The government is increasing enforcement of health-care regulations governing physician behavior. A recent settlement against a pharmaceutical manufacturer for its business arrangements with physicians should remind ACR members to monitor their relationships with the medical industry. Avoid legal pitfalls when considering whether and how to interact with a particular medical device or drug company.

A pharmaceutical company in late December 2012 settled false claims allegations that it violated the federal anti-kickback law by using sporting event tickets, spa outings, and other remuneration to induce physicians to write prescriptions for its products. Victory Pharma, Inc., a San Diego–based specialty pharmaceutical company, became one of Uncle Sam’s latest enforcement statistics. The company agreed to pay more than $11 million to resolve federal charges that it violated the federal anti-kickback law and False Claims Act (FCA).¹

Additionally, prosecutors maintained that Victory encouraged its sales representatives to initiate paid “preceptorships,” in which they shadowed physicians in their offices. Victory also settled claims that it used the preceptorships to motivate physicians to prescribe its products.

A former sales representative for Victory filed a lawsuit against the company in federal court. The local United States Attorney’s Office, with the Department of Justice and the HHS Office of Inspector General (OIG), assumed control and coordinated the government’s investigation and prosecution. Under the qui tam, or whistleblower, provisions of the FCA, this individual will receive a portion of the recoveries that the government makes — in this case, that share is about $1.7 million.

This case didn’t involve radiologists or radiation oncologists. So what’s the big deal for ACR members? Most manufacturers have stopped dispensing perks such as sports tickets, spa outings, and lavish dinners. And as long as your practice has a compliance plan that it keeps current, your legal risk should be fairly low, right? Yes to all points. However, with each settlement of fraud and abuse charges, the government reinforces that it will target economic and clinical arrangements of physicians, including radiologists and radiation oncologists. Several cases in the last five years illustrate that medical imaging and radiation therapy are no exception.

Most recently, the government took over a whistleblower suit against a major medical imaging vendor. The government contended that the company wrongly billed for services that certain physicians did not properly supervise as claimed. Ultimately, a federal court ruled in late 2011 that the imaging provider violated the FCA and was liable for $11 million in damages.² However, an appellate court recently overturned that decision. It ruled that the government cannot allege that failure to meet carrier supervision requirements constitutes a false claim.

The court noted that the government instead should have attempted to exclude the vendor from participating in federal health-care programs. This reversal may cause the government to adjust how it pursues certain fraud cases. Yet radiologists and their imaging centers still must comply with applicable supervision rules in order to be paid at all.

In addition, an imaging practice in Washington state ran afoul of the Stark self-referral law. After it self-disclosed conduct to the OIG, the practice agreed in 2010 to pay $155,000 for allegedly violating the Civil Monetary Penalties Law provisions related to the Stark law. The OIG alleged that the group provided certain outpatient radiology services to Medicare beneficiaries based on orders written by physicians who were immediate family members of three individuals who held indirect ownership interests in the practice.³

Failure to comply with Medicare billing and documentation rules also damaged a Nevada imaging practice. The OIG charged that the group intentionally defrauded Medicare by improperly providing diagnostic tests to Medicare beneficiaries without the required treating physicians’ orders. Additionally, the OIG alleged that the group billed for certain tests under CPT® codes that medical records did not support. This practice settled the case in 2009 for $2 million, one of OIG’s largest settlements under its civil monetary penalties law.⁴

Yet another example of radiology’s version of “Law & Order” occurred in 2008. A Florida MRI practice settled an FCA case that focused on the practice’s arrangements with referring clinicians. Prosecutors maintained that the radiologists offered clinicians medical directorships at the MRI sites but did not require the recipients of these posts to perform any duties. They also stated that the clinicians were offered below-market rates on leasing space at the sites. The radiologist-owner agreed to pay more than $7 million individually and on behalf of the imaging centers and related entities.

The Affordable Care Act has boosted the government’s health-care enforcement authorities and resources. In fiscal year 2012, the U.S. Department of Justice recovered more than $4.2 billion in fraud and abuse cases.⁵ Consequently, ACR

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members, like all physicians, will continue to draw federal attention. Radiologists and radiation oncologists depend on industry to help support their vital research and clinical missions. Yet the government’s relentless enforcement approach means that business opportunities that may have been legitimate only a few years ago no longer get a free pass. Practice sound risk management. Assess carefully what is being offered to you and what you may wish to offer to others. //

ENDNOTES

This conversation highlights the dilemma we face in transitioning from volume to value. So many of us are being held to productivity standards that ignore the value of building relationships with physician colleagues and engaging patients. ACR Chair of the Board of Chancellors Paul H. Ellenbogen, MD, FACR, has urged us to think about reducing our so-called productivity to spend more time on radiology citizenship activities that benefit our profession and will strengthen us in the long term. I’ve been fortunate to work with ACR Vice Chair Bibb Allen Jr., MD, FACR, and Richard Duszak Jr., MD, FACR, as well as many others associated with the Imaging 3.0 initiative, which provides radiologists with the tools they need to deliver value at every step in the patient care continuum. (See a special insert in the May Bulletin about Imaging 3.0 at http://bit.ly/InteractiveImaging3.)

Twitter is not just @KimKardashian and @KanyeWest. It’s an excellent way to follow the health-care conversation, not just for radiology but for health care in general. As more of us participate, it can become an effective way to communicate our message of value-based imaging care to our fellow radiologists and beyond.

As always, I’d love to hear your feedback. Please contact me at gmcginty@acr.org or on Twitter (@gmcginty). //

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the full spectrum of practice types, from the major academic center to the rural independent practice, can offer excellent imaging care and that it’s important that each practice be supported. Obviously, a major concern for graduating residents and fellows is how this type of consolidation affects their career prospects.

Climbing to New Heights at the RLI Expedition
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the expedition, each group presented its proposal to hospital management. Once again, we had an opportunity to role-play. Dr. Drayer was the hospital COO, Dr. Sherry acted as the CEO, and I played the role of CMO. We peppered each group with questions and concerns about its proposal. Although there was some anxiety among the groups, all of them responded to the challenge with great results!

This was an amazing experience for all those present. I hope I have captured at least some of the realism and timeliness of the simulation. The RLI Expedition was fun, informative, and unlike anything I have ever experienced. //