Pharmaceutical Marketing in Texas: look out for state privacy laws!
by John Mack, VirSci Corporation.


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SB 330, a bill signed into law on April 10, 2003, repealed sections of SB 11 relating to research, but left intact the marketing provisions.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.

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.

Subscribe to Pharma Marketing News

Pharma Marketing News (PMN) is the FREE monthly e-newsletter of the Pharma Marketing Network. Highlights are delivered to subscribers by e-mail. The full pdf version is available at www.pharma-mktng.com. You also have the option to participate in 2-way, peer-to-peer e-mail discussions with your pharmaceutical marketing colleagues through the PHARMA-MKTING list. By subscribing to PMN, you agree to receive e-mail messages through this service as well as newsletter highlights. We do not sell or share your personal information with third parties.

RED=REQUIRED INFORMATION

FIRST NAME: _______________________________ LAST NAME: ______________________________________
JOB TITLE: __________________________________ COMPANY:____________________________________
COUNTRY: __________________________________________________________________________________
E-MAIL ADDRESS: ____________________________________________________________________________
E-MAIL FORMAT PREFERENCE:   ___ HTML      ___ TEXT      ___ NONE
☐ I also wish to join the PHARMA-MKTING list to participate in 2-way peer-to-peer discussions.

BLACK=OPTIONAL INFORMATION (For our internal use only. We don’t sell or rent mailing lists/labels)

ADDRESS: __________________________________________________________________________________
CITY: ______________________ STATE/PROV:______________ POSTAL CODE: ________________________
PHONE: __________________________________ FAX: _____________________________________________

Mail or fax to: VirSci, PO Box 760, Newtown, PA 18940, 215-504-5739 (Fax)

ABOUT VirSci Corporation

VirSci Corporation publishes Pharma Marketing News and specializes in pharmaceutical marketing intelligence and best practices, development of sponsored newsletters and other educational programs, and consulting in privacy and HIPAA. Our goal is to help our clients gain access to their clients and do business via the Internet more effectively, with greater return on investment, and with enhanced trust.

For inquiries regarding article submissions, ads, or conference listings, contact:

John Mack
VirSci Corporation
www.virsci.com
PO Box 760
Newtown, PA 18940
215-504-4164, 215-504-5739 FAX
mailto:johnmack@virsci.com