Medical Schools Take Stand Against Industry Gifts

BY CATHY DOMBROWSKI AND DENISE PETERSON
"The Pink Sheet"

Medical schools and teaching hospitals should prohibit their physicians, faculty, residents, and students from taking gifts and services from drug companies, according to the Association of American Medical Colleges.

Industry support for continuing medical education activities also should be limited, according to a report unanimously adopted by the AAMC executive council.

Many Schools Are Studying Gifts Issue

The recommendations might be particularly influential because of their timeliness—AAMC notes that many academic institutions are developing policies on interactions with drug and device makers.

AAMC cites medical schools at the University of Pittsburgh, the University of Pennsylvania, Stanford University, the University of California at Davis, UCLA, and Yale University as institutions that have implemented policies in the past few years.

The association represents 129 U.S. and 17 Canadian medical schools, about 400 teaching hospitals and health systems, and a number of scientific societies.

AAMC's strong stance against industry gifts to physicians comes as drug and device makers are signing on to federal legislation that would bring transparency to their financial interactions with doctors by requiring public disclosure of gifts.

But the "sunshine" approach might prove to be temporary. In addition to AAMC's call for a ban, the Massachusetts Senate adopted a bill in April that would ban pharmaceutical industry gifts of any value to physicians, their office staffs, or their families.

The Institute of Medicine also is assessing the effectiveness of transparency in preventing conflicts of interest in such interactions, with a report due in July 2009.

The medical schools report, titled "Report of the AAMC Task Force on Industry Funding of Medical Education to the AAMC Executive Council," calls on members to take the following actions:

- ► Ban acceptance of industry gifts by doctors, faculty, students, and residents, whether given on- or off-site.
- ► Either end acceptance of drug samples or manage their distribution through a centralized process.
- ► Restrict visits to individual doctors by industry representatives to nonpatient areas and by appointment only.
- ► Create a central office to receive and coordinate distribution of industry support for CME.
- ► Strongly discourage faculty participation in industry-sponsored speaking bureaus.
- ► Bar physicians, residents, and students from using presentations ghostwritten by industry members.

Lessons on the Nature of the Industry

The group also notes that medical students often take their cue from faculty and medical residents, suggesting that those in a mentoring role must lead by example. At the same time, most medical students have "limited understanding" of such issues as the process of drug development, nature of the pharmaceutical industry, product marketing, "meaning and limitation" of FDA product approval, and physician role in adverse event reporting, the report notes. Medical curricula should include information on these topics.

The report also emphasizes that while academic institutions are not responsible for policing activities outside their facilities, faculty and students should be advised that prohibited activities are also barred off-site. For example, they should not accept meals from industry (outside of officially sanctioned CME), whether at the medical school or across the street.

The report affirms that "substantive, appropriate, and well-managed interactions between industry and academic medicine are vital to the public health," saying that industry and the medical community should work together "to develop new paradigms" for scientific information transfer.

The Accreditation Council for Continuing Medical Education is seeking comments on such a paradigm with regard to industry support for CME.

AMA Awaits Federal Legislation

The American Medical Association also has been reviewing industry funding and gifts at its annual House of Delegates meeting but declined to take a clear-cut position. Its Council on Ethical and Judicial Affairs drafted a report recommending that individual physicians and institutions of medicine not accept industry funding for education.

But during their June 14-18 session, the AMA delegates referred the report for further review at the recommendation of the group's Committee on Amendments to the Constitution and Bylaws.

The panel said testimony on the report noted a lack of clarity on certified CME and uncertified promotional education, and concern for unintended consequences.

The delegates also declined to get embroiled in the debate over reporting of industry gifts. Pending was a resolution for AMA to back annual reporting by drug and medical device firms of all physician payments with a value of more than $100.

An AMA committee advised delegates that testimony on the measure generally was unfavorable, with concerns raised about the logistics and how and to whom the information would be disclosed.

Noting that legislation on the issue "is pending and may serve to answer many of these questions," the committee recommended that the resolution not be adopted and the delegates concurred.

On the question of conflicts of interest in CME, the delegates accepted the recommendation of AMA's Council on Medical Education to monitor implementation of ACCME standards. ■

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Medicare Recovery Audit Demonstration Has Mixed Results

BY DENISE NAPOLI
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WASHINGTON — The Recovery Audit Contractor program, charged with investigating and remedying improper Medicare payments to providers, must undergo some serious structural changes before it is ready for prime time, several physicians testified before the House Committee on Small Business.

