Balancing Interests

HHS

1. Privacy interests generally

2. Special sensitivity of health records: mental health/HIV/reproduction

3. Importance of protecting health records to obtaining health care and viable doctor/patient relationship

4. Anti Big Government/snooping Government database

DOJ

1. Law enforcement effectiveness in the face of costly/time-consuming/procedural hoops

2. State and local objection to preemption Most crimes are state/local level

3. Concern re: privacy is insurers, snoopers, not legitimate law enforcement

4. Imbalance between access where crime is health care fraud v. terrorism/violent crime

Issues

What procedures are required when

- patient is a target
- crime is not health care

- Exceptions for access
  - witness
  - victim
  - fugitive

- No exception for access
  - research
  - statistical information
  - public health authorities

Question 1: Notice to Patient

HHS: list of exceptions which law enforcement must prove in court before delay of notice:
- threat of harm
- flight
- intimidation
- destruction of evidence

DOJ: heavy lawyering to establish specific exemptions, case-by-case effort to obtain delay
time consuming
delay in notice has no practical utility

Options

- Statute says when to provide notice
- Courts decide

Question 2: Standard for Court to use

HHS: clear and convincing evidence to believe information is relevant
probable cause to believe information is relevant

DOJ: balance the public interests and the need for disclosure against the injury to the patient, to the physician-patient relationship, and to the treatment services.

Can mix/match Q1/Q2
possible to expand fugitive to include perpetrator

Can have different standards for Feds v. State/local

Call Nan

- What is the status quo?
- what shld std be for obtaining records?

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

April 12, 1996

MEMORANDUM FOR THE HONORABLE LEON PANETTA

Subject: Medical Records

I am writing in response to Director Rivlin's memorandum recommending a position for the Administration on law enforcement access to medical records. I believe that our best course would be to adhere to the language we endorsed in the Mitchell health care reform bill, which was repeated in this Congress in S. 1360 as introduced.

Our approach is a balanced one. We support law enforcement access without a court proceeding:

* when the crime under investigation is related to health fraud or public benefit fraud;
* when the target of investigation is not the patient whose records are sought;
* to identify a victim, witness or fugitive; or
* to comply with state reporting laws, such as for abuse or gunshot wounds.

In other situations, we support law enforcement access if a court of competent jurisdiction allows it. That would mean that law enforcement agencies would obtain access if they could show that the information was likely to be relevant. If certain criteria are met, we agree that there would be no notice to the patient of the request. (Director Rivlin's memorandum incorrectly states my position as to the notification requirement. We have always supported a process in which notice to the individual would be *waived* if there were a showing of threat of harm or intimidation, of flight, of destruction of evidence, or of impeding an ongoing investigation.)

In addition, the situation of law enforcement pursuit of a fugitive is one which we accept as a legitimate need for quick access to records. The term "fugitive" is as yet undefined, and we are ready to work with Justice to define it in a way that permits the use of medical information when necessary to apprehend a suspect, in exigent circumstances.

There has been an important political development that strengthens my concerns. Today the Republican Senate Committee staff released the newly revised version of S. 1360. Enclosed is a copy of the relevant page of this new version. You will see that the proposed standard for law enforcement access has been changed, in that it has been *heightened*. The earlier version required a showing of "probable cause to believe that the information is relevant." The new version requires a showing of "clear and convincing evidence to believe that the information is relevant." I have attached several examples of written testimony in which privacy advocates specifically sought this higher standard for law enforcement. Most

sensitive are patient records in such areas as psychotherapy, sexually transmitted diseases such as AIDS, and records of an abortion. Obviously, the Committee has responded.

As you can appreciate, the issue of access to medical records by law enforcement agencies without notification raises serious privacy concerns in the public mind. The prospect of local sheriffs or the FBI reading medical records without any prior notice raises the specter of "big government" at its worst. Few things are more sensitive to someone who has seen a therapist or who has been diagnosed with HIV than their medical files. That is why the American Medical Association has such grave concerns with the confidentiality of medical records. (See attached letter.)

I firmly believe that the adoption of the Justice Department position would not only undermine the Administration's credibility on this important issue, it would place at serious risk our efforts to obtain the cooperation of the medical community and the insurance carriers in seeking to establish necessary data collection systems to measure the quality of health care. The same concerns which guided our decision-making process three years ago should lead us to the same conclusions. If anything, there is even more reason to arrive at this conclusion today given the current atmosphere in Congress, the anti-government mood of the country, the growth of large corporate HMOs, and the opportunities to demagogue this issue by anti-law enforcement extremists.

I believe that the Administration position to date has been the correct one, and that we can work for a bipartisan bill.

I would appreciate the opportunity to discuss with you any strategy that might be contemplated before a final decision is made.

Donna E. Shalala

DEPARTMENT OF HEALTH & HUMAN SERVICES Office of the Secretary

Office of the General Counsel
Washington, D.C. 20201

FACSIMILE TRANSMISSION

TO: Jen Klein

FAX NUMBER: 456-2878

FROM: *Nan D. Hunter*
Deputy General Counsel

Facsimile Phone number - 202-690-7998

Telephone Number - 202-690-7780

ADDRESS: *700-E H.H. Humphrey Building*
200 Independence Avenue, S.W.
Washington, D. C. 20201

COMMENTS: Old but good summary of points

Total number of pages 4

DEPARTMENT OF HEALTH & HUMAN SERVICES Office of the Secretary

Office of the Assistant Secretary
for Planning and Evaluation
Washington DC 20201

November 28, 1995

TO: Ms. Hunter, OGC
Ms. Levario, OASL/H
Ms. Wallace, OGC/I

FROM: John P. Fanning
Division of Data Policy, OASPE

SUBJECT: DoJ Draft Statement for the Record on S. 1360 – Medical Records Confidentiality Act of 1995 – Ms. Wallace's Memorandum of November 28, 1995

We should object to this statement *in toto*. There are legitimate law enforcement access issues in this bill, but this request for a total law enforcement exemption from any controls is not an appropriate beginning for the discussion. Indeed, it may ultimately result in public opposition that could cause the committee to strengthen the barriers to law enforcement access – including for purposes that are important for the program interests of this Department.

We should accept the DoJ suggestion (made in the context of DoJ review of our proposed statement) that our own statement express to the committee the need to work with the Department of Justice to accommodate law enforcement access as necessary to fight health care fraud and abuse. And then we should sit down with the Department of Justice and DHHS staff concerned with fraud and abuse and see how the bill helps or hurts. We all share the goal of catching people who defraud the health care payment system.

Meanwhile, these specific failings in the text should be noted.

- The statement sounds agitated ("An untargeted effort to expand privacy protections will erect unwarranted substantial roadblocks..."). The bill is not untargeted at all; it is quite precisely pointed at protection of a sensitive class of records.

- The proposed language for inclusion in the bill amounts to a total exemption for law enforcement purposes. Such a broad exemption is unwarranted, in view of the provisions for law enforcement access that do appear in the bill.

We should note that broader issues in the health care system are at stake in what Cabinet departments tell the Congress in this context. Continued development of the health care system will involve the use and disclosure of patient information for management and improvement of the system. This bill provides for this in a controlled, reasonable way. Likewise, it provides for disclosures necessary to combat fraud and abuse.

The necessary governmental access to patient information involved here can be alarming to the public, and we need to reassure people that their information will be treated respectfully and disclosed only as necessary, for limited purposes. There is not total comfort out there with the access provided by the present text.

The bill was generally praised in an editorial in *The New York Times*, but with the observation that "State and Federal oversight officials, and law enforcement agencies, should be required to show strong need for every medical record they seek." (Nov. 20, 1995, p. A14). Likewise, a generally favorable editorial in *The Washington Post* remarked that "Some have argued that exceptions, like those for law enforcement officers with a warrant and for public health officials at every level of government, are too broad." (Nov. 20, 1995, p. A20)

A request from the law enforcement community for unrestricted access and subsequent use could strengthen the objections to the disclosure provisions now in the bill. The result could be a bill that impairs even limited and reasonable access.

cc: Dr. Braithwaite, OASPE
Mr. Rock, OASPE
Mr. Scanlon, OASPE

bmlodel-01.jpf 11/21/95/1722

- The long discussion of the barriers created by the substance abuse confidentiality statute is not in point. This bill is not modeled on the substance abuse statute, except insofar as they are both confidentiality statutes. The tone created by this conflation is basically one of opposition to any confidentiality statute.

  We do not want the Administration to convey that tone. The substance abuse statute provides ready access to records, without patient consent, for audit purposes. Court orders are needed to get records for other purposes, because of the special sensitivity of substance abuse records.

  If there are problems in that statute or our regulations, they can be addressed on their own merits.

- The use of records in investigating health care fraud, discussed in the last paragraph on page 2, is really made quite easy by this bill. The provision for disclosure for oversight (§ 207) permits this. All the evils listed in that paragraph can be investigated with little trouble under the bill. To the extent that the bill does not make clear that use of compulsory process for oversight does not require notice to the individual, the bill does present a problem, and we have raised that point in our own statement.

- For investigating other violations, the bill provides ready access when it is the *provider* who is being investigated, e.g., for tax evasion or securities fraud. Section 212(c) permits ready disclosure for these purposes. No showing of any kind is required, nor is notice to patients.

- For investigations of *patient* wrongdoing unrelated to health care, we as a matter of rather serious principle believe that law enforcement access should be sharply restricted. Health care treatment records should not be a ready source of information for law enforcement. Such access impairs the physician-patient relationship, and otherwise distorts the healing functions of health care. It should be restricted, and the bill does that in a reasonable way.

  To the extent that there is justification for such access, the bill provides for it, after a proper showing to a court, and with notice to the individual, in section 212. This section provides for delay of notice to the individual when notice would seriously harm the investigation.

  If there are specific problems with the details of this, the DoJ should point them out so that a more refined procedure can be designed.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Office of the General Counsel
Washington, D.C. 20201

FACSIMILE TRANSMISSION

TO: Jen Klein *FAX NUMBER:* 456 2878

FROM: *Nan D. Hunter*
Deputy General Counsel

Facsimile Phone number - 202-690-7998

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COMMENTS:

Total number of pages 16

DEPARTMENT OF HEALTH & HUMAN SERVICES Office of the Secretary

Office of the General Counsel
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12 April 1996

Ms. Sally Katzen
Director, OIRA
350 OEOB
By fax: 395-3047

Dear Sally,

Enclosed you will find several documents. First is a copy of the relevant page of the what I have just been told is the new Committee-revised version of S. 1360. You will see that the proposed standard for law enforcement has been changed, in that it has been *heightened*, to a showing of "clear and convincing evidence to believe that the information is relevant to a legitimate law enforcement inquiry." I have attached several examples of written testimony in which privacy advocates specifically sought this higher standard for law enforcement. Obviously, the Committee has responded. The testimony includes that of Jan Lori Goldman of the Center for Democracy and Technology, Aimee Berenson of the AIDS Action Council, Alexander Robinson of the ACLU and the American Medical Association. I have also included a press clipping of a recent incident of law enforcement access to AIDS patient files, which has generated a lawsuit.

I think that this demonstrates both the strong objections that are held in the privacy community and the willingness of the Committee to respond to them. I believe that it would be a grave error for our Administration to be positioned as anti-privacy on this issue, asking for a weakening even past the point of the original bill language or the compromise that you, Justice and I agreed to on March 20.

Lastly, I would note as I said yesterday on the phone that HHS continues to honor our agreement with Justice that we support inserting the term "fugitive" into section 212(c)(2). This would, I believe, resolve the issue that Jamie Gorelick raised concerning the need to usue medical information when police are in pursuit of a suspect described as having a distinctive medical condition.

Sincerely,

Nan

Nan D. Hunter

(1) IN GENERAL.—A health care provider, health plan, health oversight agency, employer, insurer, school or university, may disclose protected health information under this section, except to a health oversight agency governed by section 206, if the disclosure is pursuant to—

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

(B) an administrative subpoena or summons or a judicial subpoena or warrant, which meets the conditions of paragraph (2).

(2) CLEAR AND CONVINCING EVIDENCE REQUIREMENT.—A law enforcement agency may not obtain protected health information about an individual under paragraph (1) for use in a law enforcement inquiry unless there is clear and convincing evidence to believe that the information is relevant to a legitimate law enforcement inquiry being conducted by the law enforcement agency.

(3) WARRANTS.—A law enforcement agency that obtains protected health information about an individual pursuant to a

CENTER FOR DEMOCRACY and TECHNOLOGY

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Statement of

Janlori Goldman
Deputy Director
Center for Democracy and Technology

Before the
Senate Committee on Labor and Human Resources
on

S. 1360
The Medical Records Confidentiality Act of 1995

November 14, 1995

We want to emphasize the importance of the general and specific limitations that are already in the bill. Under the general privacy rules of the bill, health oversight agencies cannot re-disclose identifiable information for other purposes not specially authorized. In addition, a health oversight agency may not use the information gathered in its oversight role for any actions against an individual other than those arising out of receipt or payment for health care or fraud.

With the inclusion of a legal process for access to identifiable information, CDT believes the bill will come closer to striking a fair balance between individual privacy and the government's legitimate needs to conduct audits and control fraud.

C. Law Enforcement

CDT strongly supports the creation of warrant requirement for law enforcement access to personal health records currently in S.1360. However, we urge that the proposed probable cause standard be heightened to equal the standard now in place for access to cable subscriber records. Under the Cable Communications Act of 1984, a warrant can not be issued for access to subscriber records until law enforcement can show "clear and convincing evidence that the subject of the information is reasonably suspected of engaging in criminal activity and the information sought would be material evidence in the case." We believe that federal privacy protection for peoples' medical records should be at least as strong– if not stronger– than we apply to peoples' cable records.

V. CONCLUSION

CDT believes the protection of personally identifiable health information is critical to ensuring public trust and confidence in the emerging health information infrastructure. Health care reform cannot move forward without assuring the American public that the highly sensitive personal information contained in their medical records will be protected from abuse and misuse. As the Harris surveys indicate, people are highly suspicious of large scale computerization and believe that their health records are in dire need of privacy protection. If people are expected to embrace and participate in a reforming health environment,

TESTIMONY OF
AIMEE R. BERENSON, LEGISLATIVE COUNSEL
AIDS ACTION COUNCIL

BEFORE THE
SENATE LABOR & HUMAN RESOURCES COMMITTEE

S. 1360 The Medical Records Confidentiality Act of 1995
November 14, 1995

exceptions to consent must be narrowly-tailored. Current federal regulations governing NIH-funded biomedical research offer a model for conducting such research, and we would urge amending S. 1360 accordingly. These regulations presume that consent will be obtained, and that presumption may only be overcome upon the finding of an Institutional Review Board (IRB) that such records are required for the effectiveness of the research; obtaining consent is not feasible; and the significance of the research outweighs the intrusion into patient privacy.

