

Congress of the United States

Washington, DC 20515

May 25, 2001

The Honorable George W. Bush
The White House
1600 Pennsylvania Avenue
Washington, D.C. 20500

Dear Mr. President:

We are writing to comment on the recently implemented medical information privacy standards mandated by the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and issued by the Department of Health and Human Services (HHS) in December 2000. We commend you for allowing these long-overdue privacy protections to be implemented as scheduled, and we look forward to working with you, and Secretary Thompson over the next two years as we move toward the compliance date of April 2003.

Medical information privacy is key to the quality of care. Unless patients are assured medical confidentiality when seeking treatment, health care is jeopardized. A 1999 survey reveals that one in six Americans has done something out of the ordinary to keep personal medical information confidential – including withholding information, providing inaccurate information or in some cases, avoiding care all together (Princeton Survey Research Associates, January 1999). We believe that the HIPAA health privacy standards are an important first step toward restoring the confidence that is required in order to provide the highest quality health care.

As you know, the process of creating the HIPAA privacy standards has been an open and extensive one. Over the years that this regulation was developed, the views of Congress and interested parties were given ample consideration. In September 1997, the Secretary of HHS presented recommendations to Congress for legislation on medical privacy. Subsequently, several bills were introduced but no law was passed. HHS then issued a proposed rule in November 1999, and at the request of industry and consumer groups, extended the comment period by 45 days. The Department then pored over 52,000 comment letters, for over a ten-month period. And only after thorough consideration and extensive fact-finding did HHS issue the final rule.

As you move forward with issuing guidelines for compliance, and as you consider making modifications to this rule, we hope that you will act carefully to assure that the strong privacy protections established are not undermined. In this letter we discuss several key areas of the rule which we believe are crucial to protecting health privacy and hope you will take them into account.

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Consent requirement for use and disclosure of identifiable health information

We strongly support the requirement of patient consent for the use and disclosure of health information. We believe this to be a patient's fundamental right and the cornerstone of any real privacy protections. Any modifications to the rule to undermine the basic principle of consent should not be permitted.

However, we understand that clarification is needed with respect to how the patient consent requirement will be carried out in some instances. For example, concerns have been raised about whether the rule would prohibit a pharmacist from filling a prescription called in from a doctor where no consent form is on hand at the pharmacy. We believe that HHS can address this concern by issuing guidance clarifying that the "substantial barriers to communication" exception set forth in 45 C.F.R. 164.506(a)(3)(i)(C) applies to this situation.

Some critics of the rule have expressed concerns that the consent requirement was not in the HHS proposed rule and therefore should not have been included in the final regulation. We note that many of the 52,000 letters received by HHS during its extended comment period expressed great concern that the rule did not require consent for health information to be used or disclosed for treatment, payment and health care operations. It was only after thorough consideration that the Department published its final rule with many modifications -- including the new requirement of patient consent.

HHS did nothing out of the ordinary with respect to the rulemaking process in requiring patient consent for the use and disclosure of health information in the final rule. In fact, this is an example of why the rulemaking process includes a public comment period so that agencies have the opportunity to correct and improve their regulations before final implementation.

Right to access protected health information

We strongly support provisions in the rule which give patients the right to see, copy and correct their own medical records. These provisions will improve quality of care by allowing patients to correct informational errors when appropriate.

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Minimum necessary requirement for use and disclosure of protected health information

We strongly support the minimum necessary standard in the rule which curtails the use and disclosure of protected health information. Some critics of the rule have suggested that this provision will undermine access to a patient's medical record by those providing direct treatment. This is not accurate.

With respect to determining what constitutes the minimum necessary amount of information to be used, HHS leaves it to providers to make this determination by establishing a general policy. A case-by-case determination is not necessary, as some critics of this requirement have stated. In its preamble HHS anticipates that with respect to treatment, "covered entities will implement policies that allow persons involved in treatment to have access to the entire record, as needed."

Requirement for business partners to adhere to privacy standards

We support the requirement that covered entities have written contracts with their business associates limiting the associates' use and disclosure of information. It is common practice that contractors are held responsible for the actions of agents. There is no reason for privacy protections to be held to a lesser standard. Further, it is already standard practice for covered entities to have contracts with their business associates. Any responsible covered entity already should have confidentiality provisions in such contracts if the business associate is handling personal patient information on behalf of the covered entity.

The medical privacy rule would be meaningless without the business associate section. As health care industry representatives have noted, covered entities often have as many as hundreds of business associates who handle the entity's confidential patient information to carry out functions for the entity. If the business associate provisions were excluded from the rule, business associates could receive patient information from a covered entity, post it on the web, release it to the press, give it to individuals' employers, or otherwise disclose it for purposes beyond carrying out functions for the covered entity without incurring a violation of the medical privacy rule.

Requirement for privacy protections to apply to oral communications

We strongly support coverage of oral communications within the rule. The rule clearly contains a "reasonableness" standard concerning its prohibition against oral disclosures.

