Congress of the United States
House of Representatives
Washington, D.C. 20515

July 23, 2002

The Honorable Tommy G. Thompson
Secretary
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Thompson:

The medical privacy rule promulgated on December 28, 2000, (the "Rule") set forth essential privacy protections for the medical records of millions of Americans. As you know, this long overdue Rule reflects years of discussion and deliberation and carefully balances the interests of many parties. We were pleased when on April 12, 2001, you announced you would not delay the effective date for implementation of these long-needed privacy protections. Unfortunately, we fear that the Administration's recent March 27, 2002, proposed changes (the "Proposal") to these regulations would create serious loopholes in the rule that would undermine medical privacy.

We are pursuing our concerns about these issues in several ways. We have submitted comments on the Proposal and may seek public hearings on this subject. The purpose of this letter is to seek responses to questions regarding the confusing and inadequate explanations the Administration has provided regarding the changes set forth in the Proposal.

Specifically, we have questions regarding three of the privacy loopholes that the Proposal would create: (1) removal of the consent requirement, allowing patients' medical records to be shared *without their permission*; (2) expansion of the circumstances under which patients' information can be shared without their knowledge to include traditional *marketing activities*; and (3) implementation of *"technical corrections"* that allow the disclosure of private medical information without patients' permission to entities regulated by the Food and Drug Administration, such as pharmaceutical companies and medical device manufacturers. We respectfully request that you respond to these questions no later than Tuesday, August 6, 2002.

I. Consent Requirement

The Administration appears to have reversed its position from the summer of 2001 when it supported the Rule's requirement to obtain patients' consent before releasing their medical information for treatment, billing, and health care operations.[1] At the time, the Administration

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[1]Department of Health and Human Services, Office of Civil Rights, *Guidance on Standards for the Privacy of Individually Identifiable Health Information*, 5 (July 6, 2001).

observed that many providers already ask for patients' permission before sharing their records with health insurance companies or other providers, and stated that this practice should continue. The Administration and many interested parties noted that there were two situations under which it would not be practical to ask patients' permission before sharing their health information, and there was broad agreement that exceptions should be allowed so that (1) pharmacists may access a patient's information without prior consent so they can fill a prescription and (2) specialists may access a patient's medical records without prior consent when a patient has been referred by a primary care provider. The Administration, however, has gone far beyond fixing those implementation problems and is now proposing to eliminate the consent requirement altogether.

The Administration has pointed out that the Proposal permits providers who want to seek patients' permission before disclosing their medical records to do so.[2] The Proposal, however, also eliminates the requirement that consent forms be in plain language and include the right for patients to change their mind or place limits on the extent to which their information can be shared. These changes certainly do not encourage providers who voluntarily seek consent to keep a patient's interests in mind.

Please respond to the following questions regarding the Proposal's modifications to the Rule's consent provisions:

(1) Is it true that under the Proposal, a doctor or hospital could disclose a patient's medical record to the patient's insurance company without the patient's permission, even if the patient paid in cash in order to keep the insurer from finding out about the visit?

(2) Why didn't the Administration limit its changes to the specific scenarios where there was broad agreement concerning the need for clarification, instead of eliminating the consent requirement entirely?

(3) With respect to *voluntary consent* allowed under the Proposal, why did the Administration weaken the requirements for what must be included in a consent form?

II. Marketing

While the Proposal requires patient consent before information can be disclosed for *marketing*, it renders this protection virtually meaningless by significantly narrowing the definition of *marketing*. As a result, the Proposal would allow disclosures of health information without a patient's knowledge for a wide range of activities that the American consumer would consider marketing. For example, under the Proposal patients could receive unsolicited

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[2]Statement of Claude Allen, Deputy Secretary of Health and Human Services, before Senate Health, Education, Labor, and Pensions Committee (Apr. 16, 2002).

telephone calls and direct mail advertisements that encourage them to purchase new products or switch to alternative treatments. These telephone calls or direct mailings would be exempt from the definition of marketing even if the calls or mailings came from a drug company instead of a patient's provider, and even if the drug company paid the provider for the patient's sensitive medical information. Because these kinds of activities are exempt from the restrictions that apply to marketing, patients would be unable to prevent these unsolicited communications.

Please answer the following questions:

(1) Is it true that under the Proposal a drug company may have access to a patient's medical records without patient consent so that it can contact the patient directly to offer new products and treatment alternatives? Also, please explain why the Administration is proposing to eliminate the Rule's specific requirement that, to be excluded from the definition of *marketing*, a communication about alternative treatments or therapies must come from a health care provider or plan, as opposed to a third party.

(2) Is it true that under the Proposal a doctor, hospital, or insurance company can be compensated for giving drug companies access to the personal medical information of its patients? Please explain why the Administration is proposing to eliminate the Rule's specific requirement that, to be excluded from the definition of *marketing*, the communication must not involve remuneration of a provider or plan by a third party.

(3) Would these kinds of communications, which are excluded from the definition of marketing under the Proposal, not be considered marketing activities by the Federal Trade Commission?

