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2005 Meeting Report Contrasting World of Medical Education Companies: United States vs. Germany

NEW YORK -- The regulatory environment in the United States is disrupting commercial support of CME, said Martin Cearnal, Chief Strategy Officer, Thomson Healthcare, Secaucus, New Jersey, here during the Tenth Annual Meeting of the Global Alliance for Medical Education.

Most recently, the U.S. government is focusing on false claims--anything that causes the government to pay either an inappropriate amount or pay for an unrealized service--and this scrutiny is being extended to CME activities. For example, if a physician attends a CME activity where off-label use was discussed and then prescribes that medication outside of the FDA-approved labeling for a patient who receives Medicare or Medicaid, is that a false claim? This government concern is a tortuous trail, but it is creating a lot of concern within the CME community, said Cearnal.

The second aspect of the federal government's scrutiny involves anti-kickback laws: for example, did a physician receive funds for a CME activity when no activity was actually ever created? Is there an organized campaign to provide large honoraria to people who happen to chair formulary committees in a hospital? In assessing these cases, the government looks at the grantor's documents to see if the CME activity was part of a larger marketing strategy and not really constructed as an independent educational program, he said. Qui Tam laws, which empower and reward whistleblowers, are making the environment even more dangerous for pharmaceutical companies, said Cearnal.

Complicating the situation for CME providers, each pharma company grantor has interpreted the rules differently. As a result, a grant proposal that meets the specifications of one potential pharma company grantor may violate the criteria established by another potential grantor, Cearnal explained. "The amount of time, manpower, and energy that is spent, especially by smaller organizations, reshaping these documents causes a huge loss of efficiency in the system and diverts efforts that should be directed toward the creation of CME activities to the creation of proposal documents. This environment of uncertainty is one that will continue to depress funding until we do something about it," he said.

To help alleviate the problem, the U.S. CME community needs to seek consistency in compliance structures, policies, procedures, and internal education, so that providers and grantors have a common understanding of 'safe' and 'effective' CME behaviors, he said.

Germany Issues Conduct Code

Germany has issued a code of conduct for pharmaceutical industry/physician relationships, said Edgar Ingold, MD, General Manager, Thomson Physicians World GmbH, Germany. Under the new guidelines, companies can finance CME activities, but the funding must be disclosed by the organizer.

According to Dr. Ingold, pharma companies may invite physicians to CME activities and pay registration fees, reasonable travel, and necessary accommodations costs as long as the event emphasizes education. Adequate food service is allowed, but companies cannot pay for entertainment or for a guest's expenses.

In addition, he noted, there has to be a relationship between the company's field of activity and the participant's area of expertise. Venues are also under the microscope, generating frustration that will sound familiar to U.S. CME organizers. One example: "Two weeks before an event at a five-star hotel, we had to relocate the meeting to a four-star hotel. It was a great mess. I didn't see any sense in that," said Dr. Ingold.