 3 of part B of title XXVII of the Public Health Service Act (relating to other requirements); and

"(3) subchapter B of chapter 100 of the Internal Revenue Code of 1986.

"(d) NO IMPACT ON SOCIAL SECURITY TRUST FUND.—

"(1) IN GENERAL.—Nothing in this section shall be construed to alter or amend the Social Security Act (or any regulation promulgated under that Act).

"(2) TRANSFERS.—

"(A) ESTIMATE OF SECRETARY.—The Secretary of the Treasury shall annually estimate the impact that the enactment of this section has on the income and balances of the trust funds established under section 201 of the Social Security Act (42 U.S.C. 401).

"(B) TRANSFER OF FUNDS.—If, under subparagraph (A), the Secretary of the Treasury estimates that the enactment of this section has a negative impact on the income and balances of the trust funds established under section 201 of the Social Security Act (42 U.S.C. 401), the Secretary shall transfer, not less frequently than quarterly, from the general revenues of the Federal Government an amount sufficient so as to ensure that the income and balances of such trust funds are not reduced as a result of the enactment of such section.

"(e) NONAPPLICATION OF CERTAIN PROVISION.—Section 2721(b)(2) of the Public Health Service Act shall not apply to the provisions of this section.

"SEC. 728. CHOICE OF PROVIDERS.

"(a) PRIMARY CARE.—A group health plan shall permit each participant and beneficiary to receive primary

care from any participating primary care provider who is available to accept such individual.

"(b) SPECIALISTS.—

"(1) IN GENERAL.—Subject to paragraph (2), a group health plan shall permit each participant or beneficiary to receive medically necessary or appropriate specialty care, pursuant to appropriate referral procedures, from any qualified participating health care provider who is available to accept such individual for such care.

"(2) LIMITATION.—Paragraph (1) shall not apply to specialty care if the plan clearly informs participants and beneficiaries of the limitations on choice of participating providers with respect to such care.

"(c) APPLICABILITY.—Notwithstanding section 729(a), the provisions of this section shall apply to group health plans and health insurance issuers as if included in—

"(1) subpart 2 of part A of title XXVII of the Public Health Service Act;

"(2) the first subpart 3 of part B of title XXVII of the Public Health Service Act (relating to other requirements); and

"(3) subchapter B of chapter 100 of the Internal Revenue Code of 1986.

"(d) NO IMPACT ON SOCIAL SECURITY TRUST FUND.—

"(1) IN GENERAL.—Nothing in this section shall be construed to alter or amend the Social Security Act (or any regulation promulgated under that Act).

"(2) TRANSFERS.—

"(A) ESTIMATE OF SECRETARY.—The Secretary of the Treasury shall annually estimate the impact that the enactment of this section has on the income and balances of the trust funds established under section 201 of the Social Security Act (42 U.S.C. 401).

"(B) TRANSFER OF FUNDS.—If, under subparagraph (A), the Secretary of the Treasury estimates that the enactment of this section has a negative impact on the income and balances of the trust funds established under section 201 of the Social Security Act (42 U.S.C. 401), the Secretary shall transfer, not less frequently than quarterly, from the general revenues of the Federal Government an amount sufficient so as to ensure that the income and

balances of such trust funds are not reduced as a result of the enactment of such section.

"(e) NONAPPLICATION OF CERTAIN PROVISION.—Section 2721(b)(2) of the Public Health Service Act shall not apply to the provisions of this section.

"SEC. 729. GENERALLY APPLICABLE PROVISIONS.

Sen P. 2

AMENDMENT NO. ____ Calendar No. ____

Purpose: To prohibit the imposition of improper financial incentives for health care providers.

IN THE SENATE OF THE UNITED STATES—105th Cong., 2d Sess.

S. 2330

To improve the access and choice of patients to quality, affordable health care.

Referred to the Committee on _____
and ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT intended to be proposed by _____

Viz:

On page 18, strike line 1, and insert the following:

"SEC. 727. PROHIBITION AGAINST IMPROPER INCENTIVE ARRANGEMENTS.

"(a) PROHIBITION OF IMPROPER PHYSICIAN INCENTIVE PLANS.—

"(1) IN GENERAL.—A group health plan may not operate any physician incentive plan (as defined in subparagraph (B) of section 1876(i)(8) of the Social Security Act) unless the requirements described

in subparagraph (A) of such section are met with respect to such a plan.

"(2) APPLICATION.—For purposes of carrying out paragraph (1), any reference in section 1876(i)(8) of the Social Security Act to the Secretary, an eligible organization, or an individual enrolled with the organization shall be treated as a reference to the applicable authority or a group health plan, respectively, and a participant or beneficiary with the plan respectively.

"(b) PROHIBITION OF CONTINGENT COMPENSATION ARRANGEMENTS IN UTILIZATION REVIEW PROGRAMS.—A utilization review program maintained by a group health plan shall not, with respect to utilization review activities, permit or provide compensation or anything of value to its employees, agents, or contractors in a manner that—

"(1) provides incentives, direct or indirect, for such persons to make inappropriate review decisions, or

"(2) is based, directly or indirectly, on the quantity or type of [adverse] determinations rendered.

"(c) PROHIBITION OF CONFLICTS.—A program described in subsection (b) shall not permit a health care professional who provides health care services to an individual to perform utilization review activities in connection

with the health care services being provided to the individual.

"(d) APPLICABILITY.—Notwithstanding section 728(a), the provisions of this section shall apply to group health plans and health insurance issuers as if included in—

"(1) subpart 2 of part A of title XXVII of the Public Health Service Act;

"(2) the first subpart 3 of part B of title XXVII of the Public Health Service Act (relating to other requirements); and

"(3) subchapter B of chapter 100 of the Internal Revenue Code of 1986.

"(e) NO IMPACT ON SOCIAL SECURITY TRUST FUND.—

"(1) IN GENERAL.—Nothing in this section shall be construed to alter or amend the Social Security Act (or any regulation promulgated under that Act).

"(2) TRANSFERS.—

"(A) ESTIMATE OF SECRETARY.—The Secretary of the Treasury shall annually estimate the impact that the enactment of this section has on the income and balances of the trust

funds established under section 201 of the Social Security Act (42 U.S.C. 401).

"(B) TRANSFER OF FUNDS.—If, under subparagraph (A), the Secretary of the Treasury estimates that the enactment of this section has a negative impact on the income and balances of the trust funds established under section 201 of the Social Security Act (42 U.S.C. 401), the Secretary shall transfer, not less frequently than quarterly, from the general revenues of the Federal Government an amount sufficient so as to ensure that the income and balances of such trust funds are not reduced as a result of the enactment of such section.

"(f) NONAPPLICATION OF CERTAIN PROVISION.—Section 2721(b)(2) of the Public Health Service Act shall not apply to the provisions of this section.