It states that covered entities must "reasonably safeguard" protected health information from intentional or unintentional disclosures that violate the rule and must develop policies and practices that limit disclosures to the amount "reasonably necessary" to achieve the purpose of the disclosure. Contrary to the industry scare stories such as how the rule supposedly would require hospitals to build "soundproof walls," the reasonableness standard argues for common sense steps that are generally already taken by covered entities, such as talking quietly to a patient or pulling a cloth curtain when the patient is in a shared hospital room. In testimony before the House Energy and Commerce Health Subcommittee, the President of the American Nurses Association commented that this requirement is already a part of accreditation standards for hospitals and that it is in no way a new or burdensome requirement.

Exclusion of oral communications would leave a gaping hole in privacy protection for millions of Americans and leave patients with virtually no assurance that their health information would be appropriately guarded. Excluding oral communications would mean that, under the rule, a covered entity would have to protect the privacy of an individual's electronic medical record but could nevertheless discuss such records freely with people outside the entity. This result goes against common sense and would be bad policy.

Minors' rights

We are supportive of provisions which permit minors to exercise rights under the regulation when state laws allow for minors to access treatment. These laws represent consensus views on this important issue within communities across the United States. Generally, these state laws apply to treatments for substance abuse, mental health and access to reproductive health care. We believe that it is crucial for confidentiality to be maintained under these circumstances and would oppose any effort to modify the rule in order to weaken these protections.

Conclusion

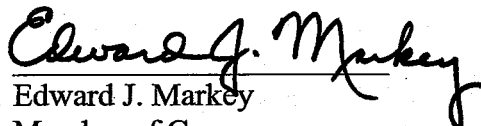
In general, we are supportive of the standards that this rule establishes and are pleased that it provides a federal floor. This approach creates national uniformity while allowing for states to maintain more narrowly focused privacy protections that are not contemplated in the rule. It also allows flexibility for states to apply stronger medical privacy laws into the future, as the need may arise.

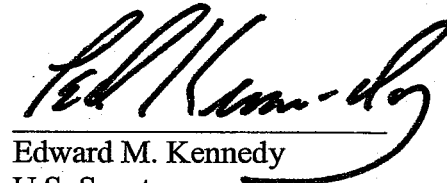
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With respect to improving and building upon the protections in the privacy rule, we are aware that legislative action is needed to close loopholes and "fill in the gaps" that remain largely due to statutory limitations imposed on HHS by HIPAA.

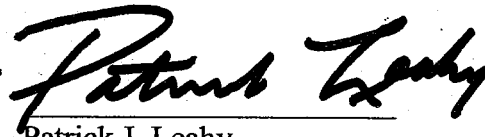
We look forward to continuing to work with the Administration in furthering the goals of protecting the health information privacy of Americans.

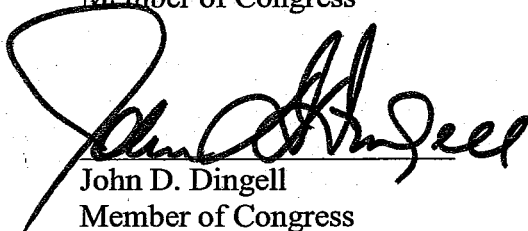
Sincerely,

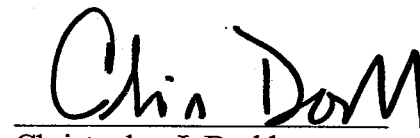

Edward J. Markey
Member of Congress

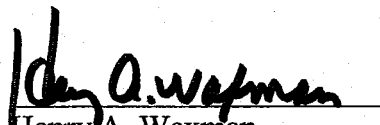

Edward M. Kennedy
U.S. Senate

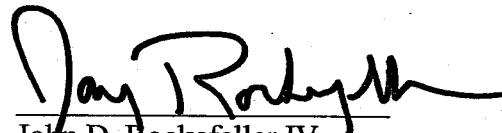

Richard A. Gephardt
Member of Congress

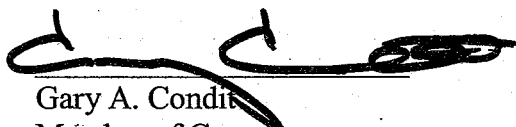

Patrick J. Leahy
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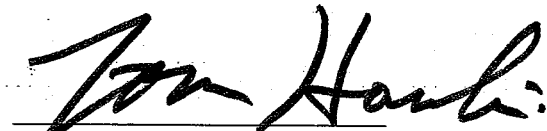

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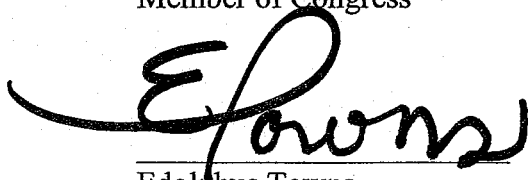

Christopher J. Dodd
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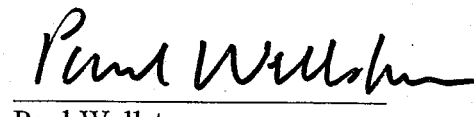

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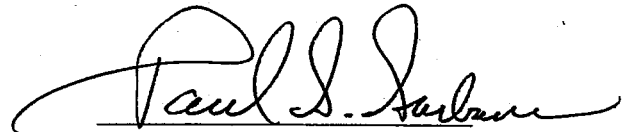

