PERSPECTIVE:
Physician-Industry Compliance Advisors

Navigating the Modern Physician-Industry Relationship

Steven J. Cagnetta, Esq, and Steven K. Ladd of Primacea describe the problems and pathways for physicians to manage their industry relationships under the bright lights of the Sunshine Act.

Particularly in device-based fields such as vascular intervention, strong, productive working relationships between physicians and industry have long been a normal if not essential component of the innovation process. From inventing a new device to providing expertise on how it might be improved or best used, physicians interact with industry in a variety of ways, often receiving paid compensation for their time and work or being provided with meals or travel expenses. While ordinarily understood to be of value by many within the field, public and political scrutiny has increased in recent years, and legislation now dictates that all financial ties be disclosed publicly, online.

Primacea is an organization aiming to work with physicians and hospitals to efficiently and appropriately manage their relationships and collaborations with industry. In order to better understand the Sunshine Act and what it means for physicians, we spoke with company founders Steven J. Cagnetta, Esq, and Steven K. Ladd.

How would you briefly summarize the background of the Sunshine Act, specifically, when and why it came into existence?

The federal government actually has a long history of overseeing physician-industry relationships. The intended purpose then (and now) was to maintain public trust in the health care system. Previously, the federal government relied on laws under Stark, the Anti-Kickback Statute, and the False Claims Act as a basis for such oversight.

The Act itself was first introduced in 2007 as the Physician Payment Sunshine Act. Although the proposed legislation never made it into law, both PhRMA and AdvaMed supported the proposed legislation. During this same period, a few states had enacted laws requiring financial disclosures and banning gifts to physicians (some even precluded cups of coffee). The issue picked up steam in 2008 with high-profile congressional investigations of physicians at Harvard, Stanford, UCLA, Texas, Wisconsin, Minnesota, Emory, and Cincinnati relating to their consulting work. At the same time, a number of public interest groups, including the Prescription Project and ProPublica, published the results of their own research, which focused substantial media attention on the issue. In 2009, both the Medicare Payment Advisory Commission and the Institute of Medicine issued reports recommending that Congress require all medical companies to report their financial relationships with physicians and that the information be provided on a public website.

The Sunshine Act was eventually incorporated into the Affordable Care Act, which became law in 2010. The final federal regulations were announced on February 1, 2013, by the Centers for Medicare & Medicaid Services (CMS).

How has the Sunshine Act changed from its initial proposals to the current iteration that was announced in February 2013?

The Act itself closely matches its original draft, although much of the implementation was left to future regulation by CMS. During the process of devel-

oping regulations, CMS received more than 300 public responses, which led to 76,000 words in the final regulations. This indicates how complex implementing the law will be.

What are some of the critical take-home messages of the Sunshine Act?

When talking to physicians, we tell them to judge every engagement using "*The New York Times* test." In other words, if you are not comfortable with the relationship being described on the front page of *The New York Times*, you should avoid it.

The next thing we tell them is that it is more than just entering into a solid legal relationship. CMS estimates that industry and hospitals will spend hundreds of millions of dollars annually to comply with the Act. Unfortunately, none of these expenditures will necessarily protect a physician. Every payment that physicians receive, directly or indirectly, will be reported on a publicly searchable website. Unless a physician has the tools to accurately record and track these relationships, he or she could find that they are ill-prepared in the event that questions arise about the work they do. In short, physicians need to take responsibility for their own compliance.

By what means must physicians publicly report any payments they receive from industry? And, by when?

Physicians are not required to publicly report the payments they receive. The public reporting requirements are held by industry. However, the information being reported is about individual physicians, and there is no guarantee that industry will get it right. The good news is that the Act provides physicians with a 45-day window to review and potentially dispute any payment. For physicians, taking the time to review what is reported and potentially dispute inaccuracies could play a big role in avoiding potential problems and negative publicity. This includes conflicts that could arise from disclosures made to hospitals, societies, and journals. Even if physicians do not believe that such public disclosures matter, there will be plenty of regulatory bodies, journalists, and other interest groups who do.

What kinds of financial exchanges must be reported? Are research grants, travel for speaking engagements and proctoring, and paid consultantships all treated the same way? What about meals and entertainment?

To keep it simple, physicians should assume that every financial exchange must be reported. CMS requires the payments to be reported by category. There are 15 such categories, including consulting fees, meals, travel, speaking at continuing medical education events, etc. Meals are part of the reporting requirement, except in limited circumstances like coffee or buffets at conferences.

