



STATEMENT OF THE
AMERICAN COLLEGE OF PHYSICIANS –
AMERICAN SOCIETY OF INTERNAL MEDICINE
TO THE NATIONAL COMMITTEE ON VITAL AND HEALTH STATISTICS
PRIVACY AND CONFIDENTIALITY SUBCOMMITTEE
HEARING ON MARKETING PROVISION OF PRIVACY
JANUARY 24, 2002

I am Dr. William J. Hall, president of the American College of Physicians-American Society of Internal Medicine (ACP-ASIM). ACP-ASIM -- representing 115,000 physicians and medical students. ACP-ASIM is the largest medical specialty society and the second largest medical organization in the United States. Of the College's many concerns regarding the HIPAA health information privacy regulation, the use and disclosure of health information for marketing is one of the most troublesome. ACP-ASIM wishes to acknowledge Mark A. Rothstein, J.D., Chair of the Privacy and Confidentiality Subcommittee, and other Subcommittee members, for holding this important hearing to discuss ways to improve the regulation's use and disclosure of health information for marketing. We appreciate the opportunity to testify today.

Marketing in General

Marketing is defined in the privacy final rule as a "communication about a product or service a purpose of which is to encourage recipients of the communication to purchase or use the product or service." Communications are not considered to fall under the rubric of marketing if they are made by the health care provider and tailored to a particular individual as part of treatment, or made by a provider or plan to manage treatment of an individual or to direct or recommend alternative therapies, providers or settings of care, and the covered entity does not receive remuneration from a third party for making a written communication.

Unfortunately, the final rule condones and perhaps even encourages a wide array of marketing activity using what is supposed to be protected health information.

Patients, in seeking care, do not generally expect their private medical information to be used for marketing purposes. In fact, the expectation is more likely that the new and long-awaited federal privacy rule would provide additional safeguards against the uses of patient information for marketing. Therefore, for reasons that will be become evident over the course of my testimony, ACP-ASIM strongly believes that the marketing loophole that has been created by these exceptions must be closed.

Under the final rule, the marketing communications exceptions for health care providers fall under health care operations that at least require a patient consent before individually identifiable information can be used or disclosed. But for health plans, these exceptions represent a major loophole. Health plans can use or disclose individually identifiable health information for various marketing purposes without patient consent.

ACP-ASIM recommends that the use of protected health information for marketing purposes be prohibited. At the very least, for any marketing contact to occur, patients should be given the opportunity to agree to, prohibit, or restrict the disclosures in advance of the communication.

Exceptions Tend to Swallow the Rule

A covered entity or third party is exempt from having to obtain patient authorization if it uses or discloses protected health information for marketing under certain conditions. Exempt marketing communications include: (1) those communications that occur in a face-to-face encounter with the patient; (2) those communications concerning products or services of nominal value; or (3) those communications concerning health related products or services of the covered entity or third party if certain disclosures are on the same communication.

Face-to-Face Encounters

The final rule exempts communications from requiring patient authorization that occur in a face-to-face encounter with the individual. Such communications are not limited to include just communications between physicians and patients – they apply to any conceivable face-to-face encounter, including door-to door salespeople or telemarketers. For example, an individual who had just been discharged after a major hospital stay could be visited or called at their home.

It's bad enough to be sought out for such solicitations and intrusions when convalescing, but the final rule goes further. The final rule does not limit the types of items or services that can be promoted. In fact, face-to-face marketing using a patient's health information can be used by third party's selling vacations, magazines, cars, and other items that may (or may not) have anything to do with your health at all.

Items and Services of Nominal Value

The final rule also exempts communications that relate to items or services of "nominal value." This portion of the rule is one of the most vague and ambiguous. What exactly does "nominal value" mean? Does it apply to the discount from the product or the service, or does it relate to the cost of the item itself? What is clear is that this exception applies to any product or service whether its health care-related item or not. Not only is health information misused, it is misused for the purpose of providing something of only nominal value. But the damage that can be done is quite significant.

Third Party and Covered Entity Exception with Disclosures

The final rule exempts a third communication from having to obtain patient authorization. Specifically, this exemption permits marketing communication of health-related products and services on behalf of third parties or covered entities if the communication meets three requirements: (1) the communication identifies the third party or covered entity as the party making the communication; (2) the communication states whether it received any remuneration; and (3) the communication allows the patient to "opt-out" from future communications from the covered entity or third-party. While this form of communication offers some protection to patients, it is significantly limited and full of loopholes for the third party or covered entity to take advantage of seeking new customers.

The first requirement throws the physician into the middle of a sale between the third party and the patient. As the solicitations and promotional communications continue, the more agitated the patient is likely to become toward the physician. Trust may be diminished. An example may be the patient who goes to their physician's office for an annual check-up and it is discovered that the patient has a high cholesterol value. The third party marketer could send a letter to the patient saying, "Now that you have high cholesterol, your physician asked us to tell you about purchasing a condominium in a health spa or re-evaluating your life insurance. In addition to the intrusiveness on a rather personal issue, it also gives the patient the impression that the product being offered is endorsed and/or approved by the physician.

