

5 Tips For An Airtight Approach To ACA Sunshine Rule

By **Jeff Overley**

Law360, New York (June 10, 2013, 10:14 PM ET) -- Less than two months remain before drug and device makers must report virtually every item of value — from speaker’s fees to pastrami sandwiches on rye — that they provide to doctors and teaching hospitals, and experts say compliance with the Affordable Care Act mandate will require extraordinary communication among the parties and plenty of technological muscle to gather data.

Law360 surveyed attorneys for their tips on abiding by the Physician Payment Sunshine Act, also known as Open Payments, and came away with five essential moves to avoid more than \$1 million in potential annual penalties and to remain in regulators’ good graces when the policy takes effect Aug. 1.

Make Your Plans Crystal Clear

There’s a good deal of uncertainty in the final rule released earlier this year regarding what types of compensation must be reported and how their values should be calculated, and the Centers for Medicare and Medicare Services is accepting “assumptions documents” in which companies explain how they’re interpreting things.

“The government is saying, ‘Hey, in good faith, give it your best shot — we’re not here to second-guess you,’” said Robyn S. Shapiro, a health partner at Drinker Biddle & Reath LLP.

In the final rule, CMS promises it won’t use any details from the documents to go after manufacturers. Although the agency reserved the right to punish improper reporting even if it’s mentioned in the document, corporations that make their assumptions clear might come away better positioned to argue that they lacked ill intent.

It’s “a prophylactic measure where the government says, ‘Wow, you didn’t report this, but ... we see why this was subject to interpretation and why you did it this way,’” Shapiro said.

Be Up Front With Patients

With certain exceptions for samples, rebates and educational materials, cash or merchandise worth at least \$10 must be reported. While patients are unlikely to care if their doctor's office was treated to a spread of coffee and maple bars from Dunkin' Donuts, they very well might raise an eyebrow if their physician is raking in fat consulting fees from a pharmaceutical company while prescribing that company's products in abundance.

Glenn Engelmann, vice chair of the life sciences group at McDermott Will & Emery LLP, said doctors who have close working relationships with drug and device companies will have to help their patients understand why those interactions are beneficial.

"The challenge is going to be, for both physicians on the one hand and companies on the other hand, to put this information in context," Engelmann said. "If you look at the drug or device development process, there's an important role for physicians to play. ... It would be a shame if that interaction is disrupted and misconstrued as a result of the data being published."

One way to go about explaining the situation would be to double down on transparency by including a page on a doctor's website explaining how and why they partner with private companies in the life sciences industry, Shapiro said. Similarly, to get everything out in the open, physicians could place brochures in their waiting rooms describing their work with the drug and device sectors.

Kathleen McDermott, a compliance expert at Morgan Lewis & Bockius LLP, said patients respect when doctors work with drug and device companies for the bona fide purpose of improving care, viewing it as evidence of their practitioner's expertise, but only if the arrangement appears to be aboveboard.

"It is important for doctors to understand that patients want this information and don't view it negatively," McDermott said. "[They are] receptive to doctors working with industry and just want to know about it."

Forget the Exceptions and Record Every Payment

While compensation worth less than \$10 is exempt from the reporting requirement, every item — no matter how valuable — must be reported if total payments to a physician tops \$100 in a year.

McDermott said that low threshold seems "administratively punitive," given that such meager payments seem unlikely to raise ethical concerns, but that its presence might nonetheless lead corporations to curtail luncheons and other small-scale affairs out of reluctance to trouble with the associated recordkeeping.

That said, the low ceiling is the law of the land, and so it makes sense to just collect everything instead of ignoring smaller payments in hopes of not crossing the \$100 mark, Engelmann said.

"Companies, I think, would be well-served to track all payments, [because otherwise], they're running the risk that they're not going to be in compliance," he said.

As with the assumptions documents, the rationale is that playing things safe will end up saving companies a lot of regulatory and administrative headaches. That cautious approach also extends to gauging the value of merchandise or deciding when an item is covered by a sunshine rule exemption, said Karen Lovitch, head of the health practice at Mintz Levin Cohn Ferris Glovsky and Popeo PC.

“The exceptions are clear as mud,” Lovitch said. “So, companies are going to have to make a judgment call.”

“Given that it’s a brand-new initiative ... I would suggest being conservative until manufacturers can see how the program plays out,” she said.

Get Your Technological House in Order

While understanding what payments are covered will be challenging, companies might find it even more demanding just to track and organize those payments, McDermott said.

It is “so much a technical issue in terms of collecting and tracking data, and less of a traditional compliance issue,” she said.

The final rule projected that the sunshine rule will cost industry \$269 million during the first year and \$180 million afterward. Factors going into that estimate include training, sorting through data and the need to “build and maintain the reporting systems, including the development of new information technology systems,” CMS wrote.

Larger companies are likely to face complicated landscapes as they attempt to monitor spending to the same physicians not only across departments but also across various subsidiaries.

“You really have to set up a separate database and have your system feed into that somehow,” Engelmann said. “There’s a huge IT finance infrastructure issue here [that] I think has been underestimated.”

Clear Communication Is Key

There is a process for resolving disputes between doctors and manufacturers over the size of payments, but one way to avoid things coming to that is being clear from the start about the value of merchandise, experts say.

Similarly, a lot of hassles will probably be avoided if everybody’s up to speed on the data that’s being reported. Doctors can register with CMS to receive updates on submissions, allowing them to take full advantage of a 60-day window for disputing and correcting information before it’s published.

Also, corporations should provide a reliable point of contact to every physician on their payroll. That will reduce misunderstandings and help keep disagreements from blossoming into full-blown regulatory scraps, McDermott said.

“It’s important for all companies — small, medium and large — to have a communication strategy with the physician,” she said. “Nobody wants to be in a dispute process.”

--Editing by Sarah Golin and Jeremy Barker.