Sunshine and scrutiny

Managing compliance with the ACA's Sunshine provisions from a provider perspective

By David M. Aafedt, JD, and Christianna L. Finnern, JD

The "Sunshine Act" certainly sounds pleasant, but don't be fooled by the name. It is a powerful tool for prosecutors. The Physician Payments Sunshine Act was signed into law by President Obama in March 2010 as part of the Patient Protection and Affordable Care Act (ACA), and will take effect Jan. 1, 2013. The act requires drug and device companies to report almost any payment or transfer of value to physicians of over $10. These reports will be made publicly available on a government website, and recipients of such payments will be identified by name. There are large fines for each unreported payment, so drug and device companies have incentive to be thorough in their reporting. The Sunshine Act also makes it much easier for prosecutors to identify transactions that violate these federal statutes, including the federal Anti-Kickback Statute (AKS), the False Claims Act, and Stark Laws.

The Sunshine Act is a game changer

With unprecedented breadth and transparency, the Sunshine Act requires pharmaceutical, device, biological, and other medical supply companies whose products are paid for by government health care programs ("covered manufacturers") to report payments or transfers of value to physicians or teaching hospitals for consulting, nonconsulting services, honoraria, gifts, entertainment, travel, food, research, charitable contributions, royalties or licenses, ownership or investment interests, faculty or speaker compensation, grants, and anything else required by Health and Human Services (HHS). There are several exceptions to the reporting requirements, including payments under $10 (or $100 aggregated annually), product samples, educational materials for patients, certain medical device loans, warranties, discounts or cash rebates, transfers of value to physician patients, charity care items, dividends from a publicly traded security fund, employee health care coverage, nonmedical professional services, and legal services. HHS will make this reported data publicly available on a government website.

The act requires drug and device companies to report almost any payments or transfer of value to physicians of over $10.

The first report is due March 31, 2013. The reports will identify the covered recipient by name, and both covered manufacturers and covered recipients have 45 days to correct any information provided to HHS before it is made public. Covered manufacturers face large fines for each unreported payment—up to $100,000 for each instance, meaning that drug and device manufacturers are unlikely to be noncompliant. Nevertheless, physicians should guard themselves against inaccurate reports; but, more importantly, they should identify and eliminate risky transactions with drug and device manufacturers. Though physicians are not subject to fines under the Sunshine Act, they are subject to civil and even criminal penalties under the AKS, the False Claims Act, and the Stark Law. Increased transparency under the Sunshine Act may allow prosecutors to identify transactions that violate these federal statutes.

Now that federal prosecutors will have easy access to the details of almost every payment made to physicians from covered manufacturers, physicians who intentionally or inadvertently walk the line in their relationships with these companies may end up on the wrong side of the law. Beyond being armed with knowledge and honestly identifying risky arrangements, physicians must also take practical steps now to prepare for more "sunlight" and to navigate the still-evolving rules of the game.

Existing federal law interaction with the Sunshine Act

The state and federal reporting requirements are sure to garner heightened scrutiny, not only by the press and public, but also regulators and prosecutors. The AKS prohibits any remuneration to physicians for speaking, travel, consulting, or other services if the payment is intended to induce the physician to prescribe a medication or device that is paid for by Medicare or Medicaid. If a physician knowingly or willfully solicits or receives payments, it is a felony under the AKS and carries civil penalties. Under the ACA, AKS violations can result in False Claims Act violations, which carry criminal and civil penalties of $5,000–$10,000 per violation.

Physicians should take steps to insulate themselves from liability by understanding and strictly adhering to these requirements, including the AKS "safe harbors" described by the Office of Inspector General (OIG), which protect certain payments and business arrangements from criminal and civil

SUNSHINE *to page 18*

Sunshine *from page 14*

prosecution. This applies equally to the Stark Law, which prohibits referrals by physicians to entities in which they or their immediate family members have a financial interest. [The Sunshine Act could implicate Stark because it requires public disclosure of physician investment or ownership interests in drug or device companies.] These federal laws mean that the increased transparency required by the Sunshine Act carries big implications for physicians.

Minnesota's Physician Gift-Ban Act and federal law

Practitioners in Minnesota already have experience with sunshine laws. In 1993, Minnesota became the first state to enact laws regulating gifts to providers from pharmaceutical manufacturers or wholesale drug distributors. The law defines "practitioner" to include doctors of medicine, doctors of osteopathy duly licensed to practice medicine, as well as doctors of dentistry, optometry, podiatry, and veterinary medicine (Minn. Stat. §151.01, subd. 23, 2011). The Physician Gift-Ban Act bans gifts from manufacturers or wholesale drug distributors, or their agents, to "practitioners," excluding such things as drug samples, items with a combined retail value of less than $50 (per calendar year), payments to medical conference sponsors, and reasonable honoraria.

Under the law, companies must file a publicly available annual report to the Board of Pharmacy (Board), detailing payments to identified recipients totaling over $100 per year to sponsors of educational programs, for honoraria, or for professional or consulting services. Requests for access to the data have been few, and Minnesota's reporting requirements are far less stringent than the Sunshine Act, meaning that Minnesota physicians who receive payments from device manufacturers will face a new level of scrutiny when the federal Sunshine Act reports are published (see Joseph S. Ross et al., Pharmaceutical company payments to physicians: early experiences with disclosure laws in Vermont and Minnesota, JAMA 2007; 297(11):1216, 1218).