Oversight Activities. The bill permits access to personally identifiable information for a specific category of oversight activities, such as oversight conducted in administering Medicaid and Medicare programs. We believe the definition of oversight activities must be clarified and narrowed to ensure that only appropriate activities and entities are covered by this exception. We note, however, that under the provisions in this bill, information accessed may not be used to prosecute the individual unless the action or investigation arises out of and is directly related to the receipt of health care or payment for health care or a fraudulent health care claim, and support this important provision.

Administrative Warrants. We believe the bill should incorporate more than a "probable cause" standard, and would urge that the bill be amended to require "clear and convincing evidence that the information is relevant to a legitimate law enforcement inquiry being conducted by the government authority". We understand there is precedent for using such a standard, and that, when combined with the "minimization" rules, such a change will place appropriate limits and safeguards on law enforcement access to information.

Civil Litigation. We are concerned that the bill does not set out clear procedures for objecting to the release of medical records in civil litigation. Currently the bill allows such access if the party seeking the information certifies that the subject of that information has put their health status at issue in pending litigation. The bill requires a 10 day waiting period after notification to the individual before disclosure is allowed, ostensibly to provide a time period for objection. However, the actual procedure for lodging objections and prohibiting disclosure is not spelled out, as it should be, under the bill, and we urge that it be amended to do so.

Conclusion

The enactment of a comprehensive federal law that protects the privacy of medical records is critical, to people living with HIV/AIDS and all Americans. People living with HIV/AIDS, perhaps more than any other group of Americans, have suffered the real consequences of the lack of such protections. Many people with AIDS have lost their lives because of this disease; but many have lost their jobs, their homes, their insurance coverage, their privacy -- not because of disease, but because of fear, hate, prejudice, and discrimination.

Congress has the power -- and the moral imperative -- to enact strong, comprehensive federal legislation to protect the privacy of medical records. Such legislation will move us that much closer toward ending the intolerable epidemic of discrimination that has tragically accompanied the AIDS epidemic in this country.

TESTIMONY OF

H. ALEXANDER ROBINSON
AMERICAN CIVIL LIBERTIES UNION

REGARDING S. 1360:
MEDICAL RECORDS CONFIDENTIALITY ACT OF 1995

NOVEMBER 28, 1995

in the disclosure forms.[11] If that interpretation is not correct, then we believe patients should have the right to give their explicit consent before their identifiable information is entered into a network or database. Even if such explicit consent is acquired, the issue remains whether the Act should allow a patient to refuse such disclosure, but still get treated or receive payment. At the very least a provision should be inserted into S.1360 that allows a patient to designate certain portions of his record as completely confidential. Upon such designation, the information contained in that zone cannot be released unless stripped of any identifier that could link it to the patient.

Such a provision would give patients another recourse by which to control information about themselves. This type of provision is in accord with the goal of S.1360 to create an enforceable privacy right in medical records.

G. Disclosure to Law Enforcement Agencies

The exceptions to the Act's general informed consent provisions which allow for access to "protected health information" by law enforcement agencies is of great concern. On the heels of much controversy regarding police abuse, we can think of nothing more chilling than the prospect of law enforcement agencies being given access to personal medical records. Any law enforcement access to personally identifiable medical records must be viewed with utmost caution. While we acknowledge that the current provision of S.1360 relating to the requirement of probable cause for law enforcement access to medical records[12] is an effort to address concerns about unauthorized disclosures to law enforcement, the approach taken is not adequately protective of personal medical information. For example, among

[11] Section 202.

[12] Section 212(a)(2).

other problems, the standard for obtaining a warrant is a dilution of the traditional probable cause standard. In many ways, the issues raised here are analogous to those regarding electronic surveillance and the 'super' protection afforded tax information. Moreover, we are concerned that the "exceptions" to the need for a warrant or subpoena can lead to abuse. Apparently, under section 210(b) of the Act, an opposing attorney in a civil case, a prosecutor in a criminal case, or an administrative agency might falsely certify to a health information trustee that notice was given to an individual and allege (in good or bad faith) that the individual's mental or physical condition is an issue in a litigation or administrative proceeding and thereby obtain whatever information is sought. We will forward our recommendations for such amendments to the Committee.

IV. Administrative, Technical and Physical Safeguards

S. 1360 imposes the general requirement on health information trustees to "establish and maintain appropriate administrative, technical, and physical safeguards to ensure the confidentiality, security, accuracy, and integrity" of health information.[13] S. 1360 contains no specific technical or administrative requirements. The Act requires trustees to take "appropriate" action to "ensure" confidentiality and security.

This is an extremely important part of the Act, and whether the Act ultimately serves to protect privacy will hinge in part on keeping this requirement on health care trustees undiluted.

A. Confidentiality and Security

S. 1360 should include at least some carefully drafted examples of specific safeguards to ensure

[13] Section 111.

American Medical Association
Physicians dedicated to the health of America

James S. Todd, MD
Executive Vice President

515 North State Street
Chicago, Illinois 60610

312 464-5000
312 464-4184 Fax

February 27, 1996

The Honorable Nancy Landon Kassebaum
United States Senate
302 Russell Senate Office Building
Washington, DC 20510

Dear Madam Chairman:

The American Medical Association (AMA) welcomes the opportunity to share with the Committee our views on the confidentiality of patient medical records, an issue brought to the fore by S. 1360, "The Medical Records Confidentiality Act of 1995." After the bill was referred to the Committee, the AMA, in conjunction with some twenty other national physician organizations, wrote the Committee requesting an opportunity to assist in refining the language of S.1360. While we noted our express support for the mission of the legislation, our concern was and remains that the language of S. 1360 must be significantly modified to adequately protect the privacy of patients' medical information. The Committee has signaled a willingness to examine the details of the bill and to seek improvement from a variety of parties. We appreciate being included in this reevaluation of the legislation.

The AMA has extensive policy concerning the ethical responsibility of physicians to protect the privacy of our patients' medical records and information in order to assure that those patients are willing to communicate sensitive and personal information to their physicians without fear of subsequent disclosure. Our Board of Trustees has reviewed AMA policy and considerable additional information in its evaluation of S. 1360, and its conclusions are reflected in the attached report.

We look forward to continuing the dialogue on S. 1360 with the Committee and urge you to bring your questions and concerns to us. The AMA supports federal legislation protecting the confidentiality of patient records; however, we regret that we cannot support, in its current form, S. 1360. Thank you for taking our views into consideration as you explore this complex and important issue.

Sincerely,

James S. Todd, MD

James S. Todd, MD
enc.

cc: The Honorable Robert Bennett
The Honorable Thomas A. Daschle
The Honorable Robert Dole
The Honorable Russ Feingold
The Honorable Orrin G. Hatch
The Honorable Herbert H. Kohl
The Honorable Patrick J. Leahy
The Honorable Alan K. Simpson
The Honorable Ted Stevens

REVIEW OF S. 1360
"THE MEDICAL RECORDS CONFIDENTIALITY ACT OF 1995"

The American Medical Association (AMA) commends the sponsors of S. 1360, "The Medical Records Confidentiality Act of 1996," for focusing attention on the important issue of confidentiality of private medical records. The bill as introduced, however, does not assure adequate confidentiality protections for personally identifiable medical information, and the AMA would discourage the Senate Labor and Human Resources Committee from reporting such legislation without significant reexamination and modification.

The AMA believes that the patient-physician relationship is based first on trust and that the confidentiality of communications within this relationship is the cornerstone of good medical care. It cannot be too strongly stated that in order for physicians to provide the best and most appropriate medical care, patients must feel that they can disclose to their physicians personal facts and information that they would not want others to know. Without such assurances, patients may not provide the information necessary to properly diagnose and treat. The evolution of electronic medical records, typified by interstate electronic transmissions and the aggregation of information into large databases that are used for non-treatment purposes, has intensified existing concerns about patients' confidentiality. While the AMA supports federal legislation to protect patients' privacy in an environment of heightened availability and access through computerized networks, we are concerned that S. 1360, without substantial modification, fails to adequately address numerous concerns about medical information privacy.

The AMA's analysis of the issue is based on a threefold premise:

- that there exists a basic right of patients to privacy of their medical information and records, and that this right should be explicitly acknowledged;
- that patients' privacy should be honored unless waived in a meaningful way (i.e., informed, noncoercive) or in rare instances of strongly countervailing public interest; and
- that the information disclosed should be limited to that information or portion of the medical record necessary to fulfill the immediate and specific purpose (i.e., no fishing expeditions).

Within the context of these three overriding principles, the AMA makes the following recommendations by which any medical information or record confidentiality legislation should be assessed:

1. **The primary purpose of the medical record is to provide a reliable tool to provide clinical treatment of patients.** The medical record is the property of the physician or responsible health care provider or entity, who has legal and ethical obligations to maintain a true and accurate record. While patients should have access to the information from the medical record (with rare exceptions to protect the mental or physical safety of the patient), the physical record is the property of the physician or provider. When a provider entity controls the medical records or information, a physician advisory body to the provider (or a medical staff if one exists) should superintend the manner in which the physical record is released. This conceptual frame of reference should be set out explicitly in some sort of legislative preamble and should be recognized in statutory language.

   The model contained in S. 1360 for disclosure and correction of patient records, based on the procedures for reporting consumer credit information, is not translatable to the medical information arena and should not be adopted. Subsequent holders of medical information (such as information data banks or other types of "trustees") should not be allowed to change medical information or conclusions. It follows that the treating physician or health care practitioner that generated the medical information should be the only "trustee" through whom patients may "amend" or "correct" their medical information or records.

2. Often, an entity will seek an individual's authorization for disclosure of his other protected health information, subsequently using the information for purposes beyond the scope for which the consent was obtained. For example, an insurer with both health and life insurance lines has a legitimate interest in medical information regarding a policy holder for administering health benefits. Without specific authorization from the individual, however, that information should not be available to the insurer for purposes of its life insurance line.

   "Firewalls" should be constructed so as to preclude a patient's first consent from applying to all subsequent disclosures (unless the patient specifically and freely waives defined rights). The specificity of the patient's consent creates the "firewall." Requests for information should be specific as to:

   - the portion of the records or information needed (the specific treatment or matter at issue);
   - the time period of the records needed (e.g., "from 1990 through the present"); and
   - the purpose for which the information is requested.

The specificity of consent is the key to imposing effective "firewalls," to preclude the lateral drift of information once an initial consent is agreed to by the patient. Patients and physicians will feel more protected if a signed consent is required for each disclosure of records, rather than continue to allow for blanket waivers by patients. Blanket authorizations are acceptable for most treatment and payment purposes and "scrubbed" charts; however redisclosure should be prohibited without subsequent authorization. In instances where personally identifiable medical information is part of a requested record that is not easily "de-identified" (for example, when a utilization review company wants to review 25 patient charts), specific permission from the patients should be required. The responsibility for obtaining consent for disclosure should rest with the entity requesting the data.

3. **Exceptions to the requirement for patient consent to disclosure should be minimal and narrowly drawn.** The burden should be on the requesting entity to demonstrate why its need should override the patient's confidentiality. This burden should be equally applicable for research (both scientific and market-based/economic), law enforcement and any other legitimate purpose.

In the particular instance of exceptions for purposes of law enforcement, the AMA believes the bill should set high standards for non-consented-to disclosures. The AMA recognizes the needs of legitimate law enforcement; however, these needs must be balanced with an individual's expectation of privacy for his or her personally identifiable medical information. The requesting entity should be required to show "probable cause" in establishing why medical records should be divulged without the patient's consent, and the particular information required to meet the immediate law enforcement purpose should be specified. Records thus disclosed for legitimate law enforcement purposes should then be held in camera by the court.

4. **Whenever possible, medical information used for research purposes should have all identifying information removed, unless the patient specifically consents to the use of his or her personally identifiable information.** The entity requesting protected medical records or information should be required to pay for "de-identifying" the record. The AMA believes that the protections contained in S. 1360 relating to release of identifiable information without authorization when an IRB determines that the need for that information outweighs the individual's right to privacy are adequate without further showing of problems that might currently exist.

5. **Regarding the issue of federal preemption of state law, any federal law should provide a "floor," rather than a "ceiling" when applied to patient confidentiality protections.** It is understood that there are many who believe that there should be a uniform federal standard to facilitate electronic data interchange (including the Work Group on Electronic Data Interchange (WEDI)). The AMA is concerned, however, that heightened state standards will be lost to federal legislation. If the bar is placed high enough to secure protection of patient information in the federal language, the AMA would revisit the preemption issue.

6. S. 1360 has major penalties for unauthorized disclosure of protected medical information. The AMA believes that **penalties and sanctions for unintentional disclosures of identifiable patient information, where the disclosure does not result in demonstrable harm to the subject of the disclosure, should be reduced or eliminated. Penalties and sanctions related to improper disclosure for commercial purposes, profit, malicious purposes or where there is significant patient harm should be commensurate with the violation.** In addition to monetary sanctions, legislation could include the loss by a database company, for example, of its privilege to hold or transmit protected medical information, thus reducing the potential for companies to accept the monetary penalties for improper, intentional disclosures as a "cost of doing business."

The AMA does not believe that S. 1360, as it currently stands, meets the principles elaborated above and therefore we do not support the bill in its present form. We do support, however, the need for federal legislation in this area so that patients will be adequately protected as medical information becomes available in new forms and with greater ease of transmission. The AMA appreciates the Committee's active efforts to seek input regarding improvements to the bill. The AMA's fundamental concern on this issue has been and continues to be the protection of the patient-physician relationship and the confidentiality that is so basic to the trust inherent in that relationship.

Lawsuit Seeks To Bar U.S. From Access To AIDS Files

By TAMAR LEWIN

Federal auditors and Boston social services agencies helping people with AIDS are battling over whether it is a grave breach of confidentiality — or a basic part of auditing Federal programs — for Federal officials to demand access to records with the names and Social Security numbers of people with AIDS.

A complaint being filed today in Federal district court in Boston seeks an injunction blocking Federal officials from obtaining such records. The complaint cites an incident last May, when Federal auditors entered a Boston center for Haitian immigrants with AIDS, took the names and Social Security numbers of dozens, then passed them on to a few other Government officials in an effort to determine whether the people receiving Federal support were in fact H.I.V. positive.

"In a program for people with AIDS, you can't do an audit without looking at the records that verify that people do have AIDS and are eligible for the program," said Joseph Vengrin, an assistant deputy inspector general at the Department of Health and Human Services. The Inspector General's Office, like those of other Federal departments, audits the use of Federal money administered by the department but carries out its audits and investigations independently.

