# Congress of the United States

Washington, DC 20515

April 26, 2002

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

Dear Secretary Thompson:

We are writing to submit comments regarding the Administration's proposal announced in the March 27, 2002, edition of the *Federal Register* to modify the final medical information privacy standards mandated by the Health Insurance Portability and Accountability Act of 1996 (HIPAA).[1]

As you know, HIPAA mandated the promulgation of these standards after Congress failed to meet its 1999 deadline to pass a medical privacy law. During development of the standards, the views of Congress and interested parties were given ample consideration. The proposed rule issued in November 1999 was subject to an extended comment period at the request of industry and consumer groups. Subsequently, the Department received and considered over 52,000 comment letters over a ten-month period before issuing a final rule in December 2000. While we believe there were aspects of the final rule that required further clarification, we firmly believe the Administration's proposal will undermine important protections built into the final rule.

The Administration has proposed several steps that would undermine privacy including: (1) elimination of the patient consent requirement for treatment, payment, and health care operations; (2) a marketing definition that would allow disclosure of patient records for a broad range of marketing activities without permission; (3) a "public health" disclosures provision that would give drug companies new access to patient records for a broad range of purposes without patient permission; and (4) the creation of a loophole that would facilitate the disclosure of medical information to non-healthcare components by expanding the category of "covered entities."

While these are just an illustrative few of the important objections we have, this letter describes our concerns with and comments on these and other proposed changes.

Consent (45 C.F.R. §164.506)

We oppose the Administration's proposal to eliminate the patient consent requirement in the final rule. This provision guarantees patients the right to exercise control over their most personal information by requiring providers to acquire a one-time consent to allow for the use of

[1]Department of Health and Human Services, *Office of the Secretary; Standards for Privacy of Individually Identifiable Health Information; Proposed Rule*, 67 Federal Register 14776-14815 (Mar. 27, 2002).

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medical information to provide treatment, obtain payments for care, or conduct the management of a health care facility.

The Administration's proposal provides for nonconsensual disclosure of an individual's health information not only for treatment and payment, but for a broad range of other activities, including:

> Conducting quality assessment and improvement activities, including outcomes evaluation and development of clinical guidelines, . . . population-based activities relating to improving health or reducing health care costs, protocol development, case management and care coordination, contacting of health care providers and patients with information about treatment alternatives; and related functions that do not include treatment . . . conducting training programs . . . accreditation, certification, licensing, or credentialing activities . . . underwriting, premium rating, and other activities relating to the creation, renewal, or replacement of a contract of health insurance or health benefits . . . business planning and development . . . business management and general administrative activities of the entity. (45 C.F.R. §164.501)

When American consumers provide their health information for treatment and payment, most do not contemplate that this information will be used for this far-reaching list of activities. Moreover, as discussed below, this list includes marketing activities for which the Administration is proposing to remove privacy protections contained in the final rule. The consent requirement helps ensure that individuals have the opportunity to indicate their preference regarding which uses and disclosures of their health information they approve.

There was widespread agreement that the final rule needed further clarification with respect to two scenarios: (1) access to protected health information by a pharmacist when a prescription is phoned in; and (2) access to health information by a specialist to whom a patient has been referred by a primary care provider. Addressing these glitches, however, does not justify wholesale abandonment of the consent requirement.

Marketing (45 C.F.R. §§164.501 & 164.508(a)(3))

The Administration's proposed authorization requirement for marketing activities is rendered virtually meaningless by the proposal's creation of broad exceptions to the "marketing" definition. For example, in contrast to the final rule, under the Administration's proposal, communications to an individual regarding medical products or services are not considered "marketing" even if (1) the communications are made by a party other than the individual's health care provider or health plan, and (2) the individual's health care provider disclosed the individual's medical records to the party for the purpose of the communications and received remuneration for this disclosure.

As a result, the Administration's proposal allows covered entities to use and disclose medical records for many activities American consumers would consider to be marketing,

without obtaining patient consent or notifying the patient of the financial interests involved. For example, under the proposal:

- A health care provider could sell an individual's records without consent to a drug company for the purpose of communicating with the individual about new drugs on the market; and

- A health plan could receive compensation from an herbal remedy manufacturer for contacting individuals to urge the usage of the manufacturer's product, regardless of whether this product is beneficial to the patient and without informing individuals of its financial interest in marketing the product.