"SEC. 728. GENERALLY APPLICABLE PROVISIONS.

AMENDMENT NO. ____ Calendar No. ____

Purpose: To ensure a patients' right to a timely and independent appeal of an adverse coverage determination.

IN THE SENATE OF THE UNITED STATES—105th Cong., 2d Sess.

S. 2330

To improve the access and choice of patients to quality, affordable health care.

Referred to the Committee on _____
and ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT intended to be proposed by _____

Viz:

Beginning on page 28, strike line 10 and all that follows through the item following line 4 on page 48, and insert the following:

SEC. 121. ESTABLISHMENT OF GRIEVANCE PROCESS.

(a) ESTABLISHMENT OF GRIEVANCE SYSTEM.—

(1) IN GENERAL.—A group health plan, and a health insurance issuer in connection with the provision of health insurance coverage, shall establish and maintain a system to provide for the presentation and resolution of oral and written grievances

brought by individuals who are participants, beneficiaries, or enrollees, or health care providers or other individuals acting on behalf of an individual and with the individual's consent, regarding any aspect of the plan's or issuer's services.

(2) SCOPE.—The system shall include grievances regarding access to and availability of services, quality of care, choice and accessibility of providers, network adequacy, and compliance with the requirements of the amendments made by subtitle A.

(b) GRIEVANCE SYSTEM.—Such system shall include the following components with respect to individuals who are participants, beneficiaries, or enrollees:

(1) Written notification to all such individuals and providers of the telephone numbers and business addresses of the plan or issuer personnel responsible for resolution of grievances and appeals.

(2) A system to record and document, over a period of at least 3 previous years, all grievances and appeals made and their status.

(3) A process providing for timely processing and resolution of grievances.

(4) Procedures for follow-up action, including the methods to inform the person making the grievance of the resolution of the grievance.

SEC. 122. INTERNAL APPEALS OF ADVERSE DETERMINATIONS.

(a) RIGHT OF APPEAL.—

(1) IN GENERAL.—A participant or beneficiary in a group health plan, and an enrollee in health insurance coverage offered by a health insurance issuer, and any provider or other person acting on behalf of such an individual with the individual's consent, may appeal any appealable decision (as defined in paragraph (2)) under the procedures described in this section and (to the extent applicable) section 123. Such individuals and providers shall be provided with a written explanation of the appeal process and the determination upon the conclusion of the appeals process.

(2) APPEALABLE DECISION DEFINED.—In this section, the term "appealable decision" means any of the following:

(A) Denial, reduction, or termination of, or failure to provide or make payment (in whole or in part) for, a benefit, including a failure to cover an item or service for which benefits are otherwise provided because it is determined to be experimental or investigational or not medically necessary or appropriate.

(B) Failure to provide coverage of emergency services or reimbursement of maintenance care or post-stabilization care under section 721 of the Employee Retirement Income Security Act of 1974.

(C) Failure to provide a choice of provider under section 722 of the Employee Retirement Income Security Act of 1974.

(D) Failure to provide access to specialty and other care under sections 723 or 724 of the Employee Retirement Income Security Act of 1974.

(E) Failure to provide continuation of care under section 725 of the Employee Retirement Income Security Act of 1974.

(b) INTERNAL APPEAL PROCESS.—

(1) IN GENERAL.—Each group health plan and health insurance issuer shall establish and maintain an internal appeal process under which any participant, beneficiary, enrollee, or provider acting on behalf of such an individual with the individual's consent, who is dissatisfied with any appealable decision has the opportunity to appeal the decision through an internal appeal process. The appeal may be communicated orally.

(2) CONDUCT OF REVIEW.—The process shall include a review of the decision by a physician or other health care professional (or professionals) who has been selected by the plan or issuer and who has not been involved in the appealable decision at issue in the appeal.

(3) DEADLINE.—

(A) IN GENERAL.—Subject to subsection (c), the plan or issuer shall conclude each appeal as soon as possible after the time of the receipt of the appeal in accordance with medical exigencies of the case involved, but in no event later than—

(i) 72 hours after the time of receipt of an expedited appeal, and

(ii) except as provided in subparagraph (B), 30 business days after such time (or, if the participant, beneficiary, or enrollee supplies additional information that was not available to the plan or issuer at the time of the receipt of the appeal, after the date of supplying such additional information) in the case of all other appeals.

(B) EXTENSION.—In the case of an appeal that does not relate to a decision regarding an expedited appeal and that does not involve medical exigencies, if a group health plan or health insurance issuer is unable to conclude the appeal within the time period provided under subparagraph (A)(ii) due to circumstances beyond the control of the plan or issuer, the deadline shall be extended for up to an additional 10 business days if the plan or issuer provides, on or before 10 days before the deadline otherwise applicable, written notice to the participant, beneficiary, or enrollee and the provider involved of the extension and the reasons for the extension.

(4) NOTICE.—If a plan or issuer denies an appeal, the plan or issuer shall provide the participant, beneficiary, or enrollee and provider involved with notice in printed form of the denial and the reasons therefore, together with a notice in printed form of rights to any further appeal.

(c) EXPEDITED REVIEW PROCESS.—

(1) IN GENERAL.—A group health plan, and a health insurance issuer, shall establish procedures in writing for the expedited consideration of appeals

under subsection (b) in situations in which the application of the normal timeframe for making a determination could seriously jeopardize the life or health of the participant, beneficiary, or enrollee or such an individual's ability to regain maximum function.

(2) PROCESS.—Under such procedures—

(A) the request for expedited appeal may be submitted orally or in writing by an individual or provider who is otherwise entitled to request the appeal;

(B) all necessary information, including the plan's or issuer's decision, shall be transmitted between the plan or issuer and the requester by telephone, facsimile, or other similarly expeditious available method; and

(C) the plan or issuer shall expedite the appeal if the request for an expedited appeal is submitted under subparagraph (A) by a physician and the request indicates that the situation described in paragraph (1) exists.

(d) DIRECT USE OF FURTHER APPEALS.—In the event that the plan or issuer fails to comply with any of the deadlines for completion of appeals under this section or in the event that the plan or issuer for any reason expressly waives its rights to an internal review of an appeal

under subsection (b), the participant, beneficiary, or enrollee involved and the provider involved shall be relieved of any obligation to complete the appeal involved and may, at such an individual's or provider's option, proceed directly to seek further appeal through any applicable external appeals process.

SEC. 123. EXTERNAL APPEALS OF ADVERSE DETERMINATIONS.

(a) RIGHT TO EXTERNAL APPEAL.—

(1) IN GENERAL.—A group health plan, and a health insurance issuer offering group health insurance coverage, shall provide for an external appeals process that meets the requirements of this section in the case of an externally appealable decision described in paragraph (2). The appropriate Secretary shall establish standards to carry out such requirements.