But the auditors' actions has provoked outrage from administrators at AIDS clinics, who say the access of the records imperils their programs. The audit also drew strong criticism within the H.H.S. from Anita Eichler, the director of the division of H.I.V services at it Health Resources and Services Administration.

The auditors committed "an egregious breach of confidentiality," Ms. Eichler wrote in a May 10, 1995, letter to the senior auditor in Boston.

The complaint charges that on May 9, 1995, auditors from the Inspector General's office came to the Haitian Multiservice Center, which gets Federal money to provide case management for AIDS patients, and compiled a list of names, Social Security numbers, dates of birth and H.I.V. status of 78 people. It was apparently the first such audit of a federally financed program to provide outpatient health and support services under the Ryan White Cares Act of 1990.

"It was the first time we had heard of anything like this, and it was kind of shocking," said Denise McWilliams, executive director of the Boston AIDS Consortium, one of the 23 Boston-area recipients of Federal money that have joined to bring the lawsuit seeking a permanent injunction blocking Government officials from demanding access to information that includes a patient's identity. "But when we met with people from the Inspector General's office, they told us this was their standard operating procedure, and they had no intention of changing it."

The inspector general's office said yesterday that its Boston auditors had acted well within their authority and that it would be impossible to conduct routine audits of the use of the Federal funds without seeing records that would show that those receiving services actually had AIDS.

Mr. Vengrin, the deputy inspector general, said that in New York City, the only other city where those receiving the AIDS money have been audited, the recipients of the money did not resist disclosing their files.

The inspector general's office said the Boston auditors showed their sensitivity to the need for confidentiality by taking the list of names to the local official responsible for administering the Federal funds, and asking him to verify that the individuals were indeed H.I.V.-positive, rather than seeking to question the recipients themselves.

But Richard Stevens, the Boston public health official the office went to, disagreed. He refused their request, telling Boston recipients of the Federal money not to release confidential client information.

In a May 10 letter to the audit manager, Mr. Stevens said he felt the breach of confidentiality was such a "gross violation" that it "jeopardizes the entire service delivery system and its integrity with regard to providing confidential services."

The Federal audit found that both Haitian Multiservice Center and SPAN, another agency it inspected, did not have the results of AIDS tests needed to confirm eligibility for services for 102 of the 113 files it reviewed. At SPAN, the auditors reviewed only 14 files before the agency asked them to leave.

Indeed, the Federal auditors said that there was evidence of fraudulent use of Social Security numbers and that they reported that to other Federal officials responsible for investigating such fraud

More national news appears on pages D19-21.

Why fed-state distinction?

Protection for certain types of records?

Hot pursuit exception?

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
WASHINGTON, D.C. 20503

THE DIRECTOR

April 11, 1996

MEMORANDUM FOR LEON E. PANETTA

FROM: Alice M. Rivlin

SUBJECT: Law Enforcement Access to Medical Records

Background

With the emergence of Health Maintenance Organizations and the expansion of electronic record keeping, there is an increased concern that health care information should have greater protection, especially for particularly sensitive information such as mental health records, or information relating to HIV testing or reproductive health. The Administration took this position during the last Congress in drafting the Health Security Act.

In this Congress, the vehicles for enhancing the protection of health care information are S.1360, the Medical Records Confidentiality Act of 1995 (introduced by Sen. Bennett and sponsored by Sens. Dole, Daschle, Kennedy, Kassebaum and others) and H.R.435, the Fair Health Information Practices Act of 1995 (introduced by Rep. Condit). The Administration has generally supported these bills which provide heightened protection for health care information and generally require notification of the patient before records are disclosed. The bills override state laws, which vary considerably, by creating a national standard for use and disclosure of medical information.

Chairman Kassebaum asked for the Administration's views on S.1360 in preparation for mark-up. In the process of clearing a response, OMB discovered a major interagency issue. While there is broad consensus on most of the policies reflected in the bill, HHS and DOJ have differing views as to the proper protection for health information in the face of legitimate needs of law enforcement. In a series of meetings culminating in one chaired by Sally Katzen, the agencies moved toward one another, although there remained some disagreement.

Issue

HHS would generally give health care privacy priority over law enforcement. HHS believes the general rule should be that law enforcement officials, state or federal, may not have access to medical information unless they establish probable cause to believe the information is relevant to a legitimate law enforcement inquiry being conducted by the government authority. The patient must be notified of the disclosure and afforded an opportunity to object.

However, HHS agreed that law enforcement officials should have access to health data in the

following limited instances:

a) to investigate a health-related criminal, civil, or administrative violation against a health care provider, third party, or patient;
b) to investigate a non-health criminal, civil or administrative violation when the target of the investigation or inquiry is not the patient.
c) to investigate a potential violation in a public benefit program, whether or not health-related, to ensure the integrity of that program; or
d) to identify or locate a victim, witness, or fugitive.

But, where the patient is a target and the violation is not health care related, law enforcement officials would have to convince a court to permit access, provide notice to the patient, and allow the patient an opportunity to object.

Justice, by contrast, would give law enforcement priority. Their going-in position was that law enforcement officials should be exempt from any additional procedural requirements for access to health care information at the Federal, State, and local level. Existing protections should apply (e.g. the Privacy Act at the Federal level, state and local restrictions where applicable).

However, where the patient is the target and the crime is not health related, DOJ would accept the requirement that Federal law enforcement officials obtain protected health information via an *ex parte* motion to a court. The court would grant access if it were persuaded that the public interest and the need for disclosure outweighed the injury to the patient, to the physician-patient relationship, and to the treatment services. Justice also agreed that law enforcement officials should not be permitted access to research or public health reporting records.

Justice does not believe the Federal government should preempt state law in this area. State and local law enforcement should not be subjected to any increased requirements—existing protections would apply.

HHS and DOJ both feel strongly about this issue. I would support the Justice position as stated above. Jack Quinn believes Justice conceded too much and that no additional restrictions on law enforcement are necessary. On the other hand, the First Lady and the Second Lady have made explicit their strong support for protecting health care information, although staff indicated they might find the modified Justice position acceptable.

Would you like to meet to discuss this?

cc: Jack Quinn/Kathleen Wallman
Carol Rasco
John Hilley
Skila Harris
Melanne Verveer/Jennifer Klein

DEPARTMENT OF HEALTH & HUMAN SERVICES
Chief of Staff
Washington D.C. 20201

FACSIMILE

DATE APR 2 1996

TO: (NAME, ORGANIZATION, CITY/STATE AND PHONE NUMBER) :
Jennifer Klein
456-7599

FROM: (NAME, ORGANIZATION, CITY/STATE AND PHONE NUMBER) :
Kevin Thurm
Chief of Staff
DHHS
690-6133

RECIPIENT'S FAX NUMBER: ( ) 456-2878

NUMBER OF PAGES TO SEND (INCLUDING COVER SHEET) 3

COMMENTS

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

APR 1 - 1996

The Honorable Alice M. Rivlin
Director
Office of Management and Budget
Washington, D.C. 20503

Dear Alice:

I am writing concerning a dispute which has arisen between the Department of Health and Human Services and the Department of Justice over an issue with serious policy ramifications and political sensitivity for health care.

S. 1360 would create a federal statute protecting the confidentiality of medical records. It is based on the confidentiality section of the Mitchell version of the Health Security Act. S. 1360 was introduced by Senator Bennett with 11 bipartisan co-sponsors, including Senators Dole, Kassebaum, Daschle, Kennedy, and Leahy. The Labor and Human Resources Committee held a hearing on the bill in November, and Committee staff plan to move the bill to mark-up by early May. Committee staff have asked for the Administration's position on the bill.

It is my understanding that the Justice Department objects to some of the bill's provisions that constrain access by law enforcement agencies to individual patient medical records. It would prefer a complete exemption from the bill's controls for law enforcement access, and failing that, would prefer not to have to notify patients when their records are sought pursuant to compulsory process. The provisions in question are the same -- virtually identical in language -- as the law enforcement access portions of the Mitchell version of the Health Security Act.

HHS and Justice staff were able to narrow the areas of disagreement through a process undertaken by OIRA. Nonetheless, they reached a point where certain basic principles established in the Mitchell bill are being called into question.

The Administration should not change its position on this issue. Justice raised the same objections during the health care reform discussion that are being raised now. The decision was made to support the Mitchell bill. The law enforcement provisions of the Mitchell HSA and of S. 1360 reflect the long-held tradition in the law and in medicine that information furnished by patients to their physicians should not be used against them in criminal proceedings. (S. 1360 was drafted to also reflect a balance with the legitimate needs of law enforcement. It makes an exception, with which we agree, so that medical records *can* be used against a patient in matters related to health care fraud. The bill also properly allows an *exception* to the requirement of notification to the patient of the seizure of his or

Law enf. can have access if identifying witness or victim and in case of fugitive
Sally - Law enf. wld have to show good cause Judge wld have to determine - never notification
1. Program cause to believe this relevant - Sally d/t std.
2. Ever notification? Or never notified
Rts once notified - they can file a motion to quash subpoena.

her records if a judge determines that such notice would result in endangerment of life or safety; flight from prosecution; tampering with evidence; intimidation of witnesses, or interference with an ongoing investigation.) We should not flip-flop on our basic position.

We especially should not change positions when that would open us to attacks as "big brother." Senator Dole is a co-sponsor of the bill and has thus established a position supporting the law enforcement access provisions as they are currently stated in the bill. There is significant popular sensitivity to access by police to psychiatric and other highly personal information contained in medical files. An Administration objection to the limited controls in the bill, or a request that patients not be notified when their records are sought in court proceedings, would activate that sensitivity.

This issue has been decided already, and decided correctly, and we should not re-visit it. I am sending a copy of my letter to Mr. John Quinn, Counsel to the President and Mr. John Hilley, Assistant to the President for Legislative Affairs.

Sincerely,

Donna E. Shalala

SPECIAL

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
Washington, D.C. 20503-0001
3/21/96
LEGISLATIVE REFERRAL MEMORANDUM

LRM NO: 3857
FILE NO: 1646
Total Page(s): 16

TO: Legislative Liaison Officer - See Distribution below:

FROM: Janet FORSGREN Janet L. Forsgren (for) Assistant Director for Legislative Reference

OMB CONTACT: Robert PELLICCI 395-4871 Legislative Assistant's line (for simple responses): 395-7362
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pellicci_r@a1.eop.gov

SUBJECT: HHS Proposed Report RE: S1360, Medical Records Confidentiality Act of 1995

DEADLINE: Monday, March 25,1996

In accordance with OMB Circular A-19, OMB requests the views of your agency on the above subject before advising on its relationship to the program of the President.

Please advise us if this item will affect direct spending or receipts for purposes of the "Pay-As-You-Go" provisions of Title XIII of the Omnibus Budget Reconciliation Act of 1990.

COMMENTS: This is a follow-up letter to Sen. Kassebaum regarding the Administration's views on pending legislation on medical records confidentiality.

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RESPONSE TO LEGISLATIVE REFERRAL MEMORANDUM

LRM NO: **3857**

FILE NO: **1646**

If your response to this request for views is simple (e.g., concur/no comment), we prefer that you respond by e-mail or by faxing us this response sheet.
If the response is simple and you prefer to call, please call the branch-wide line shown below (NOT the analyst's line) to leave a message with a legislative assistant.
You may also respond by:
(1) calling the analyst/attorney's direct line (you will be connected to voice mail if the analyst does not answer); or
(2) sending us a memo or letter
Please include the LRM number shown above, and the subject shown below.

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Fax Number: 395-6148
Branch-Wide Line (to reach legislative assistant): 395-7362

FROM: _____ (Date)

_____ (Name)

_____ (Agency)

_____ (Telephone)

SUBJECT: HHS Proposed Report RE: S1360, Medical Records Confidentiality Act of 1995

The following is the response of our agency to your request for views on the above-captioned subject:

_____ Concur

_____ No Objection

_____ No Comment

_____ See proposed edits on pages _____

_____ Other: _____

_____ FAX RETURN of ____ pages, attached to this response sheet

DRAFT

March 20, 1996

The Honorable Nancy L. Kassebaum, Chair
Committee on Labor and Human Resources
Dirksen Office Building, Room 428
United States Senate
Washington, DC 20510-6300

Dear Madam Chairman:

This letter is to transmit our further views on S. 1360, the "Medical Records Confidentiality Act of 1995."

This Department submitted a statement in connection with your hearing on the bill on November 14, 1995, in which we expressed general support for the bill, but indicated that we had suggestions for improvement.

The attached statement contains our proposals for changes in the bill. In addition, the Department of Justice is separately submitting comments with proposals for changes in the law enforcement provisions. This Department is in full concurrence with those comments.

We look forward to working closely with you on this bill.

The Office of Management and Budget has advised that there is no objection to the presentation of this report.

Sincerely yours,

Jerry D. Klepner
Assistant Secretary
for Legislation

DRAFT

March 20, 1996

COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES ON S. 1360 "MEDICAL RECORDS CONFIDENTIALITY ACT"

A. Major Issues - General

1. **Written Authorization for Treatment and Payment.** S. 1360, unlike bills considered in the previous Congress, would require written patient authorization for disclosures for treatment and payment (§ 202). This is a cumbersome and awkward requirement in the treatment context, and one that often leads to boilerplate and meaningless consents in the payment context. The goals of this requirement can be met more effectively by very strong protections for information held by providers and payers, and an opportunity for patients to object to particular disclosures or to disclosures to particular persons.

   In the treatment situation, this requirement will limit flexibility and create delay in consultation and referral. A health care provider should not have to constrain her judgment about whom to consult unless the patient has specifically indicated a sensitivity to such consultations. A physician may determine, from review of test results after the patient has left the office, that the patient should be referred for consultation; the physician should not have to get the patient to return to sign an authorization before discussing the case with the consulting specialist.

   Somewhat similarly, information should be able to flow easily and without unnecessary barriers when necessary to facilitate payment. Changes in insurance carriers, for example, should not require multiple authorizations. In the case of the Indian Health Service, patients may not be billed, but their insurance companies may be billed. A patient's refusal, inability, or failure to authorize disclosure for payment should not act to prevent the IHS from billing insurers.

   Instead of a requirement for affirmative authorization to disclose, the patient should be offered an opportunity to opt-out, by objecting to particular disclo-

sures. Absent such objections, however, a provider should have the discretion to disclose information for the purpose of treating the patient, and to disclose information for obtaining reimbursement.

2. **Compatibility; Applicability of the Standard.** The requirement that health information not be used or disclosed unless the use or disclosure is "compatible with and related to the purposes for which the information was obtained" (§ 201(b)(1)) appears to create a standard for use and disclosure in addition to the specific disclosure provisions of the bill. Such a standard would be confusing and burdensome if meant to be applied together with the specific disclosure provisions of the bill.

