

# Prepare Now for Medicare Part D Launch in January

BY ELAINE ZABLOCKI  
Contributing Writer

SAN DIEGO — Physicians will face many questions about the new Medicare Part D benefit in coming months as patients decide whether to enroll and which plan to select in the voluntary prescription drug program, Elizabeth Carder-Thompson said at the annual meeting of the American Health Lawyers Association.

CMS has begun posting informational resources on its web site, and additional materials will become available over the next few months. The best resource at this time is the "Outreach Toolkit," available by download or on CD-ROM, said Ms. Carder-Thompson, a lawyer with Reed Smith LLP. "The Outreach Toolkit doesn't answer all the questions we want answered, but it's a good start," she said.

Enrollment for Part D begins on Nov. 15, 2005, and patients must enroll by May 15, 2006, or face a financial penalty when they do.

The new coverage goes into effect Jan. 1, 2006, and the interim discount drug card program ends at that time. This means Medicare beneficiaries will need to make fairly complicated choices within a short time.

There will be at least two Part D prescription drug plans available in each geographic area, and plans may include several subplans.

A Kaiser Family Foundation survey, conducted March/April 2005, found that seniors are more likely to turn to their doctor (49%) or pharmacist (33%) for help in making these decisions, rather than to Medicare information sources (23%). About two-thirds (68%) of those surveyed said they did not have a good understanding of the new benefit.

In October 2005, Part D plans will start to send marketing materials. CMS will distribute its "Medicare and You," handbook to all beneficiaries via mail, with a description of the new benefit. A "Plan Comparison Web Tool" and "Medicare Personal Plan Finder" will be posted at [www.Medicare.gov](http://www.Medicare.gov), and there will be special mailings for low income beneficiaries.

"CMS says it will provide materials as they did for the drug discount card but this is far more complicated than the card," Ms. Carder-Thompson said.

According to Robert J. Hill, also of Reed Smith LLP, the CMS marketing guidelines on Part D include a great deal of material that will affect physicians. For example, enrollment cannot be taken at the point of care, such as a physician's office. If physicians offer their patients information on any Part D plan then they must offer information on all available Part D plans.

CMS has not released the final version of its marketing guidelines, and Mr. Hill expects these issues to be dealt with in more detail in the second part.

Once Part D becomes effective, doctors will face a different set of concerns, Ms. Carder-Thompson said.

When a plan doesn't cover a prescribed drug, physicians will need to provide supporting statements in order to get an exception, but many details are not clear at this time.

"The regulation is confusing," Ms. Carder-Thompson said. "CMS says they don't want it to be hard to seek exceptions. However, it may well become an administrative burden. This is something that's going to evolve as we go along."

Ms. Carder-Thompson advised doctors to "stay tuned" on the details of Part D, because they seem to be changing every day. ■

# HIPAA Regs Permit Consultation With Device Manufacturers

BY ELAINE ZABLOCKI  
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SAN DIEGO — Under the federal Health Insurance Portability and Accountability Act, physicians are permitted to share protected health information with medical device companies, according to Robert M. Keenan, a health lawyer based in Atlanta.

The Department of Health and Human Services Office for Civil Rights, which is responsible for enforcing HIPAA privacy regulations, recognizes the need for disclosures to device manufacturers who are counseling physicians about patient care and thereby acting as health care providers. Under these circumstances, a special authorization or business associate agreement is not needed.

"Historically, physicians share information with device companies," Mr. Keenan said during the annual meeting of the American Health Lawyers Association. "Sales representatives may be experts on the

use of a device, and it's common for surgeons to ask them questions about how to implant a device."

The Office for Civil Rights has provided specific guidance on sharing patient information. For example:

► A manufacturer's representative may be present in the operating room to provide support and guidance regarding the appropriate use, implantation, calibration, or adjustment of a medical device.

► A manufacturer's representative may view films or patient records to provide consultation, advice, or assistance with a particular patient's treatment.

► A "covered provider" under the HIPAA law may share protected health information—but only the necessary minimum amount—with a device company, so that the company can receive payment for health care services. ■

Information for physicians about HIPAA is available at [www.hhs.gov/ocr/hipaa/](http://www.hhs.gov/ocr/hipaa/).

# Drug Industry DTC Ad Guidelines Draw Criticism

BY JOYCE FRIEDEN  
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New voluntary guidelines for direct-to-consumer prescription drug advertising released by the Pharmaceutical Research and Manufacturers of America have drawn criticism from politicians and consumer groups who say they don't go far enough.

"While I wish the PhRMA guidelines would have gone farther and proposed a moratorium on DTC [direct to consumer] advertising of newly approved drugs, I hope individual pharmaceutical manufacturers will seriously consider such a measure," Senate Majority Leader Bill Frist, M.D. (R-Tenn.) said in a statement. Sidney Wolfe, M.D., director of the Public Citizen Health Research Group, called the PhRMA announcement "a meaningless attempt to fool people into believing the guidelines are stronger than they really are."

The PhRMA guidelines were released in Dallas in early August at a meeting of the American Legislative Exchange Council.

Among other things, the guidelines call for pharmaceutical manufacturers to educate physicians and other health care providers about new drugs before advertising them to consumers.

"The centerpiece is the notion that the companies are committing an appropriate amount of time to educate health care professionals about new medications and new indications ... to make sure physicians and other providers know about the medicines and benefits before," direct-to-consumer advertising campaigns are undertaken, Billy Tauzin, CEO of PhRMA and a former congressman from Louisiana, said at a press conference sponsored by PhRMA.

The length of time the companies will take to educate physicians will depend on several factors, including whether the drug is a life-saving one and how complex the risk-benefit profile is, Mr. Tauzin said. "We are also

committed to continuing to educate health care professionals as additional info about a medication is obtained from all sources, even after medication has begun being marketed."

Other provisions of the voluntary guidelines, which 23 companies have signed onto, include:

► DTC ads should be balanced, and discuss both the benefits and risks of the medication. The information should be presented in "clear, understandable language, without distraction from the content."

► Ads should be targeted to avoid audiences that are not age-appropriate. For example, Karen Katen, president of Pfizer Human Health, said that her company would not run a television advertisement for Viagra (sildenafil) during the Super Bowl, when young children may be watching.

► Companies should submit new DTC print and television advertisements to the FDA before releasing them. PhRMA board chair Bill Weldon said this does not mean that companies would submit an ad to the FDA on Tuesday and then run it on Wednesday. "The intent is to make sure that FDA has been able to comment on any programs prior to advertising," said Mr. Weldon, who is also chairman and CEO of Johnson & Johnson.

► Ads that identify a product by name should include the product's indications as well as its risks and benefits. This means no more ads that just give the name of the medication and tell what it's for, Mr. Tauzin said.

PhRMA also will convene an independent board in about a year to get outside opinion on whether the companies are following the guidelines. The panel will include experts in health care, broadcasting, and other relevant disciplines. The panel's report "will be made public, and also made available to the FDA," Mr. Tauzin said. ■

The voluntary guidelines are available at [www.phrma.org/publications/policy/admin/2005-08-02.1194.pdf](http://www.phrma.org/publications/policy/admin/2005-08-02.1194.pdf).

