FDA’s New Drug Safety Board Under Scrutiny

Critics say board may lack independence and authority and may not have sufficient resources.

BY JENNIFER SILVERMAN
Associate Editor, Practice Trends

M any questions surround the author- ity of a new drug safety board that would oversee the management of drug safety and provide emerging information to physicians and patients about the benefits and risks of medicines on the market.

The drug safety board is being touted as an independent entity; yet lawmakers and consumer groups have questioned how much independence or authority the board will actually have.

Larry Sacich, a pharmacist and research analyst for Public Citizen, noted that recommendations issued by the board that would serve as consultants.

The agency will eventually seek input on the quality and usefulness of this information, an FDA spokesman said. "We are not soliciting for public comment, or treating this as a proposed rule." The agency does plan on issuing draft guidance on procedures and criteria for identifying drugs and information for the Web page.

A spokesman for the Pharmaceutical Research and Manufacturers of America said that the organization supports any effort to address the quality of information used by the agency.

“Face-to-Face’ DME Prescribing Proposal Annoys Neurologists

BY JOYCE FRIEDEN
Associate Editor, Practice Trends

WASHINGTON — Medicare’s proposal to require a face-to-face visit before a physician can prescribe a wheelchair or other durable medical equipment to a patient is annoying and inconvenient, several physicians said at a meeting of the program’s Practicing Physicians Advisory Council.

“Face-to-face visit is a step forward” said Laura Powers, M.D., a neurologist and member of the council, which advises Medicare on issues of interest to physicians. “If I take care of stroke patients in the hospital and they leave with a walker, then progress to a cane, do they have to come back for a face-to-face visit before I can prescribe a cane?”

Herb Kuhn, director of the Center for Medicare Management at the Centers for Medicare and Medicaid Services, said that the idea behind the regulation was to deter durable medical equipment (DME) supplier fraud in the wake of the recent scandal in the power wheelchair industry.

“We’re looking for continuity of care,” Mr. Kuhn said.

“Face-to-face exam would be required to determine the medical necessity of DME.”

Dr. Rapp expressed concern that Medicare would not pay for evaluations performed solely to determine whether the patient needed a power wheelchair, despite the fact that ‘that might be an extensive evaluation.’ Mr. Kuhn responded that he did not think the agency would want to get out of paying for such an extended visit, ‘but it perhaps requires some clarification and comment,’ he added.

Although wheelchair fraud is at the heart of the agency’s fraud concerns, the CMS Physician Regulatory Issues Team (PRIT) is looking at expanding the categories of specialists permitted to prescribe power wheelchairs. Currently only physiatrists, orthopedic surgeons, neurologists, and rheumatologists can prescribe power wheelchairs, and primary care physicians and other specialists can prescribe them only if one of those specialists is not readily available—that is, if they are located more than a day’s round trip from the beneficiary’s home—or if the patient is too sick to travel to a specialist.

“We’re looking at a good resolution on this with our proposal to allow physicians of any specialty to prescribe them, and that’s in the final approval process now,” said William Rogers, M.D., director of PRIT. “It really wasn’t the best time to be broadening the number of specialties that can do it, but it is the right thing to do.”