   The standard should apply only to internal activities of the trustee, and not to disclosures, which are regulated specifically in the bill.

   In addition, there is some risk that this standard may be read to prohibit legitimate internal oversight and management uses of data. It is important not to impair normal management mechanisms. The legislative history could provide some elaboration of the limits of allowable use within an entity.

   It is desirable to prohibit some uses of patient information even within the organization, e.g., for marketing and solicitation. The bill should specifically prohibit use of treatment information or any other information regarding health status in marketing or solicitation.

3. **Internal Uses; Definition of Entity; Compatibility.** Controls on disclosure or use within a single trustee, subject to the compatibility standard (§ 201(b)(1)), raise the question of which corporate entity constitutes "the" trustee.

   In situations in which a provider or other institution is owned by a larger business entity, the bill should make clear that use of patient information beyond the institution with which the individual is directly dealing should be limited to oversight and management activities, and carefully controlled. Some activities of parent organizations (e.g., oversight and audit) need identifiable information in certain instances, but it is important that the use and circulation of this information be sharply limited in accordance with the compatibility standard in section 201.

4. **Compulsory Process Procedural Requirements; Applicability.** There is some risk that the procedural requirements for notice to the individual and an opportunity to object when compulsory process is used in certain instances (in

sections 211 and 212) will be read as applying in any instance where compulsory process is used. There are instances where officials will use compulsory process to obtain information that may, under other provisions of the bill, be disclosed without compulsory process. This occurs, for example, in investigations of health care fraud, or of other possible wrongdoing by providers. In these cases there is no need to notify the individuals. Notification may be disruptive and upsetting, and no significant privacy interest would be served.

The bill should make clear that the procedural requirements of sections 211 and 212 need not be met, even if compulsory process is used, for disclosures that are allowable under other provisions of the bill (i.e., sections 204 through 209), if the conditions of those other provisions are met.

5. **Agents and Contractors.** Many entities will assist trustees in carrying out their basic functions, typically as agents or contractors, and will need protected health information in providing that assistance. The obligations of those agents and contractors with respect to protected health information need to be specified. The bill does this simply by including agents and contractors within the term trustee (§ 3(7)(A)(iii)).

It would be preferable to provide separately for disclosure to, and handling of information by, agents and contractors, and to define their responsibilities, or provide for definition of responsibilities by trustees. In particular, it may not be appropriate to provide in all cases subject access and correction rights with respect to information held by entities that perform services on behalf of trustees, e.g., claims-processing entities hired by payers.

Health facilities in government agencies in many instances rely on units in other parts of government for functions such as legal representation, and need to disclose identifiable patient information to those other units. It may not be appropriate in the case of governments to impose the agency and contractor model. Government health care providers should be able to disclose identifiable information to other parts of government as necessary in direct service to the health care provider, subject to the requirement that the bill's internal "compatible use" protection follows the information, so that it may not be used for other purposes. Under this approach, for example, a State attorney general's office could receive patient information to defend a malpractice suit. It could not use that information for an unrelated purpose. It might be desirable to provide explicitly for authority to promulgate regulations to manage these uses of information.

6. **Role of the Secretary in Certifying Health Information Network Services.** The bill calls for the Secretary to certify health information network services (§§ 204(b) and 3(1)). This certification procedure is not spelled out, but could impose substantial time and resources demands on the Department. In any case, it is not clear that there needs to be any separate provision for health information network services. In some instances, such organizations will more properly get information as contractors or agents of trustees. In other instances, they may get information under specific disclosure provisions of the bill (e.g., research, oversight).

   We recommend deletion of the certification requirement.

7. **Redisclosures Under Specific Provisions.** The bill needs a comprehensive approach to the rules for use and redisclosure of protected health information by entities that receive it under specific disclosure provisions of the bill.

   It is not clear how the compatibility test in section 201(b)(1) applies to persons who get the information under the judicial and administrative, non-law enforcement, and law enforcement provisions (§§ 210-212).

   The obligations of these recipients with respect to use and redisclosure should be explicitly stated. They will differ depending on the character of the information and the potential recipient.

8. **Redisclosure; Obligations of Recipient Under Authorization.** The bill is not clear on the obligations of those who receive protected health information pursuant to an authorization (§ 203). The rules for disclosures generally state that trustees must identify disclosed information as subject to the bill (§ 201(d)). Is this to inform the recipient that she is subject to the bill's disclosure restrictions? It is not clear whether she is subject to the restrictions. The authorization must include a "statement of intended disclosure" (§ 203(a)(2)). Is the latter prepared by the recipient, and does it bind the recipient?

   It is difficult to impose the provisions of the bill on persons and entities (other than trustees) who get health information pursuant to authorization, when these entities are of many characters and their possible uses of information have not all been identified. The "statement of intended disclosures" (i.e., uses and intended disclosures by the recipient) might conceivably be seen as a binding obligation, violation of which by the recipient would give rise to the civil action provided in section 302. This could be made more explicit.

9. **Obligations of Emergency Recipients.** The bill makes trustees out of persons who receive information under emergency circumstances, i.e., "when necessary to protect the health or safety of an individual from serious, imminent harm." (§ 206).

Some people who will get such information will be private individuals, on whom it is inappropriate to impose confidentiality requirements. For example, mental health treatment personnel may warn a person who is at risk of harm from the behavior of a patient. The person warned should *not* be subject to the disclosure restrictions that come with trustee status. Some recipients of information in emergency circumstances will be trustees and thus otherwise obliged to protect it, e.g., emergency room personnel who receive information about a patient over the telephone from the patient's previous providers. Emergency recipients who are not already trustees may be bound by other legal obligations (e.g., the Fourth Amendment would apply to police or other governmental agencies).

If controls on further use of this information are seen as necessary, they can be written as a prohibition on use against the patient except in the context of the purpose for which the information was disclosed.

10. **Researchers and Public Health Agencies as Trustees.** The bill includes in its definition of trustees (§ 3(7)(A)(i)), and thus arguably subject to the coverage of the bill in the first instance, both researchers and public health agencies. Another approach would be to cover researchers and public health agencies only to the extent that they get information from other entities under the allowable disclosure provisions of the bill (for research and public health). These types of entities would in any case be trustees to the extent that they perform other covered trustee functions, as providers (e.g., clinical researchers and public health agency STD clinics), or payers (e.g., Medicaid agency).

11. **State Health Care Policy Oversight.** States are initiating new methods of analyzing health care outcomes, costs and patterns of utilization in order to engage in better policy planning and management. For example, Maryland has by State statute created a Health Care Access and Cost Commission which requires reporting of all claims data within the state. These data are stripped of identifiers and used to analyze trends in various health care services. It is not clear that Maryland's program would be covered by the oversight provision under S. 1360 as introduced, because the definition (§ 3(8)(B)(i)) limits oversight to matters related to "compliance" with certain standards. We suggest that this be expanded to include analysis, as well as compliance.

B. Major Issues -- Research

1. **Certification of IRBs and Review by the Secretary.** The bill would require that institutional review boards (IRBs) which review proposed disclosures of information for research be certified by the Secretary of Health and Human Services (§ 209(d)), and that disclosures of information for research in certain instances (i.e., research not conducted by providers, academic institutions or public health agencies) be approved by the Secretary (§ 209(c)).

   Certification of all IRBs is a large and impractical task. Many IRBs have approved assurances under the procedures of this and other Federal Departments in accord with the Federal Policy for the Protection of Human Subjects (56 Fed. Reg. 28,003 (1991)) (codified, in the case of this Department, at 45 C.F.R. part 46). IRBs that meet these requirements are following adequate procedures.

   These existing procedures, plus requirements for equivalent IRB review that can be enforced by civil litigation and civil money penalties, will provide an adequate basis for effective review of intended research disclosures.

   Individual review of projects by the Secretary for certain classes of research institutions is not practicable, and would involve the Secretary inappropriately in operational decisions. In addition, the distinction between research within and outside the academic community is artificial and confusing, as well as impractical to apply. There is no good basis for distinguishing among different types of organizations doing research in imposing such a requirement.

   As an alternative to the bill's requirements surrounding research disclosure, it would be preferable to permit such disclosure if the research complies with the Federal Protection of Human Subjects Policy, as evidenced by assurances approved by Federal agencies under the Policy, or if the research is approved by an IRB operated in accord with the requirements of the Policy.

2. **Disclosure from Research Records.** There are a few provisions of the bill that would permit inappropriate disclosure of information from research files. A basic principle of protection of research information is that such information should not be used for any purpose outside of the research purpose. Health data assembled for research and statistical purposes should not be used to take any individual action affecting the rights, benefits or privileges of an identified individual. Limitation on the use of research and statistical information in this

way -- called the principle of functional separation -- was recommended by the Privacy Protection Study Commission, in its report, *Personal Privacy in an Information Society*, in 1977, and the point was reiterated recently by a committee of the Committee on National Statistics in a report, *Private Lives and Public Policies* (1993).

The provisions of the bill permitting disclosure should be revised to eliminate authority for researchers to disclose for public health (§ 208) and law enforcement (§ 212(a)(1)) purposes, and to permit disclosure for oversight (§ 207(a)) only when the research itself is being reviewed. In the latter instance, no information about a subject should be used against the subject except for wrongdoing in the context of the research. The provision for emergency disclosure (§ 206) can properly be applied to research records.

Prohibitions on disclosure from research records would not, of themselves, prohibit obtaining the same information from the original source of that information (e.g., health care providers) under whatever conditions the bill would require for disclosures from the original source.

3. **Research and Statistical Confidentiality Protections.** There are existing confidentiality protections for research and statistical data in Federal and State law, and it is important not to disturb those valuable and well-understood protections. For example, certain statistical and related data are protected against use for other purposes by section 308(d) of the Public Health Service Act (42 U.S.C. § 242m(d)), health services research data are protected under section 903(c) of the Public Health Service Act (42 U.S.C. § 299a-1(c)), and protection against compulsory process is available for health research data under section 301(d) of the Public Health Service Act (42 U.S.C. § 241(d)). Some states have statutes protecting information in health research and statistical studies.

There should be explicit provision to ensure that the preemption provisions of this bill are not read as preempting those statutes or lessening their protections.

4. **Subject Access; Research and Statistical Records.** To the extent that researcher recipients of records are trustees, the bill appears to provide a right of subject access and correction for research records (§§ 101 and 102). This right is less significant with respect to research records than it is for other records, to the extent that records are protected by the bill against use and disclosure to affect the individual in any way, as the bill should provide (¶ B.2., above). In

some instances, it may be impossible or very difficult even to locate the record.

Consideration should be given to exempting these records from the subject access and correction rights. The Privacy Act of 1974, for example, permits an exemption from the subject access and correction rights generally provided by that Act with respect to records "required by statute to be maintained and used solely as statistical records;" (5 U.S.C. § 552a(k)(4)).

C. Issues Relating to Federal Records

1. **Privacy Act.** The bill does not specify how this legislation will interact with the Privacy Act of 1974 (5 U.S.C. § 552a).

   In the interests of a common set of rules for all health care institutions, private, Federal, and other public, it is desirable that the disclosure provisions of the present bill apply to Federal health care facilities, such as the Clinical Center of the National Institutes of Health, and Indian Health Service facilities.

   One approach would be to apply the bill's substantive disclosure rules to Federal facilities, and supersede the provisions of the Privacy Act that deal with those matters. Thus, agencies could make disclosures only as provided by the bill, and could not make the other disclosures identified specifically, or as routine uses, in subsection (b) of the Privacy Act.

   At the same time, the more general records management features such as the obligation to publish system notices, and the subject access and correction provisions of the Privacy Act, would continue to apply to Federal agency health care systems.

2. **Federal Agencies and State Requirements.** The bill should make clear that Federal agencies may make disclosures that States require of entities subject to State jurisdiction. Provisions of the bill that permit disclosures pursuant to requirements to report under State law will not permit disclosure by Federal agencies. By virtue of the supremacy clause of the Constitution, Federal health care facilities do not have to comply with State laws that, for example, require reporting of births, or of injuries resulting from violence, to State authorities. In fact they make such reports, and the bill should permit them.

3. **Department of Veterans Affairs (VA); Benefit Programs.** The Department of Veterans Affairs has pointed out that information currently flows as

necessary from VA medical facilities to the benefits payment elements of VA, to permit benefit determinations based on health status.

Under the bill, such a disclosure would appear to require patient consent. To the extent that the Department of Veterans Affairs wishes this changed, it would appear to be desirable in the interests of simplicity and convenience, in the controlled situation of this agency.

4. **Freedom of Information Act Disclosure.** The bill does not make clear that Federal records covered by the bill are exempt from disclosure under the Freedom of Information Act. In the vast majority of instances, the information could be withheld as "medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy;" (5 U.S.C. § 552(b)(6)).

However, to avoid the possibility of litigating specific demands, and to permit firm assurances to patients as to how their information will be treated, the bill should make clear that the information it covers is "specifically exempted from disclosure by statute" in accord with 5 U.S.C. § 552(b)(3).

D. Other Issues

1. **Minimum Disclosure.** The requirement that disclosures be limited "to the minimum amount of information necessary to accomplish the purpose for which the information is disclosed" (§ 201(b)(2)) states a worthy objective, and as a general principle is desirable.

However, sorting through records -- especially paper records -- to ensure that only the minimum amount is disclosed, is expensive and time-consuming, risks compromising the integrity of the record, and could burden the normal operational activities of the record holder. In addition, as an obligation on the holder, it could be used to withhold records in situations where the requester is best positioned to determine what information is necessary, such as oversight and public health investigations.

This requirement could be made more workable by adding "to the extent practicable."

2. **Certification by Requester of Records.** The bill permits disclosures for stated purposes, upon condition that the requester have a particular purpose, or that he

comply with certain procedural requirements. The bill does not address the question of what the holder must do, if anything, to verify the purposes for which the record is sought.

Holders of protected health information should be allowed to rely on a certification from the requester that the bill's conditions for the particular disclosure have been complied with. Good faith reliance on such certification of compliance would release the holder of the records from liability for disclosure.

3. **Authorization; Expiration.** Authorizations for disclosure for purposes other than treatment and payment must have an expiration date (or event) not longer than one year from execution (§ 203(a)(4)). This in many instances will produce repeated contacts with a person for renewal of authorizations for ongoing activities, with little practical benefit to the individual's privacy interests.

The expiration should be whatever date or event is specified in the authorization.

4. **Authorization; Connection with Provision of Health Care.** Authorizations for disclosure for purposes other than treatment and payment could not be obtained on a day on which the trustee provides health care to the individual (§ 203(a)(3)).