(2) EXTERNALLY APPEALABLE DECISION DEFINED.—For purposes of this section, the term "externally appealable decision" means an appealable decision (as defined in section 122(a)(2)) if—

(A) the amount involved exceeds a significant threshold; or

(B) the patient's life or health is jeopardized as a consequence of the decision.

Such term does not include a denial of coverage for services that are specifically listed in plan or coverage documents as excluded from coverage.

(3) EXHAUSTION OF INTERNAL APPEALS PROCESS.—A plan or issuer may condition the use of an external appeal process in the case of an externally appealable decision upon completion of the internal review process provided under section 122, but only if the decision is made in a timely basis consistent with the deadlines provided under this subtitle.

(b) GENERAL ELEMENTS OF EXTERNAL APPEALS PROCESS.—

(1) CONTRACT WITH QUALIFIED EXTERNAL APPEAL ENTITY.—

(A) CONTRACT REQUIREMENT.—Subject to subparagraph (B), the external appeal process under this section of a plan or issuer shall be conducted under a contract between the plan or issuer and one or more qualified external appeal entities (as defined in subsection (c)).

(B) RESTRICTIONS ON QUALIFIED EXTERNAL APPEAL ENTITY.—

(i) BY STATE FOR HEALTH INSURANCE ISSUERS.—With respect to health insurance issuers in a State, the State may

provide for external review activities to be conducted by a qualified external appeal entity that is designated by the State or that is selected by the State in such a manner as to assure an unbiased determination.

(ii) BY FEDERAL GOVERNMENT FOR GROUP HEALTH PLANS.—With respect to group health plans, the appropriate Secretary may exercise the same authority as a State may exercise with respect to health insurance issuers under clause (i). Such authority may include requiring the use of the qualified external appeal entity designated or selected under such clause.

(iii) LIMITATION ON PLAN OR ISSUER SELECTION.—If an applicable authority permits more than one entity to qualify as a qualified external appeal entity with respect to a group health plan or health insurance issuer and the plan or issuer may select among such qualified entities, the applicable authority—

(I) shall assure that the selection process will not create any incentives

for external appeal entities to make a decision in a biased manner, and

(II) shall implement a procedures for auditing a sample of decisions by such entities to assure that no such decisions are made in a biased manner.

(C) OTHER TERMS AND CONDITIONS.—The terms and conditions of a contract under this paragraph shall be consistent with the standards the appropriate Secretary shall establish to assure there is no real or apparent conflict of interest in the conduct of external appeal activities. Such contract shall provide that the direct costs of the process (not including costs of representation of a participant, beneficiary, or enrollee) shall be paid by the plan or issuer, and not by the participant, beneficiary, or enrollee.

(2) ELEMENTS OF PROCESS.—An external appeal process shall be conducted consistent with standards established by the appropriate Secretary that include at least the following:

(A) FAIR PROCESS; DE NOVO DETERMINATION.—The process shall provide for a fair, de novo determination.

(B) DETERMINATION CONCERNING EXTERNALLY APPEALABLE DECISIONS.—A qualified external appeal entity shall determine whether a decision is an externally appealable decision and related decisions, including—

(i) whether such a decision involves an expedited appeal;

(ii) the appropriate deadlines for internal review process required due to medical exigencies in a case; and

(iii) whether such a process has been completed.

(C) OPPORTUNITY TO SUBMIT EVIDENCE, HAVE REPRESENTATION, AND MAKE ORAL PRESENTATION.—Each party to an externally appealable decision—

(i) may submit and review evidence related to the issues in dispute,

(ii) may use the assistance or representation of one or more individuals (any of whom may be an attorney), and

(iii) may make an oral presentation.

(D) PROVISION OF INFORMATION.—The plan or issuer involved shall provide timely access to all its records relating to the matter of the externally appealable decision and to all provisions of the plan or health insurance coverage (including any coverage manual) relating to the matter.

(E) TIMELY DECISIONS.—A determination by the external appeal entity on the decision shall—

(i) be made orally or in writing and, if it is made orally, shall be supplied to the parties in writing as soon as possible;

(ii) be binding on the plan or issuer;

(iii) be made in accordance with the medical exigencies of the case involved, but in no event later than 30 days (or 72 hours in the case of an expedited appeal) from the date of completion of the filing of notice of external appeal of the decision;

(iv) state, in layperson's language, the basis for the determination, including, if relevant, any basis in the terms or conditions of the plan or coverage; and

(v) inform the participant, beneficiary, or enrollee of the individual's rights to seek further review by the courts (or other process) of the external appeal determination.

(c) QUALIFICATIONS OF EXTERNAL APPEAL ENTITIES.—

(1) IN GENERAL.—For purposes of this section, the term "qualified external appeal entity" means, in relation to a plan or issuer, an entity (which may be a governmental entity) that is certified under paragraph (2) as meeting the following requirements:

(A) There is no real or apparent conflict of interest that would impede the entity conducting external appeal activities independent of the plan or issuer.

(B) The entity conducts external appeal activities through clinical peers.

(C) The entity has sufficient medical, legal, and other expertise and sufficient staffing to conduct external appeal activities for the plan or issuer on a timely basis consistent with subsection (b)(3)(E).

(D) The entity meets such other requirements as the appropriate Secretary may impose.

(2) CERTIFICATION OF EXTERNAL APPEAL ENTITIES.—

(A) IN GENERAL.—In order to be treated as a qualified external appeal entity with respect to—

(i) a group health plan, the entity must be certified (and, in accordance with subparagraph (B), periodically recertified) as meeting the requirements of paragraph (1) by the Secretary of Labor (or under a process recognized or approved by the Secretary of Labor); or

(ii) a health insurance issuer operating in a State, the entity must be certified (and, in accordance with subparagraph (B), periodically recertified) as meeting such requirements by the applicable State authority (or, if the States has not established an adequate certification and recertification process, by the Secretary of Health and Human Services, or under a

process recognized or approved by such Secretary).

(B) RECERTIFICATION PROCESS.—The appropriate Secretary shall develop standards for the recertification of external appeal entities. Such standards shall include a specification of—

(i) the information required to be submitted as a condition of recertification on the entity's performance of external appeal activities, which information shall include the number of cases reviewed, a summary of the disposition of those cases, the length of time in making determinations on those cases, and such information as may be necessary to assure the independence of the entity from the plans or issuers for which external appeal activities are being conducted; and

(ii) the periodicity which recertification will be required.

(d) CONTINUING LEGAL RIGHTS OF ENROLLEES.—Nothing in this subtitle shall be construed as removing any legal rights of participants, beneficiaries, enrollees,

and others under State or Federal law, including the right to file judicial actions to enforce rights.

