

## Reprint

### Is Pharma Ready for HIPAA?

by

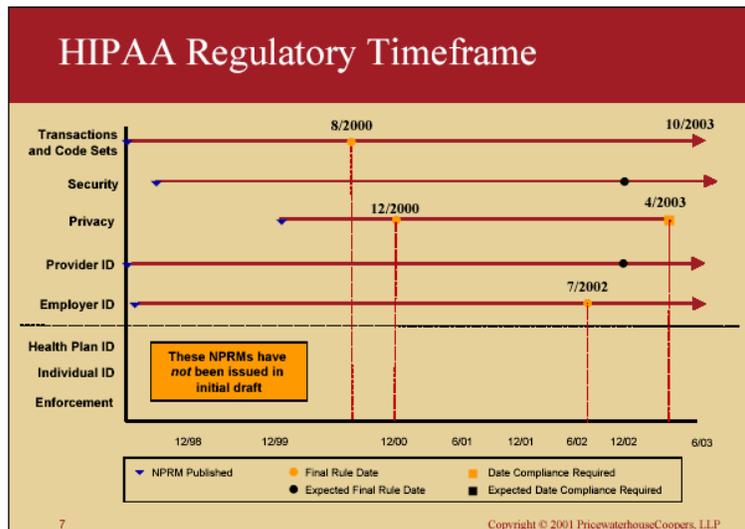
John Mack, VirSci Corporation.

I attended the Pharmaceutical Regulatory & Compliance Congress and Best Practices Forum held at the Philadelphia Marriott Hotel on November 13-15, 2002. The following is a summary of a presentation at the pre-conference Symposium on Privacy that I found interesting.

#### HIPAA Administrative Simplification Provisions – AN OVERVIEW

A presentation by **Brent Saunders**, Partner, PricewaterhouseCoopers

Although most experts agree that pharmaceutical companies are not covered entities under HIPAA, this does not mean that pharma marketers should not worry about it. As Mr. Saunders pointed out in his presentation, pharma needs to realize that HIPAA will have a significant impact on the commercial side of their business. One effect, for example, will be HIPAA's influence on state medical privacy laws, which may directly affect pharmaceutical companies and their advertising and marketing partners (see article "Texas Medical Privacy Act: A Wolf in Sheep's Clothing?" in this issue),

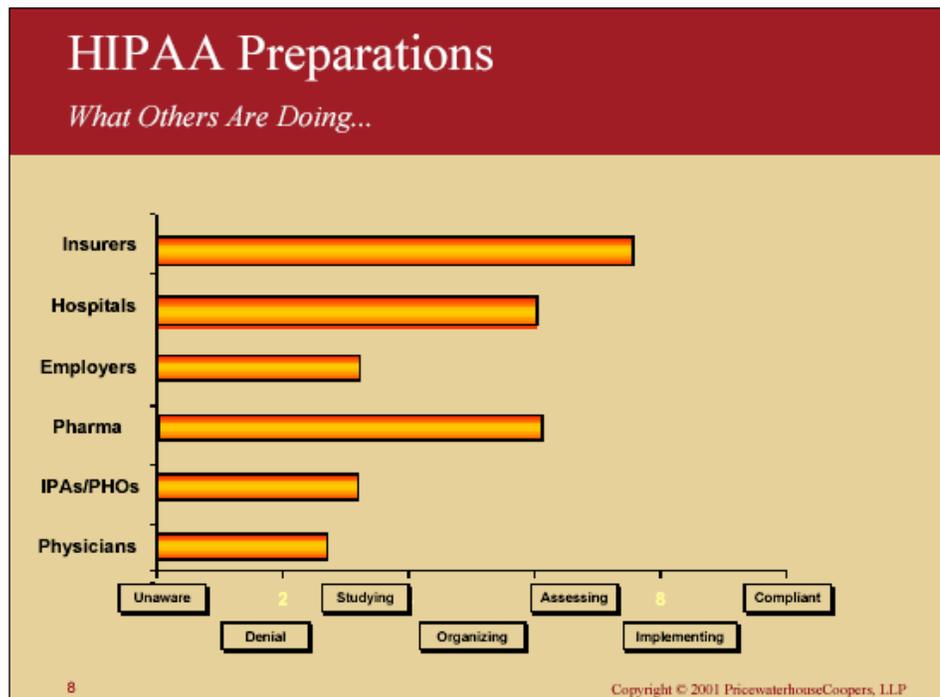


Pharma will see effects as the HIPAA regulatory timeframe moves towards important compliance dates, the first of which is April 2003 (see figure left) for the privacy rule, which will have the biggest impact on pharma. Physicians submitting electronic transactions will need to be compliant by that date. Saunders estimates that by 2006 EVERY physician accepting Medicare reimbursement will be transmitting forms

electronically and therefore will also need to be compliant with HIPAA's privacy regulations.