This is cumbersome and is especially difficult when someone other than a health care provider is requesting the authorization. A Federal employee seeking a security clearance signs a form permitting release of her medical records for a background investigation. Or a person injured through negligence of another wants to authorize his attorney to review the records of treatment to prepare a lawsuit. In these cases, the authorization is being given to someone totally unconnected with the provision of health care. Under the bill, records of treatment incidentally provided on the same day could not be released.

The requirement is directed toward the desirable goal of preventing coerced or unthinking authorizations, e.g., when a patient is considering whether to authorize a particular medical treatment and is at the same time asked to authorize disclosure of his information for some other purpose. However, the prohibition on conditioning treatment or payment on execution of an authorization, in section 203(b) offers adequate protection; the bill could in addition require that notice of this prohibition be included in the text of the authorization.

5. **Indian Tribes.** In many instances, Indian tribes operate health services or include public health authorities. It would be desirable to include tribal governments within the definition of person (§ 3(13)), and to define tribal government. Likewise, the definition of public health authorities (§ 3(15)), should include tribal governments.

6. **Patient's Rights in Litigation Disclosures.** The provision for disclosure in litigation in which the patient is a party (§ 210(a)(1)) gives the patient notice and an opportunity to object, but does not provide standards and criteria for decision about use of the information in the litigation. It would be desirable to provide such standards, of the type provided for non-law enforcement subpoenas in section 211(c)(2).

7. **Deceased Persons.** The bill calls for the Secretary to establish "a procedure for obtaining protected health information relating to a deceased individual when there is no individual representative for such individual." (section 205(c)). The "obtaining" concept is not clear; what is probably intended is a procedure for *authorizing disclosure* when there is no individual representative.

   The bill needs a distinct statement as to its applicability to deceased individuals, and a process for making decisions about use and disclosure of information about a deceased person. A possible approach is to make the rules applicable for a stated period of time (perhaps five years).

8. **Health Care Powers of Attorney.** The bill may not make effective provision for the role of persons holding health care powers of attorney, and for other legal arrangements on behalf of persons unable, in whole or part, to manage their own affairs. The bill appears to treat the individual representative (§ 3(11)) as a recipient of information, by including the individual representative in the definition of "person" (§ 3(13)) and permitting disclosure as if to next of kin (§ 205(a)).

   It might be preferable to permit that person to exercise all rights of the patient with respect to health information, including the right to access and the right to authorize disclosure. This is the approach taken by the Uniform Health-Care Decisions Act § 8 (9 Part I U.L.A. 201, 217 (Supp. 1995)).

9. **Inability to Make Decisions; Absence of Formal Legal Arrangements.** The bill has no provision for making decisions about use and disclosure of records when the patient is in fact unable to make decisions, but there is no one legally appointed to make decisions for the patient. This is a common situation, and is

currently addressed, for example, by the Department of Veterans Affairs in a routine use which authorizes certain officials of the VA to make disclosures on behalf of such patients, under specified conditions.

Some provision should be made for making decisions in such cases.

10. **Notice to Individuals of Information Practices.** Section 103 requires notice to patients of the "trustee's information practices, including a description of the trustee's health information practices". It is not clear what purpose is served by notice of practices with respect to information generally, beyond health information.

This should require notification only of a trustee's practices regarding the protected health information covered under the bill. It should be expanded, however, to require that health care provider trustees furnish each non-emergency patient with a copy. All trustees should make such a statement available upon request. The statement should include a description of the purposes for which information is collected.

11. **Provider-specific Information.** We prefer language delegating to the Secretary the promulgation of rules "regulating access to provider-specific information so as to promote the availability of health care services." (§ 201(e)).

12. **Effective Date; Regulation.** The bill would require the Secretary to promulgate regulations within six months, and the bill would become effective one year after enactment. Given the novelty and complexity of this legislation, these time periods are too short.

The bill should call for regulations within one year of enactment, and an effective date eighteen months from enactment.

13. **Negotiated Rulemaking; Advisory Committee.** The bill would require negotiated rulemaking for the regulation under this bill, and if this were not employed, would require a separate advisory committee to assist with the rulemaking (§ 111(b)). It is not desirable to impose negotiated rulemaking by statute. It can be used, if appropriate, under existing law, without a specific statutory requirement.

A separate advisory committee for this activity is unnecessary because the Department already has an advisory committee, the National Committee on Vital and Health Statistics (established under section 306(k) of the Public Health

Service Act (42 U.S.C. § 242k(k))), which will address these issues. The Department has recently written a new charter for the committee, and has placed privacy concerns explicitly within its scope. The Department has solicited nominations for membership, including for "persons who have distinguished themselves in...information, privacy and security of electronic information..." (61 Fed. Reg. 4,444 (1996)).

14. **Remedies; Civil Actions.** The civil action provision permits recovery for an individual who is "aggrieved" by conduct in violation of the bill (§ 302(a)). This provides for $5000 damages, plus attorney's fees, plus punitive damages, for any conduct that violates any requirement of the act, based solely on a showing that the plaintiff was aggrieved. There is no requirement that the violation be of any particular magnitude, and there is no requirement that the violation be intentional or willful; indeed, it is arguable that the violation need not even be negligent, and that accidental violations would make one liable.

This is too draconian. A standard like "knowingly or negligently" should be considered.

##

BEN\C 14 3/20/96/1650

DRAFT

URGENT

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
Washington, D.C. 20503-0001
4/2/96
LEGISLATIVE REFERRAL MEMORANDUM

LRM NO: 3970
FILE NO: 1646
Total Page(s): 5

TO: Legislative Liaison Officer - See Distribution below:

FROM: Janet FORSGREN (for) Assistant Director for Legislative Reference

OMB CONTACT: Robert PELLICCI 395-4871 Legislative Assistant's line (for simple responses): 395-7362
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pellicci_r@a1.eop.gov

SUBJECT: DEFENSE Views RE: S1360, Medical Records Confidentiality Act of 1995

DEADLINE: Thursday, April 04,1996

In accordance with OMB Circular A-19, OMB requests the views of your agency on the above subject before advising on its relationship to the program of the President.

Please advise us if this item will affect direct spending or receipts for purposes of the "Pay-As-You-Go" provisions of Title XIII of the Omnibus Budget Reconciliation Act of 1990.

COMMENTS: Senate Labor and Human Resources Committee staff have requested comments by 04/05/96.

DISTRIBUTION LIST:

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RESPONSE TO LEGISLATIVE REFERRAL MEMORANDUM

LRM NO: **3970**

FILE NO: **1646**

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Please include the LRM number shown above, and the subject shown below.

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_____ (Name)

_____ (Agency)

_____ (Telephone)

SUBJECT: DEFENSE Views RE: S1360, Medical Records Confidentiality Act of 1995

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_____ Concur

_____ No Objection

_____ No Comment

_____ See proposed edits on pages _____

_____ Other: _____

_____ FAX RETURN of ____ pages, attached to this response sheet

DEPARTMENT OF DEFENSE
OFFICE OF GENERAL COUNSEL
WASHINGTON, D.C. 20301-1600

March 29, 1996

MEMORANDUM FOR MR. ROBERT PELLICCI, LEGISLATIVE REFERENCE DIV, OMB

FROM: LTC TIM RAEZER, LEGISLATIVE REFERENCE SERVICE, DoD

SUBJECT: LRM NO. 3857, HHS Proposed Report RE: S1360, Medical Records Confidentiality Act of 1995

This is in response to your request for the views of the Department of Defense on the proposed report by the Department of Health and Human Services (DHHS) on S. 1360, the "Medical Records Confidentiality Act of 1995."

The Department of Defense (DoD) opposes S. 1360 as presently drafted. It is the view of DoD that the medical records of Federal agencies, including DoD, should be exempt from the coverage of the proposed legislation. The basis for this position is twofold: First, the Privacy Act of 1974 (5 U.S.C. 552a), which currently applies to all Federal records, has provided the necessary protection to medical records being sought by S. 1360. This is evidenced, in part, by the fact that DoD has not experienced widespread problems in protecting patient confidentiality during the past 20 years. Not only is the proposed legislation unnecessary given the effectiveness of the Privacy Act in protecting the confidentiality of Federal medical records, it would be burdensome, disruptive and harmful to the programs and activities of DoD related to the delivery of and payment for health care services for DoD beneficiaries, and it would inhibit essential interactions between the component agencies and institutions of the Military Health Services System, their contractors, and third party payers for DoD health services. Such an exemption of DoD medical records from the coverage of the proposed legislation would result in no disruption in the manner in which DoD currently collects, maintains and uses protected health care information.

Second, and of greater importance, is the fact that the current bill would preclude DoD from using such records for essential agency purposes critical to national defense. As written, the bill would invalidate an essential function of the DoD medical system: to provide to proper command authorities medical information critical to the national defense functions of military members, civilian employees, and certain government contractor personnel. Under the bill, all health care providers and other "health information trustees" are generally prohibited from disclosing health information regarding a person, except to the extent necessary for treatment or payment purposes, or for another purpose for which the individual provides a revocable authorization. The bill includes certain limited exceptions for public health, health research, judicial, law enforcement and several other particular purposes.

No exception is provided in the bill for necessary medical screening for military members, civilian employees or government contractor personnel performing national defense functions. As an essential element of national defense capability, responsible military command authorities must have accurate medical information regarding military members in the command

and other personnel performing certain critical functions. To list just a few examples:

- a pilot receiving medication that may affect alertness;
- an armed forces member (or civilian or contractor employee subject to deployment) with an intolerance for a vaccine necessary for deployment to certain geographical areas;
- any significant medical or psychological changes in a military member or civilian employee or government contractor employee subject to the Nuclear Weapons Personnel Reliability Program;
- an armed forces member or civilian or contractor employee with a positive test for a controlled substance;
- results of periodic monitoring in the workplace of the health status of workers exposed to hazardous materials;
- a military recruit or member with an illness or injury causing noncompliance with mandatory physical accession or retention standards.

For reasons articulated above, DoD recommends that the DHHS report on S. 1360 be modified to oppose S. 1360 unless the medical records of Federal agencies, including DoD, are exempted from coverage under the proposed legislation. It is also recommended that the DHHS report be further modified to assert that, in the absence of a broad exemption for federal agencies, the Administration deems it absolutely essential to add a new exception for national defense functions to the bill. The attached new section 214 is suggested for this purpose. This section would allow the Secretary of Defense to authorize additional disclosures of protected health information when necessary to the proper conduct of national defense functions by members of the armed forces, civilian employees of DoD, and employees of contractors of DoD.

With respect to members of the armed forces, such disclosures could cover any protected health information concerning a member to the extent proper military command authorities need such information to assure the proper conduct of national defense functions by such members. For civilian employees and employees of Defense contractors, the special authority is more limited. Disclosures of protected health information would be limited to those for which the employee grants a written authorization under section 203. However, the Secretary of Defense would be allowed to limit the employee's right to revoke or amend an authorization and to establish exceptions to the termination of an authorization to disclose when such authorization was provided by the employee as a condition of employment and the disclosure is necessary to assure the proper conduct of national defense functions by the employee. Finally, the proposed section would allow the President to grant to other heads of agencies engaged in national defense functions (for example, the Department of Energy with respect to nuclear weapons production) authorities comparable to those granted to the Secretary of Defense under this section.

DoD SUGGESTED REVISION TO S.1360

Add the following new section:

SEC. 214. NATIONAL DEFENSE FUNCTIONS.

(a) AUTHORITY OF SECRETARY OF DEFENSE.--The Secretary of Defense may by regulation, consistent with subsections (b) and (c), establish exceptions to requirements of this title to the extent the Secretary determines that disclosures of protected health information under circumstances different than those otherwise applicable under this title are necessary to the proper conduct of national defense functions by members of the armed forces, civilian employees of the Department of Defense, and employees of contractors of the Department of Defense.

(b) MEMBERS OF THE ARMED FORCES.--The Secretary of Defense may, pursuant to subsection (a), require health information trustees to disclose to proper military command authorities protected health information concerning members of the armed forces to the extent the Secretary of Defense determines that such command authorities need such information to assure the proper conduct of national defense functions by such members.

(c) CIVILIAN EMPLOYEES AND EMPLOYEES OF DEFENSE CONTRACTORS.--The Secretary of Defense may, pursuant to subsection (a), establish for civilian employees of the Department of Defense and employees of Defense contractors limitations on the right of such persons to revoke or amend an authorization and exceptions to the termination of an authorization to disclose under section 203 protected health information when such authorization was provided by such employee as a condition of employment and the disclosure is determined necessary by the Secretary of Defense to assure the proper conduct of national defense functions by such employees.

(d) AUTHORITY OF OTHER AGENCY HEADS.--The President may grant to other heads of agencies engaged in national defense functions authorities comparable to those granted to the Secretary of Defense under this section. When granted by the President, such authorities may be exercised by such agency heads with respect to personnel of the agency and employees of contractors of the agency to the extent the agency head determines necessary for the proper conduct of national defense functions by such personnel and employees.

URGENT

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
Washington, D.C. 20503-0001

4/2/96

LEGISLATIVE REFERRAL MEMORANDUM

LRM NO: 3968

FILE NO: 1646

Total Page(s): 5

TO: Legislative Liaison Officer - See Distribution below:

FROM: Janet FORSGREN (for) Assistant Director for Legislative Reference

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pellicci_r@a1.eop.gov

SUBJECT: EDUCATION Proposed Report RE: S1360, Medical Records Confidentiality Act of 1995

DEADLINE: Thursday, April 04,1996

In accordance with OMB Circular A-19, OMB requests the views of your agency on the above subject before advising on its relationship to the program of the President.

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COMMENTS: Senate Labor and Human Resources Committee staff have requested comments by 04/05/96.

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RESPONSE TO LEGISLATIVE REFERRAL MEMORANDUM

LRM NO: **3968**

FILE NO: **1646**

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SUBJECT: EDUCATION Proposed Report RE: S1360, Medical Records Confidentiality Act of 1995

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_____ Concur

_____ No Objection

_____ No Comment

_____ See proposed edits on pages _____

_____ Other: _____

_____ FAX RETURN of ____ pages, attached to this response sheet

DRAFT

Honorable Nancy Landon Kassebaum
Chairman
Committee on Labor and Human Resources
United States Senate
Washington, DC 20510

Dear Madam Chairman:

This letter provides the Department of Education's views on S. 1360, the "Medical Records Confidentiality Act of 1995." S. 1360 would provide comprehensive rules for the inspection, use, distribution, and transmission of "protected health information." Among others, these rules would apply to all educational agencies, schools, and universities, whether or not they receive Federal funds, as "health information trustees" and, with respect to certain students, as "health care providers."