The third requirement for covered entity communication gives the patient the opportunity to “opt-out” of receiving any future communications from the third-party. This “opt-out” requirement is extremely weak and ambiguous. To add insult, the patient’s right to “opt-out” does not go into effect until after the patient receives the first communication from the covered entity. ACP-ASIM believes this “opt-out” approach is too little, too late.

In giving patients the opportunity to “opt-out” from future communications, the final rule only requires that the covered entity or third party make “reasonable efforts” to ensure that those individuals do not receive another communication. Also, without any formal procedural guidance as to how a patient would go about notifying the covered entity or third party with their decision to “opt-out,” any procedure may be used – regardless of how slow or costly such notification would take. Such methods could require the patient to write a formal letter, or even have to pay a fee to the provider, health plan, insurance company, or pharmaceutical manufacturer just to get off their list – however, we don’t really know at what lengths the patient would be required to go to get their information removed from the third party’s list. A family might need to send many letters to many different marketers.

Other requirements apply if a covered entity or third party uses or discloses protected health information to target communications based on health status or condition. One such prerequisite is that a determination must be made that the communication “might be” beneficial to the patient targeted, regardless of how slight the benefit might actually be. A second prerequisite is that the communication explains why the patient has been targeted and how the product or service would benefit the patient. This requirement goes against the integrity of what privacy is all about:

For example, suppose a teen patient was recently treated for a sexually transmitted disease. The promotional communication would have to explicitly say that the teen patient was selected because the teen was treated for a sexually treated disease, and that X-brand ointment has been shown to effectively treat the sexually transmitted disease that the teen patient has. Would the teen welcome or even expect to see this in print? What if someone other than the teen patient were to open the letter? Situations such as these could easily occur and are the types of instances that a federal privacy standard was suppose to guard from happening. Other examples could include an unwanted pregnancy, confidential mental health services, and so on. The opportunity to further invade the privacy of individuals is at great risk with this provision.

Allowing these uses of what is supposed to be protected health information for marketing purposes flies in the face of respect for privacy. These exceptions should not be exceptions at all. Marketing that utilizes protected health information should be prohibited.

Other Areas of Concern

If you allow me, I would like to discuss briefly other areas of concern the College has regarding the privacy rule. Those major areas of concern include, but are not limited to, Business Associate contracts, Medical Research provisions, and Administrative Burdens on Small Practices.

Business Associate Contracts: ACP-ASIM believes that the Business Associate provisions are unfair, burdensome, and unworkable. Specifically, they unfairly shift responsibility and liability to physicians and other covered entities for ensuring that third parties with whom they contract use and disclose protected health information in accordance with the privacy rule. This provision will quite possibly open the floodgates to lawsuits that physician practices will have little or no ability to control. **ACP-ASIM recommends that the Business Associate provisions be eliminated. At a minimum, covered entities should not be held responsible for any violation of the rule’s provisions.**

Medical Research: ACP-ASIM believes that the Medical Research portion of the rule will seriously impair medicine's ability to conduct clinical trials and studies. We strongly support safeguards for patient privacy and confidentiality for research purposes. We do not believe, however, the rule successfully balances the call for enhanced privacy protections with the need for medical progress. Federal research regulations, known as the "Common Rule," grant Institutional Review Boards (IRBs) the flexibility to determine, on a case-by-case basis, the physical, procedural, and technical safeguards that are necessary to protect patient's privacy and confidentiality. The rule needlessly intrudes upon this proven system of IRB oversight, burdening research with onerous requirements, ambiguous regulatory standards, and intimidating liability. **ACP-ASIM believes that this provision of rule will potentially have a "chilling effect" on physicians who want to disclose data for research purposes, and carries too great a compliance cost and liability risk to justify their continuing sharing of important patient data.**

Administrative Burdens on Small Practices: ACP-ASIM is very concerned about the extensive administrative requirements and financial burdens that the rule imposes on physicians, especially those in solo or small practices whose administrative personnel are already stretched to the limit in trying to comply with the vast array of governmental and health plan requirements. This is especially troublesome because physicians already have an ethical obligation to protect confidential patient information. **Therefore, ACP-ASIM recommends that the flexibility and scalability approaches incorporated into the rule be applied and that physicians' existing procedures be accommodated to the extent possible when HHS is enforcing the administrative requirements of the rule.**

Guidance

The Guidance issued in July 2001 offers some indication as to which direction the Department of Health and Human Services (HHS) is heading in its interpretation of the privacy rule. While some of the examples listed were helpful, they do not carry the force and effect of the law and must be included in final form as soon as possible. Therefore, ACP-ASIM asks HHS to issue comprehensive final rules, with a single deadline for implementation and clear directives to safeguard privacy.

Conclusion

ACP-ASIM is pleased that the Subcommittee is addressing the serious problems in the implementation of the privacy regulation's provision of use and disclosure of health information for marketing. ACP-ASIM calls on HHS to achieve greater patient privacy protections by providing comprehensive final rules, with a single deadline for implementation and clear directives to safeguard privacy, and that the regulations be issued in final form as soon as possible. We ask that the Subcommittee consider recommending that the use of protected health information for marketing purposes be prohibited. At the very least, for any marketing contact to occur, patients should be given the opportunity to agree to, prohibit, or restrict the disclosures in advance of the communication. This concludes my prepared statement. Thank you for considering our views -- I look forward to your questions.