Few Marketing Obstacles in DHHS Data Privacy Rule

by Stephen Barlas

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One really needs a clear, uncluttered mind to understand the ground rules for the use of patient information that pharmacy benefit managers (PBMs) will face, now that the Bush administration has published its final rule on medical data confidentiality. This rule has been brewing since 1996, when Congress passed the Health Insurance Portability and Accountability Act (HIPAA).

The rules establish which clearances—usually patient consent—PBMs and other health care providers must get before they pass along a patient's information to someone else, or before they use that information themselves, for purposes of treatment, payment, internal administrative operations, and marketing. The marketing provisions have been the most controversial. That is doubly true for PBMs, which are caught between demands from health insurers—with regard to such issues as disease management programs—and drug manufacturers, because of their incentives. Both of those clients demand that PBMs use identifiable patient data for marketing purposes.

PBMs had worried that the final rule would get in the way of these marketing efforts. They are worried no longer. Under the final rule, a PBM, a physician, a pharmacy, or any other "covered entity" must obtain prior authorization from a patient before sending marketing communications to patients. The same would apply for the PBM that contacts a physician about a patient; the patient's prior authorization would also be needed.

The U.S. Department of Health and Human Services (DHHS), however, has exempted several items from being considered "marketing." One of these is case management or care coordination for an individual, or directions or recommendations for alternative treatments, therapies, health care providers, or settings of care for that individual.

As a result, no prior authorization is needed from a patient for a PBM to send the patient a letter suggesting that he or she take Drug A for depression instead of Drug B—even if the PBM sends the letter because the manufacturer of Drug A is paying it to do so. A DHHS spokesperson says that this is not marketing because the pharmacist is using his professional judgment in suggesting the switch to an "alternative therapy." The fact that the pharmacist is getting paid to make that recommendation doesn't make it marketing, in the view of DHHS, as long as the pharmacist believes that he is acting professionally. Of course, this differs from the situation in which a pharmacist reads in a professional journal that Drug A has tested better than Drug B in some clinical trials and then contacts patients on his own in an effort to make a switch. No one could call that marketing.

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Some view the exception for alternative therapies as a loophole in the rules. Paul Appelbaum, MD, president of the American Psychiatric Association (APA), says, "This unwarranted interference with the patient/physician relationship is not justified by any benefit to patients, but is motivated solely by the economic interests of the pharmaceutical industry."

The DHHS alternative therapy exception seems inconsistent because it requires drug companies, but not PBMs and pharmacies, to get prior authorization from a patient before sending marketing communications to the patient or his/her physician. DHHS explains that the pharmacist has a medical relationship with the patient and can be trusted—or should be encouraged—to exercise professional judgment. The drug company, which under the rule is considered a "business associate"—not a covered entity, such as a health care provider—does not have that treatment-based relationship.

Not only does DHHS give PBMS and pharmacies wide latitude on marketing, but the rule also says that they can send patients prescription refill reminders without prior authorization.

The rule takes effect on April 14, 2003. Other provisions cover nonmarketing transactions that might force pharmacies and PBMs to invest in new software and the like. However, the final medical information confidentiality rule shouldn't throw drug providers into a tailspin.

"We can live with it," says Sharon Canner, Vice President of the Pharmaceutical Care Management Association. ■