Further, unlike with the final medical privacy rule, the individual would not even have the opportunity to "opt out" of receiving communications in such circumstances.

We strongly oppose this new marketing loophole that will undermine patient confidence in the HIPAA privacy rule and the health care system altogether.

Disclosure of health information without consent to persons under the jurisdiction of the Food and Drug Administration (45 C.F.R. §164.512(b)(1)(iii))

The Administration's modification includes a significant change to the final rule's provision authorizing disclosures without consent to entities under the jurisdiction of the Food and Drug Administration. The final rule allows disclosures of health information without patient consent to these entities for a limited list of public health purposes. In contrast, the Administration's proposal authorizes nonconsensual disclosure of health information to these entities for a broad range of purposes that would include marketing.

Under the Administration's proposal, any person subject to FDA's jurisdiction could receive an individual's health information without their consent regarding any FDA-regulated product or activity for which that person has responsibility, as long as the purpose is "related to the quality, safety or effectiveness" of the product or activity. As you know, persons under FDA's jurisdiction include pharmaceutical companies, medical device manufacturers, and food processors. The proposed change potentially authorizes disclosures to these industries for a wide range of purposes, since almost any of their activities can be characterized as "related to" the quality, safety, or effectiveness of the products and activities FDA regulates. For example, a drug company whose patent on a pharmaceutical product is about to expire could collect individuals' health information without their permission to send promotional materials to these individuals, justifying its actions on the grounds that they relate to the "quality" or "effectiveness" of the product.

The rule thus puts the interests of drug companies and other industries regulated by FDA far ahead of the medical privacy interests of American consumers. Given the sweep of this proposal, we do not understand the Administration's rationale for including it under the category

of "technical corrections and other clarifications."[2] More importantly, the Administration's stated rationale for the change raises many questions.

The main argument the Administration sets forth in its explanation of the proposed change is that some voluntary adverse events reporting activities would not be covered by the list of authorized purposes in the final rule, because the final rule requires that such activities be directed or required by FDA.[3] The Administration, however, fails to identify any specific adverse events reporting activity currently conducted on a voluntary basis by industries under FDA's jurisdiction that the Administration is concerned would be hindered. Further, the Administration fails to explain why its concerns could not be addressed by changing the adverse events reporting language of the final rule.

No change to this provision should occur before the public can understand and debate the specific concerns at stake. Further, there is no good reason to create the open-ended disclosure authorization the Administration is proposing for nonconsensual disclosure of health information to entities under FDA's jurisdiction.

In short, the Administration is proposing to open up a huge loophole through which drug companies and other entities could readily access Americans' medical information without consent. Moreover, it has provided a wholly inadequate justification for taking this step. We urge the Administration to abandon this irresponsible and ill-advised proposal.

Hybrid versus covered entities (45 C.F.R. §164.504)

The Administration's proposal would modify the definition of a "hybrid entity" and give entities that could qualify as a hybrid entity the choice of classifying themselves as either a hybrid entity or a covered entity. We are concerned that this proposed change could undermine other provisions of the health privacy rule. In the final rule, an entity that engages in covered health information transactions, but whose covered transactions are not its primary functions, is classified as a hybrid entity. A hybrid entity is required to identify the components of the entity that engage in covered transactions and create "firewalls" to keep those components separate. This requirement ensures that the components of the entity that engage in covered functions comply with the privacy rule and disclosures of health information to other parts of the entity are treated as disclosures to outside organizations.

In contrast to the final rule, under the proposed rule an insurer that offers life and property insurance but has a small health insurance line could classify itself as a covered entity, for example. The insurer could thus avoid the requirement to create firewalls between its health insurance component and the rest of its business, increasing the risk that protected health

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[2] *Id.* at 14800-14804

[3] *Id.* at 14801-14802.

information would be disclosed from the health insurance department to the life insurance department without complying with the privacy rule. We believe that this proposal, which the Administration includes under "technical corrections and other clarifications," is a substantive change that could have significant consequences on an individual's privacy. We strongly recommend that the Administration not include this proposed change.