We are concerned about the confusion and burden S. 1360 would create for such agencies and institutions. Therefore, we urge you to either drop such agencies and institutions from the bill's coverage, or, at the very least, clarify how S. 1360 and other applicable privacy laws would relate to them.

Currently, educational agencies, schools, and universities that receive funds from the Department are subject to the requirements of the Family Educational Rights and Privacy Act (20 U.S.C. 1232g) (FERPA) and Part B of the Individuals with Disabilities Education Act (20 U.S.C. 1411) (IDEA) (which incorporates the major provisions of FERPA). FERPA/IDEA provides access and disclosure rules for what it defines as "education records." Such records include student health records and records that relate to special education services. Thus, education records that fall within the definition of "protected health information," including student health records maintained by all agencies, schools, or universities that receive funds from the Department, would be subject to both the requirements of FERPA/IDEA and S. 1360, requiring such agencies and institutions to apply two sets of privacy standards to the same records.

In many instances, though, the standards imposed by S. 1360 are substantially different from those imposed under FERPA/IDEA. For example:

-- S. 1360, in section 101, would provide for inspection and review of documents only by the "subject" of the information, while FERPA/IDEA vests a parent or guardian with such a right for a minor child;

-- S. 1360 contains standards for access to health information, and exceptions to such access, that differ from FERPA/IDEA's access and exceptions standards for education records. For example, S. 1360's "confidential source" exception and "treatment records" requirements would be in conflict with FERPA/IDEA requirements;

-- S. 1360 contains rules and exceptions for the disclosure of health information that differ from FERPA/IDEA's standards for education records. For example, under FERPA/IDEA, unlike S. 1360, a student's education records may be released, in certain circumstances, without prior consent to an educational institution in which the student seeks or intends to enroll;

-- S. 1360, in section 203, would require an elaborate written authorization for the transfer of health records, while FERPA/IDEA provides for a simpler form of written consent (which may be important to parents when having their children's records transferred and to States and school districts when making disclosures of health information to a State Medicaid Agency or other insurer for purposes of obtaining reimbursement for health related services);

-- S. 1360, in section 212, would provide civil and criminal penalties (including fines and incarceration) for individual violators, while FERPA/IDEA provides only for termination of Federal funds; and

-- It is unclear how S. 1360 would affect current requirements governing Institutional Review Boards. These requirements appear in the Federal Policy for the Protection of Human Subjects in Research. The Federal Policy was published in the Federal Register of June 18, 1991 and was accepted by 16 Federal departments and agencies, including the Department of Education.

As a practical matter, educational agencies, schools, and universities have a daily practice of commingling academic records and health records. Applying the provisions of S. 1360 to such agencies and institutions would effectively require them to institute new practices and procedures to distinguish and segregate any record considered health-related from the rest of a student's records.

We also note that S. 1360 would cover all schools and universities, whether or not they receive funds from the Department. FERPA/IDEA applies only to schools and universities that receive funds from the Department. Private and parochial schools at the

elementary and secondary level generally do not receive such funds. Thus, S. 1360 would have a new and significant impact on such schools.

We understand that when originally introduced and considered during the 103rd Congress as a part of health care reform, the precursor to S. 1360 did not cover educational agencies, schools, and universities. Since these agencies and institutions play a relatively small part in this large and complex piece of legislation, and most of them are already subject to laws protecting student health records, we do not believe they should be covered now. Should they remain included, though, the bill must provide greater clarity on how its requirements relate to those of FERPA/IDEA and the Federal Policy for the Protection of Human Subjects in Research.

We offer you our assistance in this regard and look forward to working with you as you continue to consider this bill.

The Office of Management and Budget has advised that there is no objection to this report from the standpoint of the Administration's program.

Yours sincerely,

Richard W. Riley

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EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
Washington, D.C. 20503-0001
4/2/96
LEGISLATIVE REFERRAL MEMORANDUM

LRM NO: 3971
FILE NO: 1646
Total Page(s): 24

TO: Legislative Liaison Officer - See Distribution below:

FROM: Janet FORSGREN (for) Assistant Director for Legislative Reference

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pellicci_r@a1.eop.gov

SUBJECT: VETERANS AFFAIRS Views RE: S1360, Medical Records Confidentiality Act of 1995

DEADLINE: Thursday, April 04,1996

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COMMENTS: Senate Labor and Human Resources Committee staff have requested comments by 04/05/96.

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RESPONSE TO LEGISLATIVE REFERRAL MEMORANDUM

LRM NO: **3971**

FILE NO: **1646**

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_____ Concur

_____ No Objection

_____ No Comment

_____ See proposed edits on pages _____

_____ Other: _____

_____ FAX RETURN of ____ pages, attached to this response sheet

DEPARTMENT OF VETERANS AFFAIRS
Office of the General Counsel
Washington DC 20420

In Reply Refer To: 024J2

Enclosed please find our detailed comments on the Health and Human Services (HHS) comments on S. 1360, Medical Records Confidentiality Act, and, comments on S. 1360, generally. The Department is continuing to study both of these items and may generate additional comments, or, adjust some of the positions taken herein.

Generally, the Department is concerned with the ramification for the Privacy Act in the event of enactment of the subject bill, since that Act now primarily governs our handling of literally millions of medical care and treatment records every year. Abandoning the Privacy Act in favor of S. 1360, in its current form, would appear to create fundamental operational difficulties.

As drafted, S. 1360 presents certain key issues, and a number of important additional concerns, which must be addressed in order to accommodate VA health care operational needs. Summarized, our key issues include the following: Any legislation must enable the continued intragency exchange of information between the Veterans Health Administration and the Veterans Benefits Administration without the patient's consent. The millions of active powers-of-attorney, by which Veterans Service Organization representatives obtain records and file claims in millions of cases before the VA cannot expire every year. Proposed remedial legislation and related text is enclosed. And the Privacy Act must be addressed - operating under that Act and S. 1360 is too complicated. If S. 1360 can be amended to meet VA's operational needs, then we would not object to having S. 1360 supersede the Privacy Act. These operational needs, and other matters, are identified in enclosures.

Thank you for this opportunity to provide our views.

Sincerely yours,

Mary Lou Keener
General Counsel

Enclosures

Comments by the Department of Veterans Affairs
on HHS Comments on S. 1360

Privacy Act (HHS, p. 8) The Department of Veterans Affairs strongly supports statutory protections for the confidentiality of Federal health care information, and aggressively protects the confidentiality of VA patient care records under the Privacy Act. The VA has had very few complaints about its methods of protecting the personal privacy of veterans medical records. While there has been some litigation, the Privacy Act generally operates quite well in balancing the competing interests of privacy and necessary disclosures. Confidentiality shortcomings could be addressed effectively and precisely by amending the Privacy Act.

If VA had to comply with S. 1360 as currently written, VA would be unable to disclose information which is operationally essential. For example, one VA health care provider could not transfer records to another health care provider in the same facility without the patient's authorization. (See Exhibit D.)

The VA provides medical treatment to large numbers of veterans every year in over 170 hospitals and 200 outpatient clinics. The VA Medical Centers currently maintain approximately 5.5 million active outpatient and inpatient medical files. VA treats 2.7 million veterans per year; in 1996, it is estimated that VA will provide one million inpatient and 26.3 million outpatient visits. We provide counseling to veterans through "storefront" locations known as Vet Centers. In providing treatment, VA has resource-sharing agreements with other medical facilities in the private sector and federal entities such as the Department of Defense and the Indian Health Service. Additionally, VA is engaged in significant medical research and helps provide training for the majority of the nation's doctors through associations with affiliated medical schools. All these activities generate individually identified and retrieved patient medical care and treatment records. Thus, it is clear that replacement of the Privacy Act with broad, new legislation would require substantial investment of resources in training and in reconfiguring VA's records management practices.

If, nevertheless, S. 1360 were applied to the federal sector, then we offer the following detailed comments.

Department of Veterans Affairs (VA); Benefit Programs (HHS, p.8-9) S. 1360 would seriously interrupt the timely flow of records between the benefits arm of the Department of Veterans Affairs, the Veterans Benefits Administration (VBA), and the health arm, Veterans Health Administration (VHA). VA performs over 1,000,000 medical examinations annually for the purpose of determining eligibility for certain veterans benefits. Once these examinations are completed, they are sent from VHA to VBA and filed in the claims file. VBA makes an additional 2,000,000

requests for medical records annually, in order to process claims. Records containing protected health information also flow from VBA to VHA. For example, VBA discloses protected health information from claims files to VHA regarding the level of medical treatment to which a veteran is entitled. Moreover, a veteran may require multiple hospitalizations thereby requiring multiple consents. ***Consents are simply inadequate to accommodate this process.*** The bill's impact would be to require multiple authorizations from a veteran to move records between these two VA components, which would significantly increase the time and cost required to develop and adjudicate a veteran's claim. We are providing language, attached as Exhibit A, to address this matter. Also, we are suggesting certain revisions, by way of a substitute paragraph 3, for pages 8-9 of the Draft HHS comments on S. 1360 (attached as Exhibit B).

In order to expedite the processing of claims from veterans recently discharged from the Armed Forces, VA and DOD have recently established a procedure whereby Service Medical Records are sent to VA for storage regardless of whether a claim has been filed. This enables prompt transfer to a VA office when a claim is filed. This recent innovation has addressed timeliness problems and should be protected. (See language in Exhibit A.)

Also included in Exhibit A is language that would allow the continuation of a long-standing practice whereby Veterans Service Organizations (VSOs) represent individual veterans who seek VA benefits in millions of cases each year. Since a VSO may represent a veteran over a number of years in a variety of proceedings, veterans currently use powers of attorney as the disclosure device for medical and benefits records. There is no "power of attorney" under S. 1360 and authorizations are inadequate for the process since they automatically expire at the end of one year. (See also HHS, p. 10, Authorization Expiration comments, with which we agree.)

Written Authorization etc. (HHS, p.1), Compatibility; etc (HHS, p. 2), Internal Uses; etc (HHS, p.2) S. 1360 does not contain an equivalent to the "need to know" provision of the Privacy Act, subsection (b)(1). We strongly agree with the HHS comments that all institutions (including VA) providing medical care, need a method for allowing their employees to gain access to protected records for a variety of purposes, such as providing medical care, medical quality assurance peer review activities, legal services, oversight, employee personnel matters and other management activities, etc. For example, patients do not expect to sign consents for every individual providing health care within an organization. Further, as pointed out in Agents and Contractors (HHS, p.3), VA and other Federal providers need to be able to disclose protected information to other parts of the Federal government for the performance of legal or other functions, although recipient government components are neither agents nor contractors. Compatibility for government operational

purposes should be measurable by the Notice to Individuals provision (see HHS, p. 12).

Certification of IRBs, etc (HHS, p. 6) We strongly endorse the alternative proposed herein which would enable VA's own IRBs to act on proposed disclosures of protected VA information.

Federal Agencies and State Requirements (HHS, p.8) We strongly agree that the bill should be clear that it is not subjecting the Federal government to State reporting statutes.

Minimum Disclosure (HHS, p.9) As a practical matter, adding the qualification "to the extent practicable," as suggested by HHS, is desirable.

Authorization; Expiration (HHS, p.10) As indicated above, specially trained claims representatives of Congressionally recognized veterans service organizations represent veterans in benefits matters before the VA, utilizing powers of attorney. These instruments provide authority for disclosure of medical care and treatment information as well as for other representational matters. These relationships are maintained for years, during which a service organization representative may appear several times on behalf of the same veteran. If the subject S. 1360 authorization time-limitation were applicable to this arrangement, the millions of power-of-attorney relationships would have to be renewed annually. This is one example of the general objections which HHS has posed on the S. 1360 provision. We strongly agree with HHS and request adoption of the language attached at Exhibit A to avoid the above result.

Authorization; Connection, etc (HHS, p.10) We strongly agree that disclosure authorizations should be obtainable at any time the patient is competent. The VA cannot condition the provision of the health care benefit on whether a disclosure authorization has been executed.

Deceased Persons (HHS, p.11) We agree that the bill needs to squarely address confidentiality of decedent records. The bill should address what interest is being protected, what disclosure mechanisms should exist, who should have disclosure authority and how are the customary decedent-related disclosures, e.g., death certificate, funeral home arrangements, to be effected.

Effective Date; Regulation (HHS, 11) The implementation period once regulations are finally adopted should be twelve months, not just six months.

Remedies; Civil Actions. (HHS, 13) We strongly agree that civil recovery actions should be predicated on some reasonable degree of knowledge and fault.

Negotiated Rulemaking; Advisory Committee (HHS, p.12) Provider-specific Information (HHS, p.12) Federal providers, such as the

VA and DoD, should have the opportunity to work on any advisory committee which will influence the implementation of S. 1360, given their size and operations. We agree with HHS that negotiated rulemaking should not be mandated by S. 1360.

Health Care Powers of Attorney (HHS, p.11), Inability to Make, etc. (HHS, p. 11). We agree with the HHS comments.

Exhibit D

DISCLOSURES OUTSIDE VA WHICH S. 1360 DOES NOT ALLOW

Under S. 1360, VA will not be authorized to make a variety of disclosures which are either required by other statutes, or are desirable from a public policy standpoint. For example, our reading of the legislation leads us to conclude that VA could not disclose medical records without authorization to the Congress, to the General Accounting Office, to the National Archives and Records Administration Administration, to the Equal Employment Opportunity Commission, to the Merit Systems Protection Board, to contractors of health care providers, to appropriate officials for civil commitments, to coroners, to organ donors, to funeral homes, to family members of deceased individuals, to the American Association of Blood Banks and JCAHO, to departments of motor vehicles or other public safety organizations, child protection agencies, to a guardian ad litem, to the Red Cross in order to facilitate their program for transporting the loved ones to the bedside of terminally-ill veterans or members of the Armed Forces, to insurance companies for collections, to the Department of Justice for litigation, to nursing home facilities for preadmission screening of mentally ill and retarded patients, to other federal agencies for computer matching, etc. (This list is exemplary, and does not include all prohibited disclosures.)

Currently, the Privacy Act permits disclosures without consent via the routine use exception. (5 U.S.C. § 552a(b)(3). This enables the VA and other Federal agencies to make adjustments to disclosure needs as circumstances require. Such flexibility is desirable for a least two reasons. It accommodates new program disclosure needs not contemplated by disclosure provisions at the time of their enactment. Further, it provides a means to confidently resolve interpretation questions regarding the scope of a disclosure provision. We strongly recommend retention of a provision such as this which will provide reasonable flexibility in the face of constantly changing circumstances.