One aspect in particular is worrisome to physicians. Investigators on research and trials run by their hospitals will be publicly "credited" with the payments that, in many cases, exceed $1 million, even if all the money went to their medical institution.

One point that is often not understood by physicians and hospitals is that industry must report reimbursed expenses even if there is no actual compensation involved. As a result, a physician may see a report of a $3,000 payment from a company, although all the physician did was get reimbursed for travel, hotel accommodations, and a taxi ride to an event where her or she gave a speech without any compensation.

What are the reporting responsibilities on the part of industry?

Industry must report payment data to CMS by April 1. At present, physicians may review and potentially dispute any reported payments through May 15. Updated final reports are due by June 1. The key point here is that physicians have the opportunity, either directly or through their representatives, to dispute the accuracy of the disclosures. Many physicians have told us that inaccurate reporting is a major concern for them.

What kinds of responses are you seeing from physicians regarding the stipulations in the Sunshine Act?

Overall, the data indicate that physician collaboration on new drugs and devices is dropping. One study showed that it is down 50% over a 5-year period. When we speak to physicians, we hear that many are contemplating whether to give up working with industry because they do not have the tools to ensure that they will remain in compliance and worry about the impact it could have on their careers.

Do you anticipate that some hospitals will enforce their own stricter regulations?

Yes, that has been the trend ever since the Institute of Medicine report. Many hospitals are adding more reporting obligations, which result in added burdens to their already overwhelmed physicians. We know of one hospital that actually banned all paid interactions between their physicians and industry. They worry about the negative publicity that could arise from a misunderstanding regarding disclosures and from studies that

show physicians had reported only half of their industry relationships.

Several hospitals, however, have told us that they see significant opportunities in the current environment. Institutionally, they want to stand out as leaders in ethical cooperation with physicians and industry. We have spoken to a number of them about the tools needed to make that happen.

Have you seen any particular impact on medical innovation?

As you know, much of medical innovation occurs in the startup community. Many of these companies are in the same position as physicians, as they do not have the resources of the big companies and hospitals to spend millions to manage compliance issues. As a result, we believe that many of these companies will be looking for services that provide streamlined and cost-effective compliance tools.

Where does AdvaMed fit in with the Sunshine Act? Are these complementary forces?

AdvaMed greatly enhanced its code of ethics in 2009. Our experience is that member firms take it very seriously. AdvaMed provided CMS with feedback on the proposed Sunshine regulations in three critical areas. First, AdvaMed requested the ability to provide descriptive context on the payments. Second, it pointed out that research payments could be subject to duplicative reporting. Third, AdvaMed suggested simplification to accounting for meals.

How does the Sunshine Act affect state-by-state regulations, such as states that have previously required more reporting and/or fewer financial ties to industry?

Sunshine supersedes state laws, except when state laws are more stringent. The practical result is that some states, including Massachusetts, have begun to adjust their regulations to try to conform with Sunshine. Unfortunately, there are still many complexities between state and federal laws, which we suspect will continue for some time.

In what ways has the physician-industry relationship changed in the past 10 years?

What has changed is society's view of these relationships and the regulations on how they must be conducted. These relationships are subject to much greater scrutiny than in the past, and the stakes are much higher.

What has not changed is that physicians still play a huge role with innovations in medications and medical devices that have significantly improved the lives of patients. These innovations include neurointervention, recanalization, renal denervation, and below-the-knee intervention.

What needs to change in the future is that physicians must make sure that they understand the rules and comply with them. They need to use a transparent system that withstands public scrutiny and maintains public trust.

How do you think it will change in the short term? In the longer term?

In the short term, public scrutiny will affect many more physicians and their hospitals, as Sunshine allows anyone with Internet access to investigate any physician's activities. Every payment will be reported in detail, and there will be many opportunities for the public to misinterpret these payments. Frankly, physicians doing good work may be viewed as "bad guys" unless they are prepared for this new environment.

Longer term, physicians will realize that they have been operating in a highly regulated and very public environment without any of the legal, accounting, staff, and other resources that their industry allies rely on. As physicians recognize that it's simply not safe to operate on their own, they will seek out these resources through their employers.

What is Primacea, and what are its goals?

Primacea provides physicians with the tools they need to continue the work they do to advance medicine. These tools will soon be available through the hospitals in which they work. We believe that providing accurate data and increasing transparency will provide enhanced public trust and provide physicians with the credit that they deserve for their critical work.

What is the most important piece of advice Primacea is giving physician clients right now?

Physicians need to take these regulations seriously and run their consulting practices like a business. The good news is that there are legal pathways available, and if they engage the appropriate resources, they can successfully continue providing these critical services. ■

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