Medicare Part D Counseling: Just One More 'Unfunded Mandate'?

BY NELLIE BRISTOL
Contributing Writer

WASHINGTON — Physician obligation to help patients negotiate the upcoming Medicare Part D outpatient drug benefit will result in "another unfunded mandate" for Medicare providers, Ronald Castellanos, M.D., chairman of the Practicing Physicians Advisory Council said at the group's recent meeting.

Noting that patients are most likely to rely on their physicians for aid in choosing among the new drug plans, Dr. Castellanos said, "Basically what you're doing is putting the burden on physicians in their offices to really educate the Medicare recipient."

PPAC members asked the Centers for Medicare and Medicaid Services to make educational materials as simple possible, including information on whether beneficiaries are eligible for the low-income portion of the program.

"I really want a lot of information, very digestible," said PPAC member Geraldine O'Shea, D.O., an internist from Jackson, Calif. "Something very easy for them to understand, because I do not want to take time out of my time to do medicine with my patient to say, 'Well, let me see your tax return.' "

"We are trying to make the information available as simple as possible," said Jeffrey Kelman, M.D., medical officer for the CMS Center for Beneficiary Choices.

Council member Barbara McAneny, M.D., an oncologist from Albuquerque, requested a computer program that would allow physicians to type in the drugs a patient is using and come up with the plan that would cover all of them. She also proposed that CMS be required to develop a reimbursement code for physician time spent on drug plan education, but it was voted down by the panel, with members saying it wasn't practical.

Dr. Kelman said CMS is getting "much more robust formularies" from drug plans than officials had anticipated. "They're looking like commercial formularies," he said, adding that the formularies would be available on the Web site in October.

All drugs approved by the Food and Drug Administration must be on the formularies, Dr. Kelman said. If a drug is not included, a beneficiary can appeal, based on medical necessity, "preferably with a physician's help," he said. "All medically necessary drugs that are approved by the FDA with certain exceptions … have to be available." In a move important to rare drug organizations, Dr. Kelman said if there is only one drug to treat a disease, it must be included in the formulary.

Part D also will ensure drugs are available for chronic conditions by "favorably risk adjusting" those diseases, Dr. Kelman said. The plans also will "overadjust" for low-income individuals and nursing homes. "We went to a lot to trouble to ensure nobody was discriminated against on the formulary or based on the Part D benefit," Dr. Kelman said. Dr. Kelman urged physicians to begin moving patients to the new formularies before the benefit is effective Jan. 1, 2006. "The last thing we want is 40 million exceptions and appeals in the first week," he said. Beneficiaries can enroll in the program from November 15 through May 15.

In other issues, Dr. Kelman pointed out that by law, barbiturates and benzodiazepines will not be covered by the plans. He said the program was hoping states would continue to pay for these inexpensive drugs for dual-eligible beneficiaries (those receiving both Medicaid and Medicare benefits). Other drugs not covered include cosmetic agents and weight-loss and weight-gain products. ■

Small-Area Analysis Can Show Hidden Disparities

BY JOYCE FRIEDEN
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WASHINGTON — It doesn't surprise most physicians to hear that populations in certain cities—especially cities with a high percentage of minorities—have higher rates of chronic disease. But small-area analysis can help pinpoint exactly which areas of a city suffer from a higher disease burden, Robert Bonow, M.D., said.

For example, Dallas is a complicated area when it comes to cardiovascular mortality, said Dr. Bonow at a meeting sponsored by the Alliance of Minority Medical Associations, the National Association for Equal Opportunity in Higher Education, and the Department of Health and Human Services.

He and Sean Cleary, Ph.D., associate professor of epidemiology and statistics at George Washington University, Washington, performed small-area analysis on the city using data from state Vital Statistics offices and the 2000 U.S. Census. The study showed that there are disparities in mortality from cardiovascular disease not only between minority and nonminority populations, but also within minority neighborhoods themselves.

The question is, Why would that be true? "Is one area more Hispanic, and one area more African American?" asked Dr. Bonow chief of the division of cardiology at Northwestern Memorial Hospital, in Evanston, Ill. Of course, there could be other factors driving differences in mortality, such as differing opportunities for exercise, lesser or greater availability of fresh fruits and vegetables, or more fast-food restaurants in one community than in another, he added.