Exhibit B

Proposed substitute for the following topic on pages 8-9, paragraph 3 of the draft "Comments of the Department of Health and Human Services on S. 1360, `Medical Records Confidentiality Act'":

Department of Veterans Affairs (VA); Benefit Programs (HHS pp. 8,9) The Department of Veterans Affairs has pointed out that there is a voluminous daily flow of electronic and paper health information between VA medical facilities and counterpart adjudication and benefits payments offices of VA on millions of cases in order to timely and efficiently provide health care and benefits payments under title 38 United States Code. For example, eligibility for health care is determined and verified by the benefits offices, while payments of disability and pension benefits by the benefits offices are dependent on admission and condition information generated by the medical facilities. The millions of veterans who receive either or both types of benefits view the Department as a single entity rather than separate components, and expect timely collaboration between these two VA components in their benefits matters.

Under the bill, this huge disclosure process would appear to require patient consent. To the extent that the Department of Veterans Affairs wishes this changed in the interests of convenience and effectiveness for the veteran and for this Department, it would appear to be desirable to do so in the controlled situation of this agency. The Department has submitted language to address this situation.

EXHIBIT C

VA'S OFFICE OF GENERAL COUNSEL
LINE-BY-LINE COMMENTS ON S. 1360 (Oct. 24, 1995 Version)

***Matters of greater concern are in boldface.**

DEFINITIONS

Sec. 3(1), p.3, l.15 - We are unable to determine what a Certified Health Information Service does. This should be clarified or deleted. See § 204, p.24,l.4

Sec. 3(2), p.3,l.22 - It doesn't define what an "institutional review board" does. We recommend that the definition include such a statement from the definition of the phrase in H.R. 3600 amendment, § 5120(c)(3), for the same term.

Sec. 3(3), p.4, l.3 - The term "disclose" must be defined to include a need-to-know concept such as is currently provided in the Privacy Act, § 552a(b)(1), to allow information to flow within a health care provider. Otherwise, even a referral to a VA component for a diagnostic service or to housekeeping for a request for clean sheets for a patient's bed could require a prior written consent from the patient. This limitation on internal disclosures is unworkable.

Sec. 3(5), p.4, l.21 - The definition of health care providers is incomplete. Subsection (C) needs to have "contractors" added. Medical facilities often use contractors who (or which) need to see the medical records to function.

Sec. 3(6) p.5, l.13 - We do not understand why the definition of a health information service is in the bill. The only clear reference to the entity is § 204, which provides for very limited functions, and should be eliminated. It would appear also that the definition is overly broad. For example, (B) would appear to cover AT&T when information is sent over their circuits between hospitals.

Sec. 3(7) p.6, l.5 - The definition of a HIT seems to contemplate a model for providing health care which is not consistent with the reality of how health care is provided. Health care, at least based on the VA experience, is not provided to individuals by discrete units. It is provided by entities such as hospitals or health care networks which need to move records between various health care providers employed or utilized by the hospital, such as a separate MRI facility. Under the structure contemplated by the bill as we understand it, VA would need consent to provide records

to various individuals and entities as part of providing health care.

Additionally, VHA provides medical care to veterans. Records of that care are used by the Veterans Benefits Administration (VBA) to determine eligibility for benfits under title 38, United States Code. This happens millions of times per year. To require a consent each time is extremely impractical and burdensome. The same would be true even where VBA asks VHA to perform a compensation and pension (C&P) examination to determine the amount of compensation to pay the veteran patient.

Finally, a HIT would not be able to release employee treatment records in order to administer the OWCP program without the employee's consent. Under (A)(ii), the IG and the FBI would be HITs if they receive records under § 212. What is the point under (B)?

Sec. 3(8) p.7, l.4 - Health Oversight Agency does not include several entities which by law have oversight responsibilities and explicit statutory access to VA records, including medical records. These include: Congress, GAO, and NARA. The IG would be, at least as to some components, a HOA. So it would be both a HIT and a HOA. Other entities such as the NPDB and occupational health monitors at DOL would not qualify, and, hence, patient consent would be required for VA to disclose records to it.

Sec. 3(9), p.8, l.3 - Health Plan is defined as including "other program providing health benefits, whether or not funded through the purchase of insurance," which is too broad.

Sec. 3(10), p.8, l.10 - Health Researcher should include contractor since many field trials are done on a contract basis.

Sec. 3(11), p.8, l.19 - Individual Representative does not cover Powers of Attorney used by VSO personnel to obtain access to records with the patient's consent. It also does not address the situation where there is no court-appointed representative of an incompetent individual. Also, the bill does not provide for the IR to do anything as subsection (h) of the Privacy Act does; they can't obtain access to the records, seek amendment or consent to release. There is no authority in the bill to release records to establish the need for the court to appoint someone to serve as an individual's representative.

Sec. 3(12), p.9, l.1 - Law enforcement inquiry needs to include investigations of possible violations of law.

Sec. 3(13), p.9, l.7 - The definition of person is different in scope than the definition of that term in 5 U.S.C. § 551(2), which applies to the Privacy Act. The different coverage could lead to conflict and confusion in application of the two statutes.

Sec. 3(14), p.9, l.13 - protected health information at (B)(ii)(II) includes information "with respect to which there is a reasonable basis to believe that the information can be used to identify an individual." This should be clarified as to whether the "individual" doing the identifying is a reasonable third party, or, someone who is a close friend of the record subject, and consequently knows details from which identification could take place.

§ 3(18) p.10, l.20 - The definition of writing is very awkward and incomplete. For example, it does not include microfiche or videotape. Rule 1001 from the Federal rules of evidence could be adapted. Alternatively, is there a need to refer to writing, except for purposes of consent, given the coverage of the definition of protected health information?

TITLE I - INDIVIDUAL'S RIGHTS

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

Sec. 101, p. 11, General Comment on Inspection Provisions - The Act does not deal with the issue of how the records are located. For example, if copies of medical records are filed legitimately in other staff offices, such as an attorney's file, or the Inspector General's Office, how is the Health Information Trustee expected to find these records when a request for inspection is made? Will employees be subject to sanctions for failure to comply with the inspection and copying provisions?

Sec. 101(a), p. 11, line 14 - There are no limitations on determining the cost of inspection and copying.

Sec. 101(b) p. 11, line 16 - There is no administrative review if a patient is not permitted to inspect or copy protected health information. We recommend that an appeal within the health information trustee of an initial adverse determination be provided.

Sec.101(b), p. 11, line 16 - There is no exception for "information compiled in reasonable anticipation of a civil action or proceeding," such as is contained in subsection (d)(5) of the Privacy Act. Patients would accordingly be entitled to access to an attorney's file, for example, in a tort litigation action, if the file contained protected health information.

There are no exceptions for law enforcement records like the (j) and (k) exemptions of the Privacy Act. Thus, copies of medical records in the hands of the Inspector General must be disclosed to the patient.

Sec. 101(b)(3)(B), p. 12, line 12 - The "Administrative Purposes" exception to inspection is very narrow, and does not solve the problems addressed by Privacy Act subsections (d)(5), (j) and (k). For example, if VA sends protected health information to the Department of Justice in the defense of an action, VA would lose the ability to invoke the exemption.

Sec. 101(d), p. 12, lines 22-23 -As stated above, VA supports an administrative review since it gets a better result, and is protection against liability under Title III of the Act. The 30-day period should accommodate an appeal as well.

Sec. 102(a), p. 13, line 4 - If the Act includes an administrative appeal of a refusal to amend information, more than 45 days is necessary.

Sec. 102(b)(2), p. 13, line 22 - VA supports the administrative review of any refusal to amend medical records. Administrative review is implied in this subsection; the Act should make the appeal right explicit.

Sec. 103(a), p. 15, line 2 - The term, "information practices," is not defined. The type of notice contemplated is unclear.

Sec. 103(b), p. 15, line 8 - The model notices should be explicitly discretionary.

Subtitle B - Establishment of Safeguards

Sec. 111(a), p. 15, line 15 The standard of "ensuring" the confidentiality, security, accuracy, and integrity of protected health information is too high; VA recommends using a "reasonable efforts" standard instead.

Sec. 111(b), p. 15, line 21-23 - VA and other Federal agencies should promulgate their own regulations in consultation with the Secretary of HHS. The citations to title 5, United States Code, sections 581 through 590, have been amended. (Sections 584-590 have been renumbered and transferred.)

Sec. 111(b)(1)(B)(ii), p. 16, line 9 - The Act should contain a membership category for VA and other federal health care providers and other representatives of federal interests (such as NIH). The representatives include categories of individuals which are not defined, such as "health care professionals," "health care entities," and "health care consumers." The membership section should utilize the defined entities, such as health information trustee, health care provider, health information service, etc.

Sec. 111(b)(2), p. 17, lines 8-10 - The Secretary should also consult with federal health care providers and other interested federal entities; such should be empowered to issue thier own regulations.

Sec. 112(a), p. 17, line 12 - This provision does not distinguish between accounting for disclosures within a health information trustee and disclosures outside. The absence of an internal "need to know" concept, such as appears in Privacy Act subsection (b)(1), creates problems when records move within an agency, and especially to staff support.

Sec. 112(b), p. 17, line 20 - The Privacy Act has a different records retention schedule; the time periods do not match precisely.

TITLE II - RESTRICTIONS ON USE AND DISCLOSURE

Sec. 201(b)(1), p. 18, line 9 - The "Compatibility" provision is not related to the rest of the Act.

The Health Information Trustee appears responsible for determining how the recipient plans to use the information, which is a difficult and unrealistic burden to impose.

The word "significant" should be placed before the word "purposes" on line 12.

If a health information trustee later develops a new purpose for the protected health information (which is legitimate within the medical community), it would be precluded from using or disclosing that information.

Sec. 201(d), p. 18, line 22, - The requirement of identifying records as "protected health information" has at least two problems. First, will the Act be retroactive, or will it apply only to records created after its enactment? VA believes that the Act should apply to all medical records regardless of when they were created. It would be too difficult to distinguish which records are covered by the Privacy Act, and which are covered by the new legislation. Second, when large volumes of records are involved, would trustees be required to separately stamp each individual record to identify it as being covered by the new legislation?

Sec. 201(e), p. 19, line 3 - The purpose of subsection (e) is unclear.

Sec. 202, p. 19, line 7 - Under title 38 U.S.C. § 1729, VA has the right to recover for services provided. VA must make protected health information available to insurance companies in order to collect. If patient refuses to consent, VA would be unable to bill for care provided, and § 1729 would be frustrated.

Sec. 202(a)(2), p. 19, line 20 - The requirement of separate forms authorizing disclosures for treatment and payment is

contrary to the "Reinventing Government" initiative, which favors simplification. Two forms are unnecessary when one would suffice.

Sec. 202(a)(4), p. 20, line 2 - The word "specifically" should be dropped. The individual executing the authorization should not be required to identify a specific VA Medical Center; identifying VA as trustee would be sufficient.

Sec. 202(a)(6), p. 20, lines 7-10 - This requirement should be eliminated since it is already covered by the revocation subsection (b), on page 21, lines 3-10.

Sec. 202(a)(7), p. 20, lines 11-16 - This requirement (that the patient has read a statement of disclosures that the recipient intends to make) should be eliminated because it is burdensome and unrealistic. Furthermore, the requirement is surplusage, since section 202 concerns authorizations for treatment and payment only.

Sec. 202(a)(8), page 20, lines 17-21 - This requirement (of disclosure only for a purpose compatible with the purposes for which the information was collected) should be eliminated. The patient should be able to consent to have records disclosed for any purpose. Furthermore, under section 202, the records are only being disclosed for treatment and payment.

Sec. 202(a)(9), page 20, line 22 - Veterans Service Organizations have a long history of assisting veterans obtain benefits (including health benefits) to which they are entitled. The mechanism used to accomplish such assistance is a power of attorney, which may or may not include an expiration date. This requirement should either be eliminated, or the Department of Veterans Affairs should have an exception for Veterans Service Organizations.

Sec. 202(b)(2), p. 21, line 16 - Delete the words "or constructive" before the phrase "notice of the revocation." This could cause a host of problems. For example, if a patient leaves a message revoking authorization with a hospital switchboard or a doctor's answering service, does this constitute constructive notice?

Sec. 202(c), p. 21, lines 18-23 - The use of the model authorizations should be discretionary.

Sec. 202(c), p. 21, line 23 - The citation should read "(a)(7)."

Sec. 203(a)(1), p. 22, lines 11-12 - Section 203 concerns authorizations for purposes "other than treatment or payment." It does not make sense to apply all of the requirements of section 202(a)(1) through (6) which covers authorizations for treatment or payment. For example subsection (a)(2) requires separate forms for "treatment" and "payment."

Section 203 would require another form. The Act requires separate authorization forms for disclosures for treatment, for payment, for other than treatment or payment, and a statement of intended disclosures. All this paperwork is contrary to the Reinventing Government initiative.

The patient should have the discretion to authorize disclosures for broad purposes or limited purposes. The Act should eliminate the purpose-based distinctions between authorizations.

Sec. 203(a)(3), p. 22, line 19 - The requirement that authorization not be requested on a day on which the trustee provides health care should be eliminated. It can be burdensome, requiring patients to return on another day. If the Act seeks to eliminate duress, add a requirement that "consent must be freely given."

Sec. 203(a)(4), p. 23, line 1 - As discussed previously, the Department of Veterans Affairs relies heavily upon the use of powers of attorney; the one year limitation must be eliminated, or VA must obtain an exception thereto.

Sec. 203(c)(2), p. 23, line 17 - Delete the words "or constructive" before the phrase "notice of revocation."

Sec. 203 (d), p. 23, line 18 - The model authorizations should be made discretionary.

Sec. 204, p. 24, lines 4-25 - This section should be deleted; it was originally included as part of the Health Security Act, H.R. 3600 (1994), and is no longer necessary under this bill.

Sec. 205, p. 25, lines 4-5 - The phrase "regarding an individual" should be deleted since it is included in the definition of protected health information.

line 6 - The definition of individual representative leaves gaps (as discussed above).

lines 7-8 - Significant personal relationship is not defined.

line 13 - The word "or" should be inserted after the semicolon.

p. 26, line 3 - Under Sec. 103, the health information trustee is already listing its information practices, so an additional notice to the patient of his or her right to object is unnecessary. The requirement of notification simply creates another barrier to admission. We suggest that Sec. 205(b)(1)(A)(i) read: "has not initiated a request for confidentiality of directory information; or"

line 5 - The word "or" should be inserted after the semicolon.

Subsection 205(b)(1)(B)(i), p. 26, line 13 - The person requesting directory information should be required to provide the name of the individual who is the subject of the information.

We also believe that a new subsection 205(b)(1)(B)(iv) should be added, to allow the release of information regarding whether the subject may receive visitors, and whether the patient's condition permits the receipt of flowers or other gifts.

