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From: Lewis Miller [mailto:lew@wentzmiller.org]
Sent: 11 March 2013 19:07
To: secretariat@aemh.org
Subject: Sunshine for whom: doctors, industry, public?

The Global CME Newsletter

Transparency is the"hot" word in CME/CPD, in the US, Europe and elsewhere in the world. The implication is that relationships between doctors and pharmaceutical funders of CME have been hidden behind seven veils of secrecy for years and now need to be disclosed. We raise the questions of to whom, and will it make a difference in the quality and delivery of continuing medical education.

The long-awaited final rule for implementation of the U.S. Physician Payment Sunshine Act was released in February: Starting August 1, pharmaceutical, device and medical supply companies must report all transfers of value over $10 to physicians and teaching hospitals. Lest you are not worried because you are from outside the U.S., don't get comfortable. A recent survey at a pharma conference indicated that every country in the world will have some sort of reporting requirements within 5 years.

In brief, the U.S. act does make an exception for speakers at CME events if the event meets standards of the Accreditation Council for CME (ACCME) or American Medical Assn. (AMA). This means the CME provider, not the company, pays the speakers and monitors the fair balance of the contents. But if a company representative provides lunch to doctors attending a hospital educational program, that must be reported.

The Center for Medicare and Medicaid Services (CMS), which will administer the program, estimates first-year total costs to government, doctors, hospitals and industry at $269 million, and $180 million thereafter. But CMS admits to being unable to estimate the monetary value of the act.

We wonder who will benefit. The sun will shine on thousands of transactions of little value, transactions that are unlikely to influence doctors' prescribing habits or the health of patients. It's true that certain abuses will be exposed to light, when a physician or hospital receives tens or hundreds of thousands of dollars for providing minor consulting or research services, or major discounts on drugs or devices. Here's a quick prediction of effects:

- *Industry will be forced to collect and organize data from local and regional representatives to fit the CMS format, but failure to report will bring what are minimal fines*
- *Doctors will nervously accept (or forego) simple meals in the hospital or office, minor gifts, etc. -- and will periodically check their listing in the Sunshine site to see what has been reported*
- *Patients are unlikely to know about the site, and to visit it with anything but curiosity*
- *Government will monitor the site seeking evidence of fraud and abuse by industry, but seldom to bring action against doctors*
- *The media will enjoy publicizing "greedy" doctors in their area*
- *Healthcare of the public: Will there be a benefit?*

France is awaiting final rules for its "LeSunshine Act", passed in 2011. In other countries, including Japan, Australia, Slovakia and the UK, industry codes call for some level of reporting either to government websites or the industry's own site. Global companies are concerned about how to coordinate all reporting activities. Will CME improve as a result of "transparency"?

Dr. Edwin Borman, Secretary General of the Union of European Medical Specialties (UEMS), sees the new UEMS requirements for CME accreditation as a "revolutionary change" that will bring up the general standard of good CME. While not disagreeing, there are voices in Europe who would like to see more done to improve and standardize CME quality and process.

In a series of interviews in pharmaphorum online, three voices are heard:

1. Dr. Borman believes that CME in Europe has changed profoundly in the past 20 years, but now needs to aim at improving quality of care, assessing learners' needs better and making events more interesting and interactive
2. Eva Thalmann, med ed leader for Janssen in Europe, agrees that CME has improved but is still concerned that it is too fragmented, with differing requirements by country and medical society
3. Dr. Robin Stevenson, editor of the Journal of European CME, believes that while there has been a positive shift to more interactive teaching, Europe won't have much chance for unified high standards until the system moves to provider accreditation

A common provider accreditation system might alleviate the fragmentation, but doesn't appear to be on the horizon soon. Italy has adopted this approach rather than program accreditation but it is too early to tell if the quality of CME programs has improved. No other country nor specialty accreditation board has moved to make a change. nor has UEMS, which could lead if there were enough support from the European specialty societies who could become the major accredited providers.

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