Device firms adjust to increased payment disclosure

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Mark DuVal's law firm has been busy teaching medical device and drug makers how to obey the Physician Payments Sunshine Act.

It is no easy task, says DuVal, a Minneapolis attorney who used to work for Medtronic Inc. and 3M Co.

New federal reporting requirements that began Feb. 18 are complicated and eventually will include public disclosure of most business expenditures to medical professionals valued at more than $5 per event or more than $100 cumulatively per year.

Thousands of companies across the country fall under the act, which arose from concerns that patient treatment was influenced by undisclosed financial relationships between drug and device makers and health care providers.

"There are things the medical community just doesn't realize are going to be reported," said DuVal, whose firm DuVal & Associates has conducted daylong Sunshine Act seminars for more than 100 companies. "Things they consider innocuous."

Businesses as well as group purchasing organizations can now be fined $1,000 to $100,000 per violation for not properly revealing their financial ties to doctors, dentists, podiatrists, optometrists, licensed chiropractors and teaching hospitals.

Health care professionals, meanwhile, fret because inaccurate disclosures may cause them undeserved criticism and hurt their reputations with patients.

Risks of discrepancies between what companies say they gave health care providers and what those same providers believe they got are high. A recent Yale Medical School study compared voluntary disclosures of financial relationships on the websites of device makers Medtronic and DePuy with voluntary disclosures by members of a spine doctors association.

More than half of Medtronic's published data did not match with what doctors reported, the study found. At DePuy, the discrepancy rate was 30 percent.

"It goes wrong in both directions," said Dr. Jonathan Grauer, the Yale orthopedics professor who directed the study. "My concern is that people will look at it as trying to hide things. But it's not. It's largely a documentation issue."

For example, Grauer said a company that makes spinal implants reported providing him a meal at a dinner that he knows he did not attend.

Such confusion has companies and health care providers on edge. The government does not resolve disputes between industry and medical professionals, although the government has made available smartphone applications that allow doctors and companies to record and store payments and other "transfers of value" as they happen.

The Centers for Medicare and Medicaid Services also allows members of the medical community to check data between the time companies submit it to the government and the time the government publishes it. During a 45-day window, providers may dispute numbers and negotiate

privately with companies to make changes. If the two sides fail to agree, however, the numbers submitted by industry go public with a notation that the amount remains contested.

Most health care providers are not aware of that, said Anita Griner, who manages Sunshine Act disclosures for the Centers for Medicare and Medicaid Services, or CMS. "The fact that they disputed (data) does not inhibit it from being posted on the public website," she explained.

That is because manufacturers, not doctors, guarantee the accuracy of data and face penalties if they violate the law.

But CMS is "encouraging physicians to ask (companies) for pre-submission review and we are also encouraging manufacturers to offer pre-submission review so the data gets cleaned up even before we get it," Griner said.

The American Medical Association also has advised members to keep careful records and to "ask your industry contacts to provide transfer information in advance for correction before transmitting it to the government."

Two of Minnesota's major med-tech companies - Medtronic and Boston Scientific Corp. - declined requests for interviews about dealing with discrepancies and instead issued statements saying they had updated their record-keeping and reporting systems to comply with the law. A third, St. Jude Medical Inc., did not respond to a request for comment.

LifeScience Alley, a trade group of Minnesota med tech companies, referred the Star Tribune to DuVal.

With registration and submission of overall 2013 data due by March 31 and specific details and legal documents promising accuracy due

sometime between May 1 and Aug. 1, DuVal says anxiety levels in the device and drug industries are rising, especially among medium-sized and small companies.

"Everyone," he said, "is extraordinarily concerned. The rules are so technical that it would be easy to make a misstep. We tell (clients) to make an 'assumptions document' that says, 'This is what we read and how we interpreted it.' "

Griner says CMS won't penalize companies "for submitting a correction. It is no indication that they were derelict in their reporting. Corrections are encouraged."

But the accuracy of the detailed data that goes public Sept. 30 appears to be something of a wild card. "There will be some bumps along the way, no doubt," said David Dvorak, CEO of Zimmer Holdings Inc., a device maker. "Those challenges are going to be driven by the newness of the legislation and clarity and understanding of what it requires in certain circumstances."

Dvorak, who chairs the board of the Advanced Medical Technology Association, called the disclosure requirements "onerous" for businesses of all sizes. The device industry collaborated with the government in formulating the disclosure law because it "is probably the best way to protect our ability to continue to collaborate (with health care providers) in useful ways," he said.

For DuVal, the level of detail in reporting will undermine a generally laudable goal and lead to "slavish government reporting on stuff that really doesn't matter."

Sen. Chuck Grassley, R-Iowa, who pushed the disclosure law along with former Sen. Herb Kohl, D-Wis., countered that "transparency fosters

accountability."

"The Sunshine Act sheds light on an area that left the public in the dark," Grassley said in a statement to the Star Tribune. "Senate investigative and oversight work exposed numerous financial relationships between drug and device companies and doctors that were undisclosed."

Among the most striking revelations was a Senate Finance Committee report that Medtronic paid $210 million over 15 years to doctors who tested and recommended its Infuse spinal fusion product. Injuries allegedly caused by Infuse are the subject of dozens of lawsuits across the country.

The impact of device and drug industry-sponsored research and marketing on patient treatment continues to be a concern, said Dr. Michael Carome, director of medical research at the consumer group Public Citizen. "Transfers of value are intended to affect prescribing behavior," he maintained. "Even small ones."

The Sunshine Act does not outlaw those transactions, he added. It merely illuminates them.

"There are a variety of ways you can vet your physician," Carome said. "This will be another one."