LAW & MEDICINE

Medicare/Medicaid Fraud

Question: Which of the following is not a violation of Medicare/Medicaid fraud statutes?

A. Referring patients to a lab of which your spouse is part owner.

B. Hospital "remuneration," such as below-market office leases or expensive tickets to events.

C. Forgiving the copay portion of a retired colleague's bill.

D. Marketing Food and Drug Administration-approved drugs for off-label use.

E. Negligently submitting a wrong-patient Medicare claim.

BY S. Y. TAN, M.D., J.D.

Best answer: E. Choice E is analyzed under the False Claims Act, which imposes liability for knowingly submitting a payment demand to Medicare/Medicaid. Legally, this means having actual knowledge (*scienter*) that the claim is false or acting in deliberate or reckless indifference to the truth. However, an error that is negligently committed is insufficient to constitute a violation. Choice A is a direct violation of the Stark Law against self-referral, and B and C are violations of the Anti-Kickback Statute (AKS). The current 2011 threshold is $359 for "complimentary" tickets to events, and the government has warned that routinely waiving copayments could implicate the AKS. Choice D, of special relevance to pharmaceutical and device manufacturers, is illegal under the False Claims Act. Whereas doctors are allowed to prescribe drugs or devices for an off-label indication, the law forbids a manufacturer from marketing its products for a non-FDA–approved use.

With an annual budget of almost $1 trillion, it is estimated that some 10% or up to $100 billion of Medicare/Medicaid funds are lost to fraud, waste, and abuse. The Office of Inspector General is the independent oversight agency regulating such sources of loss. "Fraud" includes the obtaining something of value through intentional misrepresentation or concealment of material facts, "waste" includes the incurring of unnecessary costs as a result of deficient management, practices, systems, or controls, and "abuse" includes any practice that is not consistent with the goals of providing patients with services that are medically necessary, meet professionally recognized standards, and are fairly priced. A Roadmap for New Physicians: Avoiding Medicare and Medicaid Fraud and Abuse is available at http://oig.hhs.gov/compliance/physician-education/index.asp.

To combat fraud, waste, and abuse, Congress has enacted three separate laws: The False Claims Act, the Anti-Kickback Statute, and the Physician Self-Referral Statute. In addition, states have their own versions of these laws. Stiff penalties for violations include fines, restriction of practice privileges, and imprisonment. More than 5,000 physicians in the United States are currently excluded from participation in Medicare/Medicaid programs because of violations (N. Engl. J. Med. 2011;364:102-3).

It is illegal under the False Claims Act to submit false or fraudulent claims for payment to Medicare or Medicaid (31 U.S.C. §§3729-3733). Private individuals, frequently former employees, consultants, even competitors, can file a so-called *qui tam* action alone or in concert with the government, and they stand to collect a substantial bounty in the event the prosecution proves successful. The Act originated during the Civil War, when increased government procurement led to fraudulent claims by contracting parties, prompting President Abraham Lincoln to state: "Worse than traitors in arms are the men who pretend loyalty to the flag, feast and fatten on the misfortunes of the Nation while patriotic blood is crimsoning the plains of the South, and their countrymen are moldering in the dust."

In the health care field, claims may be false if the service is not actually rendered to the patient, is provided but already covered under another claim, is miscoded, or is not supported by the medical record. Intent to defraud is not a required element; deliberate ignorance or reckless disregard of the truth will suffice. Whistle-blowers, that is, *qui tam* plaintiffs, can receive up to 30% of any False Claims Act recovery. Penalties are severe and include treble damages, costs and attorney fees, and fines of $11,000 per false claim. Imprisonment and criminal fines are additional penalties.

One of the latest criminal schemes to defraud Medicare involved organized crime's establishment of more than 100 bogus clinics in 25 states, using stolen identities of doctors and patients. The government became suspicious when submitted bills purportedly came from ophthalmologists for bladder tests, ENT surgeons for ultrasounds, and office visits from a forensic pathologist. The Department of Justice has reportedly arrested 28 people linked to this fraud (BMJ 2010;341:c5865).