The Recovery Audit Contractor (RAC) program employs private contractors to investigate improper payments by Medicare to providers. The program was mandated in the Medicare Modernization Act and tested in New York, California, and Florida beginning in 2005. With the pilot now completed, nationwide adoption is scheduled to begin in 2010.

Dr. Michael Schweitz, a rheumatologist from West Palm Beach, Fla., testified that "the demonstration has created unfair and expensive administrative burdens for physician practices, which are after all small businesses with limited capacity for dealing with arbitrary, ill-informed, and often very confusing policies of those contractors." He added that he supports the institution of a moratorium on RAC activities and expansion until the program's flaws are addressed and corrected.

Dr. Karen Smith, a member of the American Academy of Family Physician's Commission on Practice Enhancement, testified about her own experience with RAC audits. She said that in 2005, two representatives from one contractor, AdvanceMed, showed up at her office unannounced and requested 72 charts for records from the previous year and a half. "The care of my patients was disrupted in our open access, rural family practice as patients, pharmaceutical vendors, and other visitors of the practice observed the unannounced review," according to her submitted testimony.

Five months after the audit, Dr. Smith received notice that 72 claims with 154 services were reviewed by the RAC, of which 91 services were disallowed for payment. The RAC then used an extrapolation formula to determine how much Dr. Smith owed, except it relied on an incorrect "sampling frame size" of 2,935 Medicare patients, nearly 2,000 more than Dr. Smith had in her practice. The alleged Medicare overpayment, using this flawed calculation, totalled $48,245, said Dr. Smith.

After a lengthy, costly, and ultimately not totally successful series of appeals, Dr. Smith was forced to use proceeds from a home equity loan to pay CMS an adjusted sum of $18,158. "The 'guilty until proven innocent' audit we endured used sampling and extrapolation calculations [that] are not properly verified for validity," said Dr. Smith.

Dr. William A. Dolan, a member of the American Medical Association board of trustees, also testified before the committee, which is chaired by Rep. Charles Gonzalez (D-Texas).

"The best way to reduce common billing and coding mistakes is through targeted education and outreach, rather than onerous audits performed by outside contractors provided with incentives to deny claims," he wrote in his testimony.

The RAC program has many problems, according to all three physicians. One of the greatest is contractors' ability to designate improper payments based on contractors' judgment of "medical necessity." Dr. Schweitz, who is also the vice president of the Coalition of State Rheumatology Associations (CSRA), said, "These reviews should be conducted by clinicians with relevant experience and expertise." Dr. Schweitz testified on behalf of the Alliance of Specialty Medicine, a coalition of medical societies including CSRA that represents more than 200,000 physicians.

Mr. Timothy B. Hill, chief financial officer and director of CMS' office of financial management, testified that once the RAC program is made permanent in 2010, each contractor will be required to have a medical director who oversees medical necessity questions. This was not the case in the demonstration project.

Another request from Dr. Dolan was that contractors be prohibited from reviewing claims from the past 12 months, which may be "still under review by carriers and other fiscal intermediaries." He also called for a limit on the number of medical records requested from individuals.

"CMS should also raise the minimum claim level from $10 to at least $25," he added. In a question-and-answer period after the testimony, Dr. Dolan amended his recommendation to $100.

All three physicians also testified that the "look-back" period, which allowed contractors to audit records from as far back as 4 years ago, should be shortened.

Responding to accusations by Dr. Schweitz and others that contractors operate under a "bounty hunter mechanism," Mr. Hill said that contractors are paid a negotiated commission on all improper payments they recover—both under- and overpayments—upon recoupment of the payment by Medicare. "The incentive to identify underpayments is exactly the same as the incentive to identify overpayments," he said. However, in 10 years, he testified that "the vast majority of the improper payments" are overpayments.

Mr. Hill added that a January 2008 report from the Office of Management and Budget reported that Medicare made an estimated $10.8 billion worth of improper payments in fiscal year 2007. The RACs corrected more than $1 billion in improper payments during the 3-year demonstration period, he added.

"If a provider disagrees with the RAC's overpayment determination, he or she can appeal the decision." ■