SEC. 124. DEFINITIONS.

The definitions contained in section 2791 of the Public Health Service Act (42 U.S.C. 300gg-91) shall apply for purposes of this subtitle.

SEC. 125. APPLICABILITY.

The provisions of this subtitle shall apply to group health plans and health insurance issuers as if included in—

"(1) subpart 2 of part A of title XXVII of the Public Health Service Act;

"(2) the first subpart 3 of part B of title XXVII of the Public Health Service Act (relating to other requirements); and

"(3) subchapter B of chapter 100 of the Internal Revenue Code of 1986.

AMENDMENT NO. ____ Calendar No. ____

Purpose: To prohibit retaliation against health care providers who advocate on behalf of patients.

IN THE SENATE OF THE UNITED STATES—105th Cong., 2d Sess.

S. 2330

To improve the access and choice of patients to quality, affordable health care.

Referred to the Committee on _____
and ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT intended to be proposed by _____

Viz:

On page 17, after line 23, add the following:

"(c) PROTECTION FOR USE OF UTILIZATION REVIEW AND GRIEVANCE PROCESS.—A group health plan may not retaliate against a participant or beneficiary, or health care provider based on the participant's or beneficiary's, or provider's use of, or participation in, a utilization review process or a grievance process of the plan (including an internal or external review or appeal process).

AMENDMENT NO. ____ Calendar No. ____

Purpose: To strike provisions relating to medical savings accounts.

IN THE SENATE OF THE UNITED STATES—105th Cong., 2d Sess.

S. 2330

To improve the access and choice of patients to quality, affordable health care.

Referred to the Committee on _____
and ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT intended to be proposed by _____

Viz:

Beginning on page 179, strike line 9 and all that follows through line 18 on page 182.

U.S. Department of Justice
Office of Legislative Affairs

clearance due noon on 6/7

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

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

Dear Mr. Chairman:

This responds to questions forwarded to the Department of Justice following the appearance before your Committee on April 27, 1999, of Mr. John T. Bentivoglio, the Department's Special Counsel for Health Care Fraud and Chief Privacy Officer, regarding the confidentiality of health care records. Our responses are enclosed. In accordance with your request, we have also enclosed a diskette, which contains identical responses.

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.

Sincerely,

Jon P. Jennings
Acting Assistant Attorney General

Enclosures

cc: The Honorable Edward M. Kennedy
Ranking Minority Member

Senator Wellstone:

In the course of a fraud and abuse investigation of a substance abuse clinic, what happens if DOJ uncovers evidence of illegal drug use on the part of a patient -- can that information be used to prosecute the patient?

The short answer is no. Pursuant to the implementing regulations of the Substance Abuse Prevention, Treatment, and Rehabilitation Act, a law enforcement agency investigating a substance abuse clinic may obtain the clinic's patient records without the consent of the patients only (i) for a Medicare or Medicaid audit or evaluation under 42 C.F.R. § 2.53, or (ii) through a court order under 42 C.F.R. § 2.66 that permits use and disclosure of the records to investigate the provider. Records obtained by law enforcement for a Medicare or Medicaid audit or evaluation may only be used for the audit or evaluation activity (see 42 C.F.R. § 2.53(c)(4)), and records obtained through the court order to investigate the provider may not be used to conduct any investigation or prosecution of the patient, or even to seek authority to use records for such a purpose. (See 42 C.F.R. § 2.66(c)(2)).

Do these protections apply only to patients who receive federally funded treatment?

The inclusive definitions included in substance abuse patient regulations insure that a broad universe of patients is protected. The protections stated above apply to patients whose records are held by any program or activity relating to substance abuse education, prevention, training, treatment, rehabilitation, or research, which is conducted, regulated or directly or indirectly assisted by any department or agency of the United States. 42 U.S.C. § 290dd-2 (a). This covers nearly all substance abuse programs and activities as set forth in the implementing

regulations. The term "program" is broadly defined in 42 C.F.R. § 2.11.

The term "federal assistance" is also broadly defined and includes programs which, for example: 1) receive direct or indirect financial assistance for any purpose; 2) are conducted by a State or local government which receives revenue sharing funds which could be (but are not necessarily) spent on the substance abuse program; 3) are certified Medicare providers; 4) are ruled tax exempt charitable organizations by the Internal Revenue Service whose contributors may deduct contributions to the programs on their income tax; 4) authorized to conduct methadone maintenance treatment; or 5) registered to dispense controlled substances, all pursuant to 42 C.F.R. §2.12 (b). There are specific exceptions from these regulations only for the Veterans' Administration and the Armed Services.

What can be done for those citizens whose confidentiality has been violated? For example, recently, at the University of Michigan, medical records were made available through the Internet. Anyone searching for publications by name could also find the medical records of the same person online. To avoid this in the future, what mechanisms would be most helpful to your job to proactively uncover breaches of confidentiality?

The bills being considered by the Committee on Health, Education, Labor and Pension, S. 573, S. 578 and S. 881, all contain strong criminal provisions which will act as an effective deterrent to knowing and intentional breaches of medical record confidentiality for personal or commercial gain. The Department of Justice strongly endorses these provisions. In addition, the pending bills would also create an administrative process for circumstances which do not arise to criminal violations, where aggrieved individuals would be able to seek the imposition of civil monetary penalties on persons or entities which violated medical record privacy. These two

complementary provisions should provide new assurance to patients that confidentiality of their medical records will be maintained, and when it is not, that strong penalties will be applied.

Senator DeWine:

Could you please briefly describe the significance of the "routine use" exception to the Privacy Act, how often your agency relies on this exception, and examples of cases in which your agency invokes this exception?

The Department of Justice relies on the "routine use" exception to the Privacy Act both to access patient records held by other agencies, and to disclose such records as appropriate to investigate, prosecute and file civil actions based on misconduct. For example, the Department of Justice will sometimes request patient records from the Health Care Financing Administration (HCFA) in connection with an investigation of a provider's billings to Medicare. HCFA is authorized to release records covered by the Privacy Act to the Department of Justice by its published routine uses, which permit disclosure for " . . . the purpose of preventing, deterring, discovering, detecting, investigating, examining, prosecuting, suing with respect to, defending against, correcting, remedying, or otherwise combating fraud or abuse in a health benefits program funded in whole or in part by Federal funds." *See* 63 F.R. 38414 (7/16/98). With regard to the Department of Justice's disclosure of those patient records in its files which are covered by the Privacy Act, the Department's published routine uses as a general matter permit the Department to use information covered by the Privacy Act to investigate, litigate and prosecute potential violations of law. *See, e.g.*, 63 Fed. Register 8659 (2/20/98)

Currently, if you obtain health information during a Medicare fraud investigation against a doctor and you discover in those records that some patients of the doctor were also involved in the fraudulent record keeping scheme in order to defraud an insurance company (and not just Medicare), what would you currently do with that additional information and would any of these bills inhibit your ability to pass on the results of your investigation to the private insurance company?

