Opinion

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Privacy rights vs. access to health info: Should we have to make a choice?

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What's a patient rights advocate to do? On the one hand, you want to support a patient's right to privacy. On the other hand, you favor a patient's right of access to health information from a variety of sources, not just from his or her physician. So what happens when you are confronted with a situation where both these rights seem to conflict? A medical privacy law in Texas raises this issue.

Specifically, the new Texas Medical Privacy Act, also known as SB 11 and, in some quarters, as "super HIPAA," is aimed squarely at hampering the ability – and, some say, the freedom – of pharmaceutical companies to market their products to consumers in Texas. The Texas Medical Association strongly endorsed the act, which becomes effective September 2003, with the stated intent to prevent the transfer of "patient data" from health entities to marketing or advertising entities without consent. However, the real intent may have more to do with limiting the ability of pharmaceutical companies to do direct-to-consumer communications than to protect patient privacy. Before you condemn me as a shill for the industry, consider the following:

• Pharmaceutical companies are spending a larger portion of their promotional budget than ever on direct-to-consumer marketing – $2.8 billion in 2001 compared to $0.7 billion in 1996, according to an article in the September 1, 2001 issue of *Pharmaceutical Executive* magazine.

• The money is well-spent: Studies show that direct-to-consumer marketing is effective in influencing prescribing. Depending on the study, approximately 20%-to-30% of consumers say advertising prompted them to call or visit their doctor about the advertised drug. According to a 2001 Kaiser Family Foundation study, nearly one in eight adults actually received a prescription in response to an ad they have seen.

"Super HIPAA" vs. patient empowerment

No wonder a recent AMA House of Delegates Resolution proclaimed that direct-to-consumer marketing "by virtue of its design to create patient demand invades the patient-physician relationship." But the pharmaceutical industry believes that this type of marketing helps empower patients and saves lives by getting more people to seek treatment. The Patient Empowerment Study conducted by Pfizer in 2000, for example, found that 62% of respondents agreed that advertising made them aware of new treatment options and 44% agreed that it provided them with information on medical conditions that they did not know about before. According to the study, more than one third of consumers agreed that direct-to-consumer ads encourage better communication with their doctor.

While it's not certain whether physicians like or dislike direct-to-consumer marketing, it is clear that the American Medical Association and some of its

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affiliate state organizations are trying to curtail the practice, if not ban it outright. Traditionally, the AMA and other physician organizations have relied upon the FDA to regulate pharmaceutical advertising and have taken "an active role in ensuring that proper advertising guidelines are enforced." However, the FDA is re-examining these regulations in light of recent court decisions that have found the FDA in violation of the First Amendment freedom of speech protection.

If the FDA caves in and the public continues to respond to direct-to-consumer marketing, then physicians who are opposed to this marketing may need to find a new ally in their fight against the practice. This weapon, it seems, is "patient privacy." Apparently, the Texas Medical Association, which strongly endorsed SB 11, agrees.

The thinking goes like this: if you can pass new laws making pharmaceutical companies subject to exacting medical privacy regulations, then it will be virtually impossible for them to promote their products directly to consumers. Politically, such laws are overwhelmingly supported by the public, who may have issues with pharmaceutical companies over high prescription drug prices. It's not surprising that Texas was able to pass SB 11.

Texas law goes too far

The act adopts HIPAA medical privacy rules as they originally appeared in December 2000, before the rules were modified and finalized. This is especially apparent with regard to marketing, which SB 11 defines as "the promotion or advertisement, by a covered entity, of specific products or services if the covered entity receives, directly or indirectly, a financial incentive or remuneration for the use, access, or disclosure of protected health information." The final HIPAA privacy rule eliminates the remuneration prohibition to the exceptions, so the fact that a covered entity receives payment for a written communication to a patient does not automatically qualify the communication as "marketing." Thus, SB 11 is much broader when it comes to what can be considered marketing.

Pharmaceutical companies, health Web sites and other entities that collect or use protected health information in Texas also are beleaguered by the fact that SB 11 applies to them as well as other "covered entities." SB 11 mandates that personally identifiable health information created or maintained by anybody – including pharmaceutical companies, independent Web sites, etc. – is considered protected health information. Therefore, pharmaceutical companies cannot use information they collect for consumer marketing unless they get prior authorization.

Prior authorization in and of itself is not an insurmountable problem for pharmaceutical companies, and the best marketing practices should require consent. However, SB 11 has other provisions that are more difficult to implement. For example, it requires that consumers have access to their data and gives consumers the right to have their names removed from all databases within five days. That could be unreasonable considering the myriad databases that pharmaceutical companies maintain. They collect personal data from 1-800 numbers, Web sites, patient assistance programs, health care providers, etc. If pharmaceutical companies really want to interact directly with consumers, they must eliminate the roadblocks that prevent them from tracking consumer data across their entire business. After all, the financial industry seems to do this quite well.

SB 11 goes beyond "[preventing] the transfer of patient data from health entities to marketing or advertising entities without consent," as the TMA describes. The law has less to do with protecting "patient privacy" than with protecting the physician-patient relationship by preventing pharmaceutical companies – and other health-related companies such as disease-management organizations – from communicating directly with patients and consumers about their health. This limits a patient's or consumer's right to

access health information from a variety of sources, including pharmaceutical companies.

If protecting patient privacy is the primary goal, it should be sufficient to regulate what physicians do with this data. They are the ones who produce and maintain “patient data” and many spectacular breaches of patient privacy happen because physicians or pharmacists sell patient data to marketers. If Texas and the TMA really wanted to prevent the inappropriate use of patient information for marketing purposes, SB 11 could have tightened the definition of marketing to prevent physicians and pharmacists from releasing protected health information to pharmaceutical companies instead of regulating what pharmaceutical companies do with the data. Then, I would be less inclined to view SB 11 as a bid to derail direct-to-consumer marketing and patient empowerment that’s cleverly disguised as “patient privacy” protection.

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