According to Saunders, the pharmaceutical industry was "slow to get off the dime, then got on it in a big way." It now appears to be at the stage of assessing HIPAA's impact and what to do about compliance (see Fig. 2, next page). Physicians, on the other hand, are just coming out of the denial stage, according to Saunders. The consequence of this is that pharma is "starting to see a lot of physicians hang their hats on HIPAA to deny access" to

sales representatives. This is also what we have learned from the VirSci Pharma HIPAA & Privacy Impact/Readiness Survey ([click here to access](#)). “Companies are seeing a need to educate their sales forces to counteract this,” said Saunders.



**Figure 2: HIPAA Preparedness**

Saunders put HIPAA into perspective by relating it to general privacy issues faced by pharma in the marketplace and especially at the state level. He pointed out that Americans, compared to Europeans, are “[more] likely to give information away...” However, this is true only when they perceive they are getting some value, even if it is “limited.” Therefore, personal information is easy to get, but consumers are concerned and this, according to Saunders, is a “problem for big business.” I would add that it is a problem for small business as well.

### Gold vs. Platinum

The “golden rule,” according to Saunders, is “tell them what you are going to do, then do what you say.” This may be golden, but in a competitive world where customer acquisition and retention is a huge factor in ROI analyses, you might want to strive for the “Platinum Privacy Level.”™ Since I just made up this term, let me explain what I mean. It is simply this, promise more than the minimum necessary to protect consumer privacy, deliver on your promises, increase consumer trust, collect more information, deliver more targeted services, and retain more customers. For more details, see “Protecting Privacy and Gaining Pharmaceutical Customer Trust,” <http://www.virsci.com/presentations/ProtectPrivacy-GainTrust.pdf>.

### HIPAA and States’ Rights

As was mentioned above, HIPAA also will affect the pharmaceutical industry through its influence on state laws, which may be even more stringent than HIPAA. The pharmaceutical industry, according to Saunders, should not expect any help from pre-emption, i.e., legislation in Congress to make HIPAA pre-empt state laws. This is not likely to happen, says Saunders, because of the current Republican administration’s dependency on supporting state rights on abortion, an important reason why HIPAA allows states to pass more stringent privacy

legislation, which pre-empts HIPAA rather than the other way around. A prime example of this is the Texas Medical Privacy Act (see article in this issue). According to Saunders, some states have “pulled back” on enacting privacy laws to see how the Texas law makes out.

### **A Slippery Slope**

Another problem HIPAA is causing pharmaceutical companies has to do with the Business Associate Contract (BAC) requirements of the privacy rule. Simply stated, this requires covered entities (CEs) to enter into contracts with partners – not necessarily another covered entity – that uses protected health information from the CE to perform a function or service on *behalf* of the CE. Many hospitals are finding it easier to require everyone to sign BACs whether they are performing a service for the hospital or not. According to one respondent of the “Hot Button” survey, his company “needs to find a way to respond to physicians’ and other CEs’ concerns that doesn’t bind [it] by a BA contract — but also doesn’t end up disgruntling [it’s] customers.” A symposium participant pointed out that if you sign a BAC, “it’s a slippery slope.” Saunders concurred and said that some of his clients will not enter into any agreement that “remotely resembles a BAC.” A better solution may be for the industry to formulate a standardized response, which is exactly what a consortium of pharma companies – the International Pharmaceutical Privacy Consortium – is doing.

### **Need for Sales Rep Education**

Saunders also suggested that pharmaceutical companies “educate sales reps and enable them to explain why they do not need to sign BACs.” Sales reps should also be “conversant about the finer points” of the HIPAA privacy regulations. Otherwise, warns Saunders, you will be in a “competitive disadvantage.”

### **April is the Crueliest Month**

Saunders anticipates that problems will really come to a head in the spring as HHS rolls out more education about HIPAA and consumers – who do not realize that pharma companies are not covered entities – begin to bombard pharma with inquiries. “You are going to get requests for access and amendments to personal data,” warns Saunders. Complying with such requests is the most difficult aspect of any privacy compliance program and something that pharma is ill-equipped to handle because of the multiple databases a company maintains.

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