An evaluation would be conducted by the investigative agency and the Department of Justice officials handling the matter to determine whether the patient's behavior in the scheme justifies further investigation. If a decision were made to proceed with a criminal or civil investigation of the patient for participation in the fraudulent activity, a new case file, or sub-file might be opened by the investigative agency. The investigative agency would use customary investigative techniques in support of the new investigation which could include interviews of witnesses (including private insurance companies which may have been victimized by the scheme), issuing compulsory process for production of documentary evidence, including medical records, conducting grand jury proceedings in criminal cases for the presentation of oral and documentary evidence.

The disclosure of general investigative results to a victim health insurance company should not be foreclosed by any of the three pending bills. However, the disclosure of personally identifiable health information as part of such a report could be problematic. For example, pursuant to S. 881, § 206, a health oversight agency, including a law enforcement agency acting in that capacity, would be foreclosed from further distributing protected health information for a purpose unrelated to the oversight activity. Since the victim insurance company is not a health oversight agency, and could not conduct health oversight as defined in the bill, this section could be interpreted to prohibit disclosure of protected health information to the victim. Similarly, S.

578, § 206, and S. 573 § 207 which both address oversight functions, do not include any authorization for oversight agencies to disclose protected health information to victim health insurance companies. New language would have to be added to explicitly authorize the health oversight agency to disclose protected health information to a victim health care benefit program for the purpose of enabling the victim to pursue other lawful and available remedies.

Mr. Bentivoglio, in your testimony you stated that in cases involving Medicare billing fraud, investigators would need access to hundreds of patient medical files, generally through an administrative or grand jury subpoena. How often are such subpoenas quashed upon filing of a motion to quash, and would this ability to quash a court order under S. 573 create difficulties for law enforcement?

Although motions to quash grand jury or administrative subpoenas in Medicare billing fraud investigations are sometimes filed now, they are seldom granted because federal law does not provide a general medical record privacy privilege. Furthermore, federal courts have been unsympathetic to medical record holders who argue for a new patient medical record privacy privilege to shield record holders from producing the medical records which would document the record holders' wrongdoing, thereby thwarting oversight investigations into health care fraud.

S. 573 would create a new patient privilege which could be used to thwart legitimate law enforcement investigations. Two specific provisions of S. 573 would operate to create serious problems for law enforcement.

Sec. 207 of S. 573 would prohibit an oversight agency from obtaining protected health information unless: 1) the purpose for which the disclosure is to be made cannot be accomplished without protected health information; 2) the purpose for which the protected health information is sought is of sufficient importance to "warrant the effect on, or the risk to, the

privacy" of the individuals "that additional exposure might bring"; and 3) there is a reasonable probability that the purpose of the disclosure will be accomplished. While Sec. 207 itself does not provide for judicial review of these factors, such a review may occur anyway when law enforcement resorts to obtaining a court order during an oversight function to obtain protected records, thereby invoking the requirements of Sec. 208.

Sec. 208 imposes new prerequisites to be met before "a court order for access to protected health information" can be issued. The use of the term "court order" will apply to a broader range of situations than seems to be anticipated and potentially could cover many situations where a warrant or subpoena is used, even during health oversight functions. While Sec. 207 authorizes law enforcement to obtain protected health information for health care fraud oversight activities, law enforcement will continue to use warrants, subpoenas and court orders, as it does now, before protected records will actually be produced. Whenever a record holder does not comply with a subpoena, or seeks to quash the results of an executed search warrant, a "court order" will be necessary Sec. 208 creates a special process for court review of requested disclosures of protected health information through all "court orders."

Sec. 208 would require a Court to consider a three part test before granting such an order: 1) the information sought is relevant and material to an ongoing criminal investigation; 2) "deidentified" information would not be sufficient, and 3) the law enforcement need would outweigh the privacy interest of the individual to whom the information pertains. The third standard under Sec. 208 for the first time would permit a record-holder to oppose disclosure of protected health information on behalf of a patient. In addition, the review process under Sec. 208, would provide a vehicle by which the Sec. 207 standards would be subject to Court review

as well.

The provisions of S. 578 would invite a substantial increase in the numbers of motions to quash, and would override judicial precedent limiting medical record holders from concealing their wrongdoing by asserting patient privacy concerns as a shield to disclosure. The successful assertion of patient privacy by a medical record holder that is under scrutiny could result in the suppression of critical evidence and cause the termination of a legitimate investigation. The requirement of S. 578 would divert law enforcement resources and could result in substantial delays while Courts consider whether to grant disclosure orders, and while such decisions are on appeal. Since these proceedings would not suspend statutes of limitations, the timing and length of such delays could extend beyond the expiration of statutes of limitations foreclosing certain criminal or civil proceedings entirely.

Would you please give an example that illustrates the significance of the hot pursuit or exigent circumstances exception in S. 573, and why a simple waiver of any notice requirement to the individual when a risk of destruction of property or unavailability of the evidence may result is not enough to negate the need for this hot pursuit or exigent circumstances exception, as some may argue?

The hot pursuit and exigent circumstances exceptions to the general compulsory process requirement that would be imposed under S. 573, §208 (i) would be of limited utility to law enforcement insofar as "hot pursuit" and "exigent circumstances" are terms of legal art which have been narrowly defined by judicial precedent which carves out limited exceptions to the necessity for search warrants. The exigent circumstance and hot pursuit exceptions in S. 573 appear to restrict current law enforcement practice.

For example "hot pursuit" is generally defined to include "immediate and continuous

pursuit" of the escapee. *Welsh v. Wisconsin*, 466 U.S. 740, 753 (1984). Where the suspect has fled, possibly to unknown emergency rooms, the police could not be said to be in immediate and continuous pursuit.

The term "exigent circumstances" has also been narrowly interpreted. "As an exception to the warrant requirement, exigent circumstances must be 'jealously and carefully drawn.' " *United States v. Anderson*, 981 F.2d 1560, 1567 (10th Cir. 1992) (quoting *United States v.* Aquino, 836 F.2d 1268, 1270 (10th Cir. 1988). *Accord*, *United States v. Anderson*, 154 F.3d 1225, 1233 (10th Cir. 1998). One trial court recently defined exigent circumstances to exist when a warrantless search is made: 1) to render emergency aid or assistance to persons reasonably believed to be in distress or in need of assistance; 2) to prevent destruction of evidence or contraband; or 3) to protect officers from other suspects or persons from whom [the law enforcement officers] reasonably believe may be present, and if so, whom they reasonably believe may be armed and dangerous. *Tamez v. City of San Marcos, Texas*, 118 F.3d 1085, 1095, note 4 (5th Cir. 1998). The Supreme Court has found as a matter of law that exigent circumstances justify a warrantless search when in the first instance, there is probable cause for the search or seizure, and in addition: 1) there is an imminent danger someone may destroy evidence; 2) the safety of law enforcement officers or the general public is threatened, or 3) the suspect is likely to flee the premises before the officer can obtain a warrant. *Tamez*, 118 F.3d, at 1095 (citations omitted).