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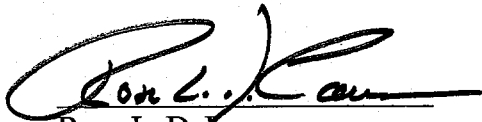

Tom Harkin
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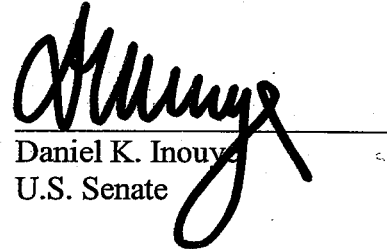

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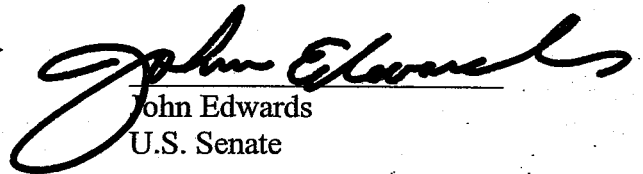

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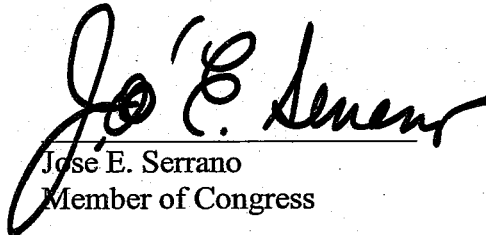

Paul S. Sarbanes
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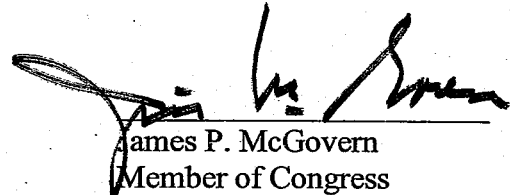

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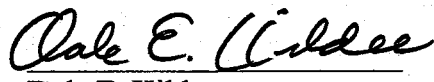

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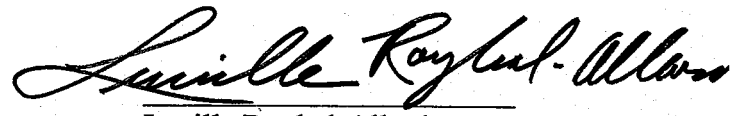

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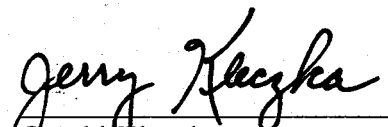

James P. McGovern
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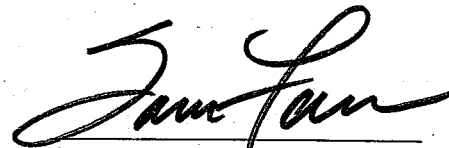

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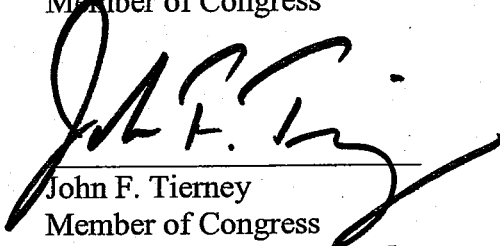

Gerald Kleczka
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Sam Farr
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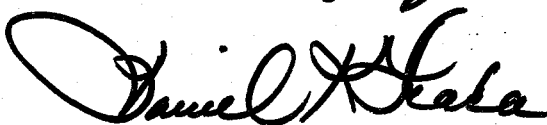
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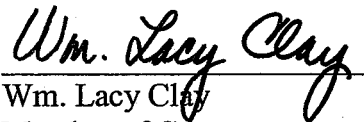
William D. Delahunt
Member of Congress



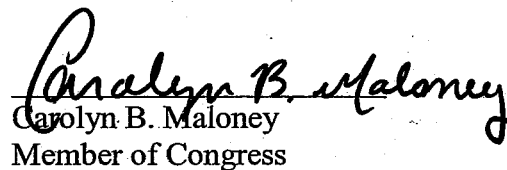
John F. Tierney
Member of Congress



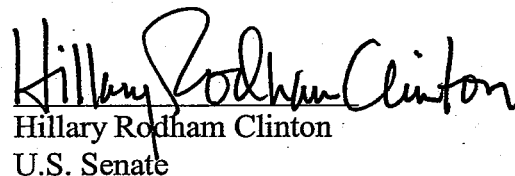
Daniel K. Akaka
U.S. Senate



Wm. Lacy Clay
Member of Congress



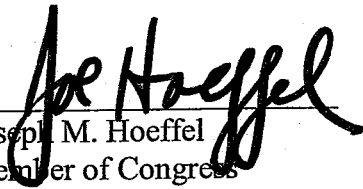
Carolyn B. Maloney
Member of Congress




Hillary Rodham Clinton
U.S. Senate

cc: The Honorable Tommy Thompson

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Joseph M. Hoeffel
Member of Congress



Barbara Lee
Member of Congress