Disclosures for health care operations of another covered entity (45 C.F.R. §164.506(c)(4))

We are concerned about the Administration's proposal to allow covered entities to disclose an individual's health information without patient consent to other covered entities for a long list of "health care operations" purposes. The stated rationale is the concern that covered entities need access to such information for "quality assessment and accreditation purposes."[4] Yet the Administration's modification does not limit the disclosures to other covered entities to information needed for these purposes. Instead, the proposed rule would allow disclosures for many other activities, including "case management and care coordination, contacting of health care providers and patients with information about treatment alternatives; and related functions that do not include treatment." The Administration should not implement this provision without narrowing the activities for which disclosures are allowed to address the specific concerns raised about quality assessment and accreditation.

Minors' privacy rights (45 C.F.R. §164.502(g)(3))

The final rule recognized that the minor's right to confidentiality is integral to obtaining health care services without parental consent, and provided minors with control over their own medical information where minors could obtain health care based on their own consent. To encourage minors to seek health care services on sensitive matters such as substance abuse, sexuality, and mental health, many states provide that minors may lawfully obtain health care without parental consent.

However, the Administration is now proposing to eliminate the logical connection drawn in the final rule between a minor's right to obtain health care without parental consent and the minor's right to health information privacy. Under the final rule, minors have the right to control their own health information pursuant to care they receive without parental consent, unless state law explicitly authorizes or requires disclosure to a parent. The Administration's proposal would allow a provider to disclose the minor's health information if state law permits or requires it, or if state law is silent on the issue. In some states, this subtle shift in language would have no substantive effect. However, in other states the proposed rule would shift control of health information from the minor by presuming that covered entities have the discretion to disclose the information to a parent. This presumption would apply even in cases where the minor is legally permitted to obtain health care without parental consent.

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[4] *Id.* at 14781-14782.

We believe that the Administration's proposal could discourage minors from seeking critical health care services. We urge the Administration not to include its proposed change on this matter.

Accounting of disclosures made pursuant to an authorization (45 C.F.R. §164.528)

We oppose the Administration's proposal to eliminate the right an individual has under the final medical privacy rule to receive an accounting of disclosures of the individual's medical records by an entity pursuant to the individual's authorization. The Administration argues that such an accounting is not necessary because an individual would know which disclosures have been authorized. However, such authorizations often provide for the use and disclosure of medical records for a broad range of purposes, by a variety of covered entities. The right to an accounting provides the important opportunity to confirm that medical information is used and disclosed as specifically authorized, including the opportunity to identify which particular entities have disclosed any or all information and to whom they have disclosed it. The Administration's proposal to take away this right would effectively leave no check on what an entity does with an individual's health information once the individuals have signed an authorization. We urge you to abandon this proposal.

Authorization requirements (45 C.F.R. §164.508)

The Administration is proposing to change the requirements concerning what elements must be included in a valid authorization. We are concerned that, with respect to authorizations concerning disclosures by a covered entity for its own uses and disclosures, the Administration would eliminate the requirement that the authorization state when disclosures by the covered entity will result in remuneration by a third party. Such statements are important for notifying individuals that a potential financial conflict of interest may exist with respect to the use of their health information. We recommend that the Administration require all authorizations to state when a covered entity may receive remuneration for disclosures of the individual's health information.

De-identification of protected health information (45 C.F.R. §164.514(a)-(c))

Based on comments it received expressing concern about the de-identification standard in the rule, the Administration is inviting suggestions about alternative approaches that would "permit uses and disclosures of a limited data set which does not include facially identifiable information but in which certain identifiers would remain."[5] As described by the Administration's preamble to the proposed rule, however, the comments the Administration received lack the specificity necessary to fully understand and debate the concerns at issue.

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[5] *Id.* at 14799.

For example, the Administration reported that some comments said the final rule doesn't allow for the collection of data elements such as "dates on which the injury or illness was treated and the patient released from the hospital" and "the month of birth" that are necessary for analyses "useful for hospitals in making decisions about quality and efficiency improvements."[6] There is no explanation, however, of what these specific analyses are and why the specific data elements cited are "necessary" for such analyses. It would not be responsible to make a change in this standard before the public can gain adequate understanding of specifically how the standard in the final rule is impeding important health activities.

In summary, Americans deserve strong medical privacy protections in order to maintain peace of mind and to ensure quality health care. We urge you to maintain the important protections established in the December 2000, final rule and to abandon the detrimental Administration proposal which would undermine the medical privacy of this nation.

Sincerely,

Richard A. Gephardt
Member of Congress

John D. Dingell
Member of Congress

Henry A. Waxman
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Edward J. Markey
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[6] *Id.* at 14799.

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