Dr. Bonow noted that the maps produced by small-area analysis could be a lobbying tool for health care advocates. "Imagine walking into [a Congressman's office] with a map showing that minority areas in his district have very high rates of cardiovascular disease," he said. And if the analysis also found that there were very few neighborhood health centers in the area, advocates could argue that services are not being offered where they are needed.

Dr. Bonow hopes to eventually get data for all the Zip codes in the United States. "The results hopefully will inform community-based intervention and treatment programs targeting higher-risk uninsured areas," he said. ■

FDA Looks to IOM for Solutions to Drug Safety Problems

BY ALICIA AULT
Contributing Writer

WASHINGTON — Acknowledging that its drug safety system is inadequate, several Food and Drug Administration officials told an Institute of Medicine panel examining the issue that the agency is ready for recommendations on how to better protect the public's health.

The IOM committee was convened at FDA's request and has been charged with examining every aspect of the agency's drug safety program, including whether it needs new powers to mandate postmarketing safety studies by pharmaceutical companies.

At its first meeting in June, the panel heard from representatives of the FDA, the pharmaceutical industry, and consumers. Each had had divergent views on how well the system works.

Janet Woodcock, M.D., acting deputy commissioner for FDA operations, said the agency had come a long way, but that it could improve on predicting, preventing, monitoring, and mitigating adverse drug events. Changes over the past decade have made it more difficult to ensure safety, Dr. Woodcock added.

Before, most drugs were marketed in other countries first, giving the agency a track record to evaluate, she said. Now, the United States is often the first avenue for sales. Huge drug company marketing campaigns aimed at physicians and consumers have led to a much quicker uptake of new drugs, which brings safety issues to a head even faster. Recalls are happening faster after a drug comes to market, but there has been no big increase in the number of withdrawals, Dr. Woodcock said.

'One of the questions on the table really is how much uncertainty are we willing to tolerate, because we will never have total certainty.'

She also said the agency was hamstrung by international agreements on how much premarket safety data could be requested; the agency can't force drug makers to conduct postmarketing safety studies.

MedWatch, FDA's postmarketing surveillance system, is full of gaps, Dr. Woodcock added. Pharmaceutical makers are required to report adverse events to MedWatch, but reports from physicians, pharmacists, and other health care providers, and patients are voluntary. MedWatch receives 400,000 reports a year, but the FDA acknowledges it captures only a fraction of the events.

Alan Goldhammer, Ph.D., associate vice president of regulatory affairs at the Pharmaceutical Research and Manufacturers of America, said, "simply increasing the number of spontaneous reports is not the answer" because it might just "increase the noise" instead of providing real signals about side effects.

He said the system was not broken. "We know more about safety profiles of drugs approved today than those approved 20 years ago," Dr. Goldhammer said, adding that "FDA's current legal authorities over drug safety are robust and do not need to be changed."

Bill Vaughan, a senior policy analyst with Consumers Union, vehemently disagreed, saying that the Washington-based nonprofit believes that "legislative action is essential to address the substantial problems in drug safety and oversight that have been highlighted over the last year."

Mr. Vaughan urged the IOM panel to make interim recommendations to Congress as early as this summer, rather than waiting until its final report, due out next year. "It looks like the industry looks at the FDA like it's a paper tiger, and that needs to be addressed, and addressed soon," Mr. Vaughan said.

Steven Galson, M.D., the acting director for FDA's Center for Drug Evaluation and Research touted the FDA's new Drug Safety Oversight Board, saying it would help provide "independent" oversight and advice. The board's first meeting was in late June.

Sen. Chuck Grassley (R-Iowa), chairman of the Senate Finance Committee, said he was skeptical of the board's capabilities, noting in a letter to FDA acting commissioner Lester Crawford, D.V.M., that it does not seem independent enough.

Overall, Dr. Woodcock told the panel, "one of the questions on the table really is how much uncertainty are we willing to tolerate, because we will never have total certainty." When FDA approves a drug for marketing, "that doesn't mean there are no risks, or that there are no risks to the individual patient," she said, adding that patients and doctors together should weigh benefits and risks.

The next meetings of the panel are scheduled for July 20 and October 25. ■