Subsection 205(c), p. 27, line 1 - This bill creates a new rule, granting personal privacy to decedents, which is contrary to the common law, and the court cases interpreting the Privacy Act and the Freedom of Information Act. A better rule would be disclosure is permitted when it will not invade the personal privacy of a living individual, or be harmful to the memory of the deceased.

The bill does not recognize the wide variety of disclosures currently made regarding decedents. For example, the health information trustee would not be permitted to release information to the coroner about the cause of death, to funeral homes, to organ donors. The bill would prevent VA from sending the death certificate to the Social Security Administration, as required by law.

This section does not permit anyone to exercise consent on behalf of the deceased individual. The bill should at minimum permit disclosure to the family.

The bill does not provide an end point, after which the records of a deceased individual are no longer confidential. This will bar genealogical research, for example.

line 6-10 - Even if a deceased individual has an individual representative, this bill does not grant an individual representative the power to consent to the release of protected health information.

Sec. 207, p. 27, line 17 - The "oversight" provision would not allow VA to release medical information to the Congress, the General Accounting Office, or the National Archives.

line 20 - The term "authorized by law" should be deleted, since there are many industry-driven oversight agencies such as JCAHO, the American Association of Blood Banks, etc. This section should be redefined in order to permit continued access by accrediting bodies.

, p. 28, lines 1-6 - VA often uses medical records when employees are involved in a proceeding, such as reprivileging, disciplinary proceedings, Equal Employment Opportunity proceedings, and Merit Systems Protection Board.

Sec. 208, p. 28, line 7 - The concept of public safety should be added into this section. For example, reporting when a patient might be a danger to others. This section or another must contain a mechanism for permitting disclosures to appropriate authorities (such as the county attorney) for commitments when an individual is a danger to him/herself or others. (The exception allowing disclosure for judicial purposes would not suffice, since it requires that the individual must have placed his or her own condition at issue.)

Sec. 209, p. 28, line 18 - VA and any other Federal providers which have their own Institutional Review Boards (IRBs) should certify their own IRBs. VA currently complies with all the bill's substantive requirements applicable to institutional review boards, and therefore does not object to the requirements contained therein. However, VA's procedures for releasing records to researchers are long-standing and well-established, and do not need revision. Furthermore, VA has as much expertise as anyone else in this area.

Sec. 210, p. 30, line 22 - The list of entities which may disclose protected health information for judicial and administrative purposes is not consistent with the definition of health information trustees (i.e., some HITS are not covered). The term "HIT" should be used instead. If the bill does intend to exclude some categories of HITS, the legislative history should explain why.

, p. 30, lines 3-17 - The bill only permits disclosure for three limited purposes. It is essential that the bill include a general provision allowing disclosure pursuant to a court order without specifying a purpose. It is widely accepted in the community that a court order can reach this information. The bill does not permit disclosure pursuant to a court order when another person has made the individual's condition an issue; there are many legitimate times records would be necessary such as child custody (when the patient might be incapable of caring for a child), an Equal Employment Opportunity case, etc.

, p. 31, line 10 - The word "or" should be added after the semicolon.

, p. 31, lines 3-14 - We suggest that subsections 210(a)(1) and (2) be amended to read as follows:

(1) pursuant to The Federal Rules of Civil Procedure, The Federal Rules of Criminal Procedure, or comparable rules of other courts or administrative agencies; or

(2) to a court, or pursuant to an order of a court of competent jurisdiction; or

, line 16 - The term "law enforcement authority" is not defined. Would it include departments of motor vehicles, cancer tumor registries, child protection agencies, state licensing boards, or the EEOC?

Sec. 210, p. 31, line 18 - Subsection (b) should be deleted.

Sec. 211, p. 32, l. 10 - The comments on 210 coverage of the HIT apply to subsection 211(a). Like Section 210, this section should specify the subpoenas to which it applies, e.g., administrative, judicial. The interrelation between sections 210 and 211 may need to be clarified since 210 seems to limit disclosure of the records, but by use of a subpoena under 211 it appears that, if the sections are deemed exclusive in coverage, those 210 limitations may be avoided. Additionally, if the records can be subpoenaed in situations in which they cannot be reached under 210, why

impose the limitations in 210? The notice and procedures to quash a subpoena are a little sketchy. The procedures under the Right to Financial Privacy Act may be appropriate for consideration. The section should clarify that the Bill does not impinge on the sovereign immunity of the Federal government by allowing suit against it in state court.

Sec. 212, p. 34, l.21 - Under paragraph (a)(2) it is unclear who determines whether probable cause exists? The recordholder in many instances is simply not qualified to make such a determination, and it is not uncommon in court proceedings to have a probable cause determination for a warrant overturned on appeal. The bill should specify that a recordholder should be able to rely on the representations of the law enforcement entity seeking the records that it has complied with the bill's requirements as is done in the Right to Financial Privacy Act.

p. 35, l.11 - delete the word "legitimate" in front of the phrase "law enforcement inquiry." The definition of the phrase (p. 9) makes the word redundant.

p. 36, l.6 of subsection (a)(4) provides "[i]f the identity of the individual [patient] is not known at the time the subpoena is served, the individual shall be served not later than 30 days thereafter." I would suggest the Act clarify that notice be given not later than 30 days after the identity of the patient is learned.

p. 38, l.8 subsection (a)(6) limits the use of information obtained pursuant to section 211 to actions arising out of or directly related to the law enforcement inquiry for which the information was obtained. This seems unduly restrictive. Assume an individual is investigated for and convicted of fraud in obtaining prescriptions. Two years later, the same individual engages in the same activities using the same MO. Under this provision, it would appear that the law enforcement activity could not look at those records unless they regathered them from the original records source. This seems wasteful and unduly burdensome.

p. 39, l.19 - The exceptions provision of section 212 does not appear to use language consistent with the rest of the bill. Possibly something along the line of the following would be helpful. "Notwithstanding subsection (a), a health information trustee may release the records of an individual without the individual's consent in response to a request from a law enforcement entity when the entity seeks the records for use - (1) in an law enforcement inquiry or prosecution concerning a health information trustee; or (2) to assist in the identification of a person in a law enforcement inquiry or prosecution; or (3) in connection with a law enforcement inquiry or prosecution of actions or

activities committed against the health information trustee or on premises used by the trustee."

Sec. 213, p. 40, l.4 - Federal agencies are subject to electronic records standards promulgated by the Secretary of Commerce, and to regulations on electronic records promulgated by the National Archives and Records Administration. These entities currently coordinate their activities. If those standards are preempted for Federal agencies, the bill should say so. If not, then the bill should provide some means of coordination so that Federal agencies are not subject to two sets of standards.

TITLE III - SANCTIONS

Sec. 301, 6p.40, l.11 - (a) A HIT is exposed to civil liability whenever the Secretary determines that the HIT has "substantially and materially" failed to comply with the statute. The phrase should be amended to include some element of intentional conduct or gross negligence to avoid liability exposure under inappropriate situations. For example, a local newspaper article advises readers to file access requests for their medical records. The local hospital is inundated with hundreds of requests. It could not respond timely without significant diversion of personnel and resources from other operations-related activities. As a result, a significant number of the requests are not answered within the statutory time limit, resulting in a substantial and material noncompliance even though no one suffered any injury as a result of the delay.

(a)(2), l.18 - It appears that § 301, the civil penalty provisions, were intended to apply only to private sector entities. Otherwise, if applicable to federal entities, appropriated tax dollars for one agency would be paid to another Federal agency, HHS, to be covered to the Treasury. Passing money in a circle with no expenditure to accomplish an agency purpose in a time of limited appropriations for agency program activities seems questionable at best.

Additionally, the language that the Secretary could exclude a HIT from participation in medicare, medicaid or "*any <u>other</u> federally funded health care programs,*" could mean that a VA Medical Center found to have violated (a)(2) by the HHS Secretary would not be able to receive and expend appropriated funds provided by Congress in the annual appropriations legislation to implement title 38 obligations to provide medical care to the nation's veterans. Clearly this frustration of Congressional intent is not acceptable.

Finally on this point, it would be inappropriate for one agency, HHS, to, in effect, tell another Federal agency how it is to spend its appropriated funds to accomplish

statutory missions within its exclusive jurisdiction. This legislation would require VA to do whatever HHS required.

p.40, l.24 - The exclusion provision implementation in (b) needs clarification. There is no provision in (a)(2) for how long the exclusion would be, or under what circumstances, if ever, that a HIT may apply for reinstatement. As the language now reads, the Secretary's exclusion appears to be permanent. The reference in (b) to section 1128A of the Social Security Act may be confusing, and the procedures and substantive rules governing sanctions under this legislation should be set forth in this bill.

The application of section 1128A could cause confusion because it contains many references to matters not relevant to this legislation. For instance, the heading for this provision of the bill is entitled "procedures for inpostion of penalties." Yet, section 1128A deals with more than procedural matters. Are only the procedural parts of section 1128A to apply?

Additionally, the bill specifically provides that the second sentence of 1128A(f) is not applicable. That sentence reads: "Amounts recovered under this section [1128A, not this bill] shall be paid to the Secretary and disposed of as follows: [the disposition alternatives are then stated, including as a last option covering the monies to the Treasury]". This deletion appears to leave unanswered what the Secretary is to do with any penalty recovered under the bill, in which case, the general rule would seem to apply and all funds would be covered to the Treasury. If that is the intent of the bill, then no additional action on this point is needed.

Sec. 302, p.41, l.6 - This section has several significant problems. First, subsection (a) imposes a strict liability standard for violating the statute. ANY conduct in violation of the statute, no matter how inadvertent or inconsequential, is sufficient to support a civil action. The section should require the plaintiff to allege and prove that the defendant's conduct was willful or intentional or at least grossly negligent.

Second, § 302 provides that an individual who is aggrieved by the violation may bring suit. Since "individual" is not defined, even a person who is not the record subject could bring suit upon an allegation of being aggrieved. Essentially, the number of potential plaintiffs is unlimited. The bill should limit the class of potential plaintiffs to the record subjects.

Third, given the scope of coverage of the bill, the class of potential defendants is almost as large as the class of potential plaintiffs. The exposure of these

entities to potential liability is another reason to require some showing of intent in a violation before recovery would be permitted. For example, the definition of a HIT includes any contractor of a health care provider who transmits protected health information. Thus, AT&T as a provider of health care data transmission services could be sued for an inadvertent disclosure under this bill.

Fourth, the term "aggrieved" is not defined. Under a standard dictionary definition of the term, simply being upset that the HIT took an extra day to provide access to records would be sufficient to state a cause of action. In fact, given the language of the bill, the simple act of noncompliance with the statute may be enough to establish that an individual is aggrieved.

Fifth, § 302 permits the recovery of actual damages or liquidated damages. If an individual establishes a technical, inadvertent violation of the statute which results in some aggrievement, the individual gets a minimum of $5,000. Additionally, under the Privacy Act, the courts have split as to what constitutes actual damages: only out-of-pocket expenses or also items such as emotional distress and pain and suffering. The bill should specify what constitutes actual damages.

Sixth, § 302 does not address how Federal entities are limited in their ability to respond to claims for damages under a statute. Briefly, it would appear that under this statute, as under the Privacy Act, a federal agency could not settle a claim under § 302 until after the individual has filed suit. Hence, VA could not settle a claim, no matter how meritorious, prior to that time. If Federal agencies are to be covered by this statute, unless the proponents of this legislation wish to force every claimant to file suit in order to pursue a claim, § 302 needs to provide Federal agencies with authority to settle claims prior to litigation.

Sec. 311(a), p. 42, l.5 - given the definition of protected health information, there does not appear to be a need for the language following that phrase in 311(a)(1) "relating to an individual."

The definition of a person in the bill differs from that in title 5 and elsewhere, and federal agencies or entities such as a VA Medical Center, could be charged with a criminal offense under the statute.

TITLE IV - MISCELLANEOUS

Sec. 401, p. 43, l.4 - There is no mention of Federal statutes or legal mandates which apply to federal agencies generally, and to VA particularly. The lack of

consideration of the unique legal nature of Federal agencies creates several problems in the implementation of this statute by Federal agencies, and particularly by the Department of Veterans Affairs.

The Privacy Act, 5 U.S.C. § 552a, and the Freedom of Information Act (FOIA), 5 U.S.C. § 552, would apply to the records covered also by this statute when held by a Federal agency. It would appear that this bill would qualify as a basis to withhold records under subsection (b)(3) of the FOIA, but it would be helpful in avoiding litigation if language was inserted in the bill expressly providing that FOIA did not apply.

As to the Privacy Act, that statute was specifically crafted to provide for the confidentiality of documents in the hands of a Federal agency while accommodating other interests which Congress recognised as of sufficient significance as a matter of public policy so as to merit inclusion in the Privacy Act. One primary policy reflected in the Act is that there are certain situations where Congress decided that it was appropriate to disclose an individual's records without his or her prior written consent. These include disclosure to: Congress or its committees, the National Archives and Records Administration, the General Accounting Office, the Bureau of the Census, law enforcement entities for a qualifying purpose, and most importantly, within an entity on a need-to-know basis.

p. 43, l.16 - Subsection (c) should include authorisation for exclusive application of the Privacy Act to Federal agencies rather than this bill. Otherwise, the bill needs to provide specifically for the release of information as discussed elsewhere in these comments. It might be appropriate to simply delete section 208 and provide in subsection (c) that other state and federal reporting laws would not be preempted by this bill.

1.19 - Subsection (c)(1) allows reporting of vital statistics. Section 210(a)(3) allows reporting of matters pursuant to a law requiring reporting to law enforcement entities. We recommend that section 210(a)(3) be deleted and 410(c) be amended to provide that this bill does not supersede any law providing for such reporting. Also, States require health care professionals and entities to report information such as the fact that a driver suffers epileptic seizures or has another medical problem which adversely affects his or her ability to safely operate a motor vehicle to its component which issues drivers licenses. The bill should make clear that this reporting may continue. Otherwise, the state will be unable to ensure that individuals operate motor vehicles such as school buses or tractor trailers only if it may be done safely.

1.21 - Federal entities are not subject to state reporting requirements. However, VA complies with them for public policy reasons under the Privacy Act. Thus, to allow this practice to continue, subsection (c)(2) should be amended to allow reporting under any law "providing" for reporting.

p. 44, l.9 - Subsection (c)(6) should be amended to allow inclusion of sickle cell anemia and infection with the human immunodeficiency virus which are covered by 38 U.S.C. § 7332.

Sec. 403, p. 44, l.21 - We recommend that the time periods be extended by six months based on the experience of the Federal government in implementing the computer matching provisions of the Privacy Act.

p. 44, l.11 - Federal agencies are subject to the Rehabilitation Act of 1974, not the Americans with Disabilities Act. Consequently, subsection (c)(7) should be amended to include the former Act as well.