A simple waiver of patient notice where destruction of evidence or unavailability of evidence is a concern, would not obviate the need for the exigent circumstances exception to a requirement for compulsory process. Furthermore, the waiver of patient notice would also be

insufficient to preserve current law enforcement practice.

This can be illustrated by the following example: A victim is raped in the District of Columbia, and during the course of the crime, a car door is slammed on the assailant's hand. By the time the D.C. police arrive at the scene, the assailant has fled ten minutes earlier by running into the Metro Center Metro station. The D.C. police have no idea which Metro line the assailant took, in which direction he headed, or what stop he may have gotten off. This would not be a situation that could be classified as "hot pursuit."

The D.C. police do have a general description of the victim and know that the assailant's right hand was slammed in the car door, probably causing injuries sufficient to require emergency room care. The D.C. police put out an all points bulletin within the District and surrounding counties in Maryland and Virginia, and request law enforcement agencies in those jurisdictions to check with hospital emergency rooms and all night emergency clinics to determine whether any persons with the injury described and the physical description have been treated within the last three hours. Information comes back that 7 individuals meeting the description with the injury have been treated. The facilities are in Fairfax, Montgomery and the District of Columbia. Since 7 facilities have reported back, its is unlikely the threshold requirement of probable cause exists to search any of the emergency rooms since the law enforcement agencies could not show that there is probable cause to believe there is evidence of a crime at each of the emergency rooms. After all, there was only one assailant and only one of the emergency rooms of the seven would have evidence of the crime. The officer would have to show that there was probable cause to search each emergency room individually. *United States v. Johnson*, 26 F.3d 669, 694 (7th Cir. 1994) (probable cause for each apartment to be searched in a multiple dwelling facility must be shown).

In a multi-location search warrant, the reviewing magistrate must make a probable cause determination for each of the locations to be searched independently. *Greenstreet v. County of San Bernardino*, 41 F.3d 1306, 1309 (9th Cir. 1994).

Even if probable cause could somehow be shown for each emergency facility, under search warrant jurisprudence defining exigent, it is unlikely that the "exigency" test could be met. There would be no fear of destruction of evidence, or threatened harm to the public or a law enforcement officer, and the law enforcement agency would not be able to demonstrate a belief that the suspect would flee, particularly if a suspect who matched the description recently left a particular emergency room.

Senator Jeffords:

At the hearing, the Chairman asked for a copy of any new guidance the Department issues regarding obtaining and using protected health information.

As Mr. Bentivoglio testified at the hearing, the Department is in the process of developing more comprehensive guidance on obtaining and handling protected health information. When this guidance is finalized, a copy will be supplied to the Committee.

In the interim, the Department previously circulated two documents which address medical record confidentiality which are attached for your information. The first is an excerpt from the "Guidelines Implementing the Fraud and Abuse Control Program" jointly issued in January, 1997, by the Attorney General and the Secretary of Health and Human Services, as required by the Health Insurance Portability and Accountability Act of 1996. The second is a memorandum dated October 15, 1998 from Deputy Attorney General Eric H. Holder, Jr. which contains an extended discussion of medical record privacy considerations.

Enc. 2

DATE: 6/1/99

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
ROOM 405H, HUMPHREY BUILDING
200 INDEPENDENCE AVE, SW
WASHINGTON, D.C. 20201

PHONE: (202)690-7450 *FAX: (202)690-8425*

TO: Chris J

OFFICE: _____

ROOM: _____

PHONE: _____

FAX: 456-5557

FROM:

[ ] JANE HORVATH

[ ] HOLLY BODE

[ ] SHARON CLARKIN

[ ] BOB GUIDOS

[ ] GREG JONES

[ ] ANDREA LEVARIO

[ ] ROGER MCCLUNG

[ ] TANISHA PARKER

[ ] JON RETZLAFF

[ ] MARC SMOLONSKY

[ ] STEPHANIE WILSON

[ ]

(INCLUDING COVER): 2

REMARKS:

Privacy - HELP Comm.

Amendment Status - 5/28

Amendments Agreed To
Kennedy #1 -- Disclosure of a Key as modified

Kennedy #5 -- Drug Testing as modified

Wellstone #1 -- Application to Deceased Individuals

Wellstone #2 -- Findings and Psychotherapists as modified

Jeffords #1 -- Technical Package (will be the vehicle for additional technicals)

Jeffords/Dodd #2 -- Deemed Disclosure

Jeffords #3 -- Workers' Compensation - Congress acts' delete'd.

Jeffords #4 -- Adverse Event Reporting

Amendments Under Negotiation
Kennedy #2 -- Communicable Diseases

Kennedy #3 -- Rights of Minors

Kennedy #4 -- Underwriting

Kennedy #7 -- Law Enforcement

Wellstone #5 -- Workers' Compensation

Amendments that May Be Offered
Kennedy #6 -- Private Right of Action

Wellstone #3 -- Federal Floor Preemption - back to leahy language

Wellstone #4 -- Partitioning of Health Information

DeWine -- Title II

Sessions -- Private Right of Action

OFFICE OF MANAGEMENT AND BUDGET

Legislative Reference Division

Labor-Welfare-Personnel Branch

Telecopier Transmittal Sheet

SPECIAL

FROM: Bob Pellicci -- 395-4871

DATE: 6/1 **TIME:** 1040 am

Pages sent (including transmittal sheet): 4

COMMENTS: Signed Justice letter on medical records privacy.

TO:

Sally Katzen
Chris Jennings / Devorah
Peter Swire
Andrea Levario (HHS)

PLEASE CALL THE PERSON(S) NAMED ABOVE FOR IMMEDIATE PICK-UP.

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
Acting Assistant Attorney General

cc: The Honorable Edward M. Kennedy
Ranking Minority Member

Privacy - HELP Comm.