Under the Anti-Kickback Statute (42 U.S.C. §1320a-7b), it is illegal to knowingly or willfully offer, pay, solicit, or receive remuneration, directly or indirectly, in cash or in kind, in exchange for referring an individual or furnishing or arranging for a good or service, and for which payment may be made under Medicare or Medicaid. Importantly, the case of the *United States v. Greber* established that there is a statutory violation even if only one purpose of the remuneration is to induce referrals. Several hospitals have paid multimillion dollar settlements for kickback "remunerations."

The Physician Self-Referral Statute, commonly called the Stark Law, prohibits a physician from making a referral to an entity for the furnishing of a designated health service for which payment may be made under Medicare or Medicaid if the physician or an immediate family member has a financial relationship with the entity, unless an exception applies. This being a strict liability law, no proof of specific intent is required. There are strict, complex, and narrowly construed "safe harbors" and exceptions to both the Anti-Kickback and Stark laws, but the field is complex, so providers contemplating health care business deals should proceed cautiously and seek specific advice from experienced legal counsel. ■

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AMA House Adopts Conflict of Interest Policy

BY ALICIA AULT

FROM THE ANNUAL MEETING OF THE AMERICAN MEDICAL ASSOCIATION'S HOUSE OF DELEGATES

CHICAGO – After 5 years of discussion and attempts at passage, the American Medical Association's House of Delegates adopted a conflict of interest policy to help guide physicians on the ethics of receiving pharmaceutical or device company funding for continuing medical education.

The House was asked to approve a report on financial arrangements prepared by the AMA Council on Ethical and Judicial Affairs (CEJA). But because so many members continued to be divided on what the AMA policy should be, the Reference Committee on Amendments to Constitution and Bylaws recommended that delegates put off any formal action and refer the matter yet again, this time to the AMA Board of Trustees.

When the resolution to refer came to the House floor, the vote was close, with 48% of delegates wanting to put off any action, and 52% voting against referral. Delegates were then asked whether to adopt the CEJA report. The vote was less ambiguous, with 60% voting in favor of adoption.

The report was supported by primary care delegations and many state delegations. Dr. Lori J. Heim, board chair of the American Academy of Family Physicians, said on the House floor that the latest iteration of the report addressed her organization's concerns and should be adopted.

"I hope we can deal with this today rather than refer it back," said Dr. Heim, a family physician and hospitalist in Laurinburg, N.C. "The CEJA has found a compromise that we can all live with."

Dr. William Golden, a delegate from the American College of Physicians, and a professor of medicine and public health at the University of Arkansas, Little Rock, said on the House floor that "version 5.0 is ready for distribution," and urged passage of the policy.

Several delegates said that although most specialty societies have conflict of interest policies, it was important for the AMA to have its own.

But some delegates from surgical societies said that passage of the policy might harm important relationships between surgeons and industry.

The American College of Surgeons spoke against adoption of the policy.

In the report, the CEJA said it recognized that it could have looked more broadly at conflict of interest issues, but decided to focus on pharmaceutical, biotechnology, and medical device company sponsorship of continuing medical education.

"Narrowing our focus to CME allows us to explore the complex considerations at stake in a manageable context and to provide practical ethical guidance on issues that increasingly challenge physicians as professionals," according to the CEJA report.

The CEJA concluded that "physicians should strive to avoid financial relationships with industry."

Instead, physicians should "cultivate alternative sources of support" and "design and conduct educational activities so as to reduce costs."

They also "should insist that content developers and faculty members not have problematic ties with industry, to ensure independent, unbiased, high-quality educational programming that best meets physicians' needs and is accessible and affordable for all practitioners," according to the report.

The report recognized that "it is not always feasible, or necessarily desirable, for professional education to disengage from industry completely." In the cases where industry funding could not be avoided, "vigorous efforts must be made to mitigate the potential influence of financial relationships." ■