Prepare to face the light

Physicians must prepare for the Sunshine Act's implementation by understanding the specifics of their interactions with covered manufacturers and identifying all areas of potential risk, including consulting agreements, purchasing deals, research funding, speaker honoraria, and the like. High-volume providers or physicians on formulary committees should be especially vigilant because they are enticing targets for prosecutors looking to make headlines. In addition, physicians should take practical steps now to prepare for the new disclosure rules.

Practices should prepare a Sunshine Act compliance policy, including, for example, a hard dollar limit on payments from covered manufacturers, recognizing that patients, competitors, and prosecutors now have access to the records of these payments. If the physician is confident that all arrangements with a covered manufacturer are legitimate and represent fair market value, existing arrangements may be safe. Substantial consulting agreements and purchasing contracts for drugs and equipment must be evaluated for fairness. A legal opinion may be advisable for large contracts. A copy of the compliance program should be attached to consulting agreements, and, most importantly, a physician should objec-

Highlights from an interview with Minnesota's "Physician Gift-Ban" regulator

We recently had the opportunity to interview the person responsible for administering and enforcing Minnesota's "Physician Gift-Ban," Cody Wiberg, PharmD, the executive director of the Minnesota Board of Pharmacy (Board). Here are key takeaways from the interview:

- Minnesota has never taken action against anyone for improper or inadequate reporting, or for failure to report. To Dr. Wiberg's knowledge, there have not been any major reporting issues warranting discipline.
- The Legislature has not provided the Board with resources to audit the reports and compare them with the actual payments made by regulated companies, so it is possible that some reports are inaccurate.
- Notwithstanding the absence of funding, the Board does not believe any large companies are noncompliant.
- If the Board did find that a smaller company did not report, the Board would likely not discipline the company but simply send a letter asking the company to comply.
- The Board has never disciplined a company for violating the partial gift ban.
- Dr. Wiberg noted that, candidly, it would be difficult to uncover violations of the law unless a competitor of the company alerted the Board or if there was a whistleblower at the provider's office, clinic, or hospital.
- Dr. Wiberg believes the partial gift ban and the publicity surrounding it has changed the behavior of companies within the state. He believes that companies are no longer providing dinners to physicians at educational/promotional events and are no longer providing lunches.
- After an article appeared in the Journal of the American Medical Association, the Board received numerous requests for the payment reports from doctors, clinics, and hospitals all the way back to the date the law took effect. Dr. Wiberg said that physicians were concerned to see what was publicly reported about their relationships with companies.
- Dr. Wiberg is often asked whether the partial gift ban and reporting requirements led to an increased use of generic drugs. He said that while the state Medicare agency has seen increased prescriptions for generic drugs (he said generic drugs make up 70 percent of the total, versus 60 percent a few years ago), he is not sure it is because of this particular law because there are so many variables at play.

tively assess whether his or her prescribing habits could appear to be influenced by any such arrangements.

As with many state and federal laws, a Sunshine Act compliance policy can be a mitigating factor if a violation occurs. But merely having a policy is not enough. If, during the course of an investigation, an employee cannot describe the policy—or, worse, does not know of the policy—the practice may as well not have one at all. Practice managers and physicians must set the tone from the top; employees should be trained on the policy when they are hired, and trained and tested on it periodically thereafter. The behavior of the entire staff either implicates or protects physicians from liability under these statutes.

Although employee satisfaction is often overlooked as an issue relating to compliance, creating a positive atmosphere where employees feel supported and appreciated is a smart compliance strategy for physicians to employ. If employees do leave, exit interviews should be conducted and any concerns immediately addressed. Other-wise, disgruntled employees can become *qui tam* plaintiffs.

Physicians must take practical steps now to prepare for more "sunlight" and to navigate the still-evolving rules of the game.

Designating a single point of contact to control and monitor practice interaction with drug and device companies is another practical way to facilitate compliance with the Sunshine Act. This person can police interactions and track remuneration passing to each physician. For example, although physicians have 45 days after data is reported to HHS to submit corrections, physicians should request and review this data well before it is reported. This will allow physicians more time to evaluate the data before it is made public and immediately address inaccuracies.

Kickbacks from sales representatives historically have been problematic and will be even more so under the Sunshine Act. Physicians must be brutally honest in assessing relationships with sales representatives, and must be careful to avoid kickbacks or the appearance of a kickback. For example, a medical education conference in Las Vegas may be legitimately aimed at education, and Las Vegas may be the most cost-effective location for the drug or device company to hold the conference. But if it looks inappropriate, physicians should either step away or clearly document why it is in compliance with federal law.

Take control now

The Sunshine Act's reporting requirements do create additional risks for physicians. Physicians should not rely on the reports by the drug and device companies, but should verify that the information being supplied is correct before the reports are even published. Physicians should take control now, by arming themselves with knowledge, evaluating their arrangements with covered manufacturers, and taking practical steps to ensure their compliance with federal law.

David M. Aafedt, JD, *is a shareholder at Winthrop & Weinstine, PA, where he practices in the areas of health care regulatory law and health care litigation. As a former Assistant Attorney General, he represented the Minnesota departments of commerce and health.* **Christianna L. Finnern, JD**, *is a shareholder at Winthrop & Weinstine, PA, and focuses her practice on health care regulatory compliance and complex commercial and health care litigation.*

The authors acknowledge and thank Elizabeth R. Malay for her valuable assistance with this article.