Amendment Status - 5/28

Amendments Agreed To
Kennedy #1 -- Disclosure of a Key as mod:
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Kennedy #6 -- Private Right of Action
Wellstone #3 -- Federal Floor Preemption - back to Leahy language.
Wellstone #4 -- Partitioning of Health Information
DeWine -- Title II
Sessions -- Private Right of Action

PRIVACY MTG 6/2

Chairman's mark didn't come out last Friday; expected to come out this Tuesday

1. right of action (private) / Underwriting
2. abortion

most of issues on top tier list have been resolved

private research been agreed to on a staff level; HHS wants more external oversight by Fed government.

can we meet the current language? Jane says yes

Jeanie Lucy & minor abortions

Kennedy wants right of action in IRs no.
precedent that would hurt us in terms of PBGR

supports will only go to markup if there's bipartisan support
Dreggs will not permit a voice vote.

HAA, Blues, NFIB do not want a right of action – this raises the stakes on an agreement

preemption; no proactive stance – no need to tip our hand.

Standards of proof
ban on class action
$1000 damages

models for pattern or practice for individuals

Conference call on Monday / after Chairman's mark.

The Honorable James M. Jeffords
Chairman
Committee on Health, Education, Labor and Pensions
United States Senate
Washington, D.C. 20510-6300

Dear Chairman Jeffords:

I understand that the Committee on Health, Education, Labor and Pensions may soon consider a bill entitled the "Health Information Confidentiality Act of 1999." I would like to take this opportunity to present the views of the Department of Labor on that bill.

The bill's purpose is to ensure confidentiality with respect to medical records and health care-related information. It would impose guidelines for the use and disclosure of medical records by health care providers, researchers, insurers, and employers. It would also impose civil and criminal penalties on individuals who use information improperly through unauthorized disclosure.

The Department of Labor strongly supports the bill's intention of protecting the confidentiality of personal health care information. We do, however, have a number of general comments regarding the bill as well as questions and concerns about specific provisions. These comments are listed in the enclosure for the Committee's consideration.

The Office of Management and Budget advises that there is no objection to the submission of this report from the standpoint of the President's program.

Sincerely,

Alexis M. Herman

Enclosure

DEPARTMENT OF LABOR COMMENTS
ON
THE HEALTH INFORMATION CONFIDENTIALITY ACT OF 1999

GENERAL COMMENTS:

Relation to Civil Rights Laws

Several civil rights laws, such as the Americans with Disabilities Act of 1990 and the Rehabilitation Act of 1973, as well as their implementing regulations, incorporate standards of confidentiality of medical information and specify those individuals who may have access to that information and the circumstances under which access is available. We recommend that language be added to the bill to ensure that the rights and protections provided under laws such as the ADA and the Rehabilitation Act are unaffected by this bill.

After-the-Fact Notice

Except where it would interfere with an on-going civil or criminal investigation, an " after-the-fact" notice should be required to be given to individuals when their health information has been disclosed to third parties (including law enforcement) without their notice or consent. Such a provision would allow patients to pursue appropriate legal remedies.

Technical Security

Pursuant to HHS model standards, the bill should include provisions regarding technical security for computerized data, including audit trails showing who accessed the information.

Workers Compensation Application

We believe that workers compensation programs should not be included in the proposed legislation, which would add an unnecessary and burdensome step to the existing regulations. Our current mechanisms already provide sufficient protection and confidentiality of claimants' records and rights. This bill, however, is silent concerning whether workers compensation programs are to be covered. We suggest adding a provision similar to S. 881, presently before Congress, which expressly excludes "any policy, plan or program to the extent that it provides, arranges or administers health benefits pursuant to a program of workers compensation or automobile insurance" from the definition of health plan.

OALJ Application

The application of this bill to the Office of Administrative Law Judges (OALJ) is problematic. The OALJ conducts public hearings under the Administrative Procedure Act (APA). Thus, hearing transcripts and documents submitted to the OALJ are public court records, generally

subject to public inspection. Section 201 of the bill, however, bars disclosure of protected health information by a "health oversight agency," a "public health authority," and a "law enforcement official," among others. When adjudicating physician/health care provider debarment cases under the Longshore and Harbor Workers Compensation Act and the Federal Employees Compensation Act, OALJ might meet the definition of "health oversight agency." OALJ might also meet the other two definitions when adjudicating many types of cases, such as workers compensation claims under the Black Lung Benefits Act and the Longshore and Harbor Workers Compensation Act. Arguably, then, OALJ could be simultaneously subject to the nondisclosure provisions of the bill and the full disclosure provisions of the APA. It is not clear that this situation is addressed by section 401(a)(3) which provides that the bill should not be construed as " repealing, 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." This situation should be clarified.

MEWA Application

It is not clear whether Multi Employer Welfare Arrangements (MEWAs) would be covered by this bill. Generally, a MEWA is any arrangement established for the purpose of providing benefits to employees (or their beneficiaries) of two or more employers. The question arises whether the MEWA itself (as distinct from the employer whose employees receive benefits from the MEWA) should meet the requirements of the legislation. To ensure that MEWAs are covered, those MEWAs that provide health benefits could be included in the definition of "health plan" or "group health plan."

SPECIFIC COMMENTS:

Section 4(9) -- Definition of Health Oversight Agency.

It is unclear whether the Department of Labor's Pension and Welfare Benefits Administration (PWBA) is a "health oversight agency" as defined by this section, or whether it is subject to the more stringent standards imposed on law enforcement agencies. Clearly, PWBA conducts some law enforcement activities such as investigations and litigation of cases involving pension plans and employee benefit plans. However, the agency also conducts oversight activities such as audits of health plans to ensure compliance with the fiduciary requirements of the Employee Retirement Income Security Act (ERISA), its claims review procedures and other requirements of ERISA. Thus for purposes of this law, PWBA could be considered a "health oversight agency." However, only some parts of the definition of "health oversight agency" apply to PWBA. Specifically, subsection 4(9)(B)(i) does apply to PWBA, i.e. "Person who performs or oversees performances of an audit, ...or investigation relating to...compliance with...legal...standards." In contrast, the language regarding a public agency dealing with the licensing, accreditation, or provider credentialling in subsection 4(9)(B)(ii) does not apply to PWBA. We recommend changing the "and" to an "or" between subsections 4(9)(B)(i) and (ii).

Section 4(10) -- Definition of Health Plan.

As written, the definition of "health plan" includes health insurance plans such as Health Maintenance Organizations and Provider Sponsored Organizations, as well as ERISA employee welfare benefit plans and group health plans. Because these are two different concepts, the definition could be confusing. We recommend, therefore, defining the terms "ERISA employee welfare benefit plans" and "ERISA group health plans" separately from the term "health plan."

Moreover, the definition of "health plan" does not include third party administrators who contract with group health plans to administer health benefits (even though such administrators regularly handle personal health information). We recommend that the definition of "group health plan" be amended to include "third party administrator or other person acting for or on behalf of the plan." Alternatively, the definition of "agent" in section 4(2) could be expanded to specifically include third party administrators.

Section 4(24) -- Definition of School or University.

