Pharma Marketing News™

www.pharmamarketingnetwork.com

May 2003
Vol. 2, No. 5
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Published by
VirSci Corp.
www.virsci.com

Reprint

Pharmaceutical Marketing in Texas: look out for state privacy laws!

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Not too long ago, I reviewed the new Texas Medical Privacy Act (also known as SB 11) and warned that it will adversely affect pharmaceutical marketing and research in Texas (see "Texas Medical Privacy Act: A Wolf in Sheep's Clothing?", Pharma Marketing News, November 2002, Vol. 1, #9. http://www.pharma-mkting.com/news/pmn19-article02.html). This article provides an update on medical privacy legislation in Texas and its effect on pharma marketing in that state.

Background

SB 11 was signed into law on June 17, 2001 by Governor Rick Perry. The law becomes effective September 1, 2003. Known in some quarters as "super HIPAA," SB 11 provides more protection for patient privacy than is provided for under HIPAA. Specifically, SB 11 adopted HIPAA privacy rules as they originally appeared in December 2000, before the rules were modified in March 2002 and finalized in August 2002. This is apparent especially with regard to marketing.

Of particular concern to pharmaceutical companies and their agents, health web sites, and other entities that collect or use individually identifiable health information or "protected health information" (PHI) in Texas is the fact that SB 11 applies to them as well as "covered entities" as defined by HIPAA.

Effect on Research

SB 11 also will have an impact on clinical research in Texas and, privately, several pharmaceutical company compliance officers expressed doubt about the future of pharmaceutical-sponsored research in Texas. Under SB 11, clinical research sponsors would be subject to regulations requiring patient authorization for disclosure of PHI, access, and amendment of medical records.

SB 330, a bill signed into law on April 10, 2003, repealed sections of SB 11 relating to research, but left intact the marketing provisions. These provisions of the Texas Medical Privacy Act define marketing as virtually any communication that is paid for by a third party and prohibited any release of PHI for marketing purposes without specific authorization from the individual. The final Privacy Rule of HIPAA removed receipt of remuneration from a third party as a condition for defining written communications as marketing. Thus, under SB 11 (but *not* HIPAA), patient authorization is required for a physician or pharmacist to send a letter paid for by a pharmaceutical company encouraging their patients to switch to a new dosage form as part of a disease management program.

To learn more about SB 11 and SB 1136, order reprint VS003A at http://www.virsci.com/PPW-Order.html.

SB 1136 to the Rescue

Senate Bill 1136, also introduced by Sen. Nelson and expected to be signed into law soon, creates a marketing standard in Texas that more closely tracks the HIPAA marketing standard. However, as explained below, SB 1136 includes stricter standards related to certain product-specific communications that encourage a change in prescription drugs or prescription medical devices.

Some say that the Texas Medical Privacy Act is aimed squarely at hampering the ability of pharmaceutical companies and their agents to market products to consumers in Texas.

Although SB 1136, for example, changes Texas state law to be more consistent with HIPAA as regards marketing, it specifically states that any "product-specific written communication to a consumer that encourages a change in products" is considered marketing. "Product" means "a prescription drug or … medical device."

The important marketing provisions of SB 1136, however, do not take effect until January 1, 2004. Therefore, in the period between September 1, 2003, when SB 11 becomes effective, and January 1, 2004, when SB 1136 kicks in, pharmaceutical marketers better be wary of how they use PHI in Texas.

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