III. Disclosures to FDA-Regulated Entities

The Proposal would open a broad new avenue through which drug companies could receive patients' medical records without their knowledge or consent. As you know, the Rule would permit health care providers and health plans to disclose protected health information to entities under the jurisdiction of the Food and Drug Administration (FDA) without a patient's permission for a limited list of public health priorities, such as reporting serious side effects from a prescription drug to FDA.[3] In contrast, the Administration's Proposal allows health care providers and health plans to disclose an individual's medical records without consent to any

[3]Department of Health and Human Services, *Standards for Privacy of Individually Identifiable Health Information*, 45 C.F.R. §164.512(b)(1)(iii), Federal Register, 82813-14 (Dec. 28, 2000).

entity regulated by FDA if the disclosure can be considered "*related to* quality, safety, or effectiveness of such FDA-regulated product or activity."[4]

A significant portion of the nation's economy is subject to FDA's jurisdiction, including companies with a substantial financial interest in obtaining access to patients' medical records. Furthermore, almost any activity concerning the manufacture, storage, distribution, or marketing of products could be considered "related" to the "quality, safety, or effectiveness" of FDA-regulated products and activities.

The Administration's stated justification for this broad change is baffling. In the Proposal, the Administration explains that the more limited list of disclosures allowed by the Rule would exclude quality and safety communications being conducted by the private sector on a voluntary basis. While the prudent response would have been to name these private sector activities and develop specific modifications to accommodate them, the Proposal vastly expands the relevant provision in the Rule to allow disclosure for just about anything related to FDA-regulated products and activities. For example, a drug company could use this provision in the Proposal to access the medical records of every individual using a particular drug it manufactures in order to identify candidates for a marketing campaign that promotes other drugs the company manufactures. This proposed change is especially dangerous because once a drug company receives an individual's medical records, it would not be subject to any restrictions concerning the use and disclosure of the individual's information.

Accordingly, we request that you respond to the following questions:

(1) The Rule allows disclosures to entities under FDA's jurisdiction for four categories of activities: (1) reporting of adverse events, product defects or problems, or biological product deviations, (2) product tracking, (3) product recall, repair, or replacement, and (4) post-marketing surveillance. In proposing to substitute a broad disclosure rule for this list, the Administration has not explained in detail any specific activities that the Administration is concerned do not fall under the scope of the activities listed in the Rule. Therefore:

   (a) Please describe in detail any specific reporting activities concerning adverse events, product defects or problems, or biological product deviations that the Administration is concerned do not fall under the scope of the Rule's language

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[4]Department of Health and Human Services, *Office of the Secretary; Standards for Privacy of Individually Identifiable Health Information; Proposed Rule*, Federal Register, 14814 (Mar. 27, 2002) (emphasis added).

allowing disclosures to a person "required or directed to report such information to the Food and Drug Administration";[5]

(b) Please describe in detail any specific product tracking activities that the Administration is concerned do not fall under the scope of the Rule's language allowing disclosures "to track products if the disclosure is made to a person required or directed by the Food and Drug Administration to track the product";[6]

(c) Please describe in detail any specific product recall, repair, or replacement activities that the Administration is concerned do not fall under the scope of the Rule's language allowing disclosures "to enable product recalls, repairs, or replacement (including locating and notifying individuals who have received products of product recalls, withdrawals, or other problems)";[7]

(d) Please describe in detail any specific post-marketing surveillance activities that the Administration is concerned do not fall under the scope of the Rule's language allowing disclosures "to conduct post marketing surveillance to comply with requirements or at the direction of the Food and Drug Administration";[8]

(e) Please describe in detail any other specific public health activities that the Administration believes are not currently but should be permitted under 45 C.F.R. §164.512(b)(1)(iii); and

(f) Please explain why the Administration believes it is necessary to establish a general rule allowing disclosures to entities under FDA's jurisdiction for activities related to the safety, quality, or effectiveness of FDA-regulated products and activities, as opposed to providing a finite, specific list of purposes for which the Administration believes disclosures should be allowed.

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[5]Department of Health and Human Services, *Standards for Privacy of Individually Identifiable Health Information*, 45 C.F.R. §164.512(b)(1)(iii)(A), Federal Register, 82813 (Dec. 28, 2000).

[6]*Id.*, §164.512(b)(1)(iii)(B).

[7]*Id.*, at 82813-14, §164.512(b)(1)(iii)(C).

[8]*Id.* at 82814, §164.512(b)(1)(iii)(D).

(2) Is it the Administration's position that the Proposal would allow drug companies to receive protected health information to assess the effectiveness of a direct-to-consumer advertising campaign?

(3) Under the Proposal, could a drug manufacturer receive the medical records of every individual using the medications it manufactures without the individuals' permission? Are there any practical limits to the provision in the Proposal that would permit drug manufacturers to access personal health information "related to" the "safety, quality, or effectiveness" of its products? Are there any limits on what drug manufacturers could do with the medical records they receive, or would the manufacturers be free to sell this information to any interested party?

(4) Did pharmaceutical companies or other industries subject to FDA's jurisdiction request a change in this section of the Rule (45 C.F.R. §164.512(b)(1)(iii))? If so, please provide us with copies of all comments from such entities relating to this provision.

We look forward to receiving answers to these questions. Thank you in advance for your attention to this matter. If you have any questions regarding this request, please contact us or have your staff contact Kristin Amerling with Rep. Waxman's staff (225-5051).

Sincerely,

Henry A. Waxman
Member of Congress

Edward J. Markey
Member of Congress

John D. Dingell
Member of Congress

Richard A. Gephardt
Member of Congress

Sherrod Brown
Member of Congress

Edolphus Towns
Member of Congress