We recommend adding preschools and day care centers to this definition. Both have health information about students as well as employees.

Section 101 -- Inspection and Copying of Protected Health Information.

Subsection 101(d)(3) would give an individual the right to file with the person who denies a request for inspection or copying of protected information a "concise statement setting forth the request for inspection or copying." In order to conform this subsection with subsection 102(c)(3) which deals with a refusal to amend the information, the following should be added to the end of subsection 101(d)(3): "and the individual's reasons for disagreeing with the refusal."

Section 103 -- Notice of Confidentiality Practices.

Section 103(a) states that health care providers, employers, insurers, etc., shall "post or provide, in writing and in a clear and conspicuous manner, notice of the entity's confidentiality practices...." This notice needs to be available in alternate formats (including, but not limited to, braille, large print, and electronic format) for those individuals with disabilities who are unable to read a written notice that is posted or handed out.

Section 202 -- Procurement of Authorizations for Disclosure of Protected Health Information for Treatment, Payment and Health Care Operations.

Subsection 202(a)(2) allows for a "consolidated" authorization: a single authorization may be secured for each individual in connection with treatment, payment, and health care operations. We strongly oppose this type of authorization. Authorizing release of information for payment purposes can be totally unrelated to what an individual feels is necessary to release for treatment purposes. In addition, the term "health care operations" is very broad. Allowing a single authorization to release information for "health care operations" would allow release for many

more purposes than the average person would expect. Furthermore, it is inappropriate to impose a requirement that patients sign blanket consent forms for release of information as a condition of getting treatment.

Subsection 202(a)(3) [and subsequent paragraphs allowing for a one-time authorization] states that "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." Again, we strongly oppose this "one-time only" consent at the time of enrollment. S. 573, addressing this same subject, requires patient consent for each instance of sharing information. That is a better approach. In addition, the term "legal, informed authorization," as used in this and the following sections, seeds to be defined.

Subsection 202(a)(4), when referring to authorizations for disclosure by individuals in plans other than employer-provided plans, refers to both individual and non-employer groups. This is redundant because the definition of "individual market" in Section 2791(e) of the Public Health Service Act as amended by the Health Insurance Portability and Accountability Act, already encompasses non-employer groups, i.e., "Market for health insurance coverage offered to individuals other than in connection with a group health plan." Therefore, we recommend substituting "through the individual market" for "to individual and non-employer groups", and defining "individual market" consistent with Section 2791(e) of the Public Health Service Act.

Section 202(b)(3) -- Termination of Plan.

This section would allow a health plan to terminate an enrollee's coverage if the enrollee revokes the disclosure authorization. We oppose this section and recommend that it be deleted.

Section 204 -- Next of Kin and Directory Information

Section 204(b)(1)(A) would permit unlimited disclosure where a person with a mental condition has not objected and there are no indications that he or she would object. A person who is not capable of objecting because of either a physical or mental condition is entitled to some form of representation before a disclosure is made.

Section 206 -- Oversight
Section 207 -- Public Health
Section 208 -- Health Research

Unauthorized disclosures are permitted in far too many circumstances. Each of these sections allows the disclosure of protected health information, with very few limits or restrictions. There is no justification given and, without such justification, it is unclear to the Department of Labor why this should be allowed.

Section 210 -- Disclosure for Law Enforcement Purposes.

Again, this appears to be overly broad, allowing the release of protected information in many

circumstances. The legislation states that protected health information may be used only for purposes of a "legitimate law enforcement activity" but that term is not defined. At a minimum, the meaning of this term should be clearly delineated.

Section 213(d) -- Application to Deceased Individuals.

There does not appear to be a reason to limit the confidentiality protection after a person dies. The U. S. Supreme Court has held that the attorney-client privilege continues after death because of the risk of embarrassment to the family, and other reasons. We believe that a time limit is equally inappropriate when dealing with confidential medical records. If, however, a time limit is deemed necessary, two years (as provided by the bill) is too short.

Section 312 -- Procedures for Imposition of Penalties.

This section of the bill would establish a procedure for imposition of civil and criminal penalties on all entities that violate the Act, including ERISA plans. Sections 501 and 502 of ERISA respectively provide procedures for imposing criminal and civil penalties on ERISA plans. Thus, although the Department of Labor has the tools to enforce these protections against group health plans, and this bill would apply to ERISA plans, the Department is not given a role. This may complicate the coordination of regulation and enforcement.

Section 401(a) -- Relationship to State and Federal laws.

Section 401(a)(1) would preempt any State law "treatment, payment and health care operations...or...health research" if such State law is less restrictive than the provisions of this Act. This language may give the bill an overly broad reach by preempting State laws that are not directed at entities covered by the bill. We recommend adding language clarifying that this section only preempts State laws related to the privacy of protected health information that are directed at the entities covered by this bill.

Section 401(a)(2) would preempt State laws that grant more protection to confidential health information if they were enacted after the effective date of the Act. This legislation should create a minimum acceptable standard for basic Federal privacy protection. It should not preempt States from taking even stronger steps to protect privacy.

U.S. Department of Justice

Office of the Deputy Attorney General

Washington, D.C. 20530

CJ okay
gc okay
Sally
David

FAX TRANSMISSION SHEET

TO: Chris Jennings

Phone: _____ **Fax:** 456-5557

FROM: John T. Bentivoglio
Special Counsel for Health Care Fraud

Phone: (202) 514-2707 Fax: (202) 616-1239

DATE: 5/24/99

NUMBER OF PAGES (including this cover sheet): 4

MESSAGE: Revised draft.

Note: The information in this facsimile should be considered confidential.

U.S. Department of Justice

Office of the Deputy Attorney General

Special Counsel for Health Care Fraud *Washington, D.C. 20530*

[Monday, May 24, 1999]

DRAFT

The Honorable James M. Jeffords
Chairman
Committee on Health, Education, Labor and Pensions
United States Senate
Washington, D.C. 20510-6300

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 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.

Sincerely,

DRAFT

John T. Bentivoglio

cc: The Honorable Edward M. Kennedy
Ranking Minority Member

5-5167

DRAFT DRAFT

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 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 will re-identify that information. 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.

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.

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

PRIVACY

202 362 8003 May 24

5 Amendments

1. exigent circumstances
2. hot pursuit "attempting to locate or identify"; DOJ (striking) doesn't like this.

210(g) doesn't give comfort b/c it's of great concern to Kennedy people.

not clear that we need both exceptions.

Bentivoglio giving in on exigent circumstances → they'll hold on

210(g) Name, address, SS#, type of injury & treatment, MD providing treatment.

hot pursuit is too narrow.

STOP ~~[illegible]~~ exigent after request

→ or is attempt to locate or identify

DOL pros [illegible]