

Docs Fear For Reputations Under Final Sunshine Rule

By **Rachel Slajda**

Law360, New York (February 07, 2013, 6:55 PM ET) -- Doctors concerned that their reputations could be damaged by inaccurate public reporting of payments they've received from drug and device makers did not find much relief in the final version of the physician payment sunshine rule, which offers doctors little time to dispute information before it's published.

The final rule, released last week, leaves a window of 60 days for physicians to review and dispute the payment information submitted by manufacturers, and to agree on corrected information, before the information is published.

Ahead of the final rule, doctors' groups lobbied the Centers for Medicare & Medicaid Services for a longer review time, as well as a chance to publicly rebut or block disputed information from being published.

CMS did not oblige.

"Did the doctors get what they wanted? The answer's no," said Robyn Shapiro, a health care partner at Drinker Biddle & Reath LLP.

Doctors are concerned that the database could include inaccurate information or accurate data without enough context, such as large payments for research activities that don't go into the doctor's pocket but to the research itself. That could harm their reputation among patients and colleagues or in the press, if they're represented as having received more from drug companies than they actually did.

"They're worried it's going to look like they're on the take," Shapiro said.

Under the final rule, information submitted by drug and device makers detailing payments and gifts they made to physicians and teaching hospitals will be published in a new CMS database once a year. After the submissions are made, physicians and teaching hospitals will have 45 days to review and, if they choose, formally dispute the information. They and the manufacturer will have the rest of the 45-day period, and another 15 days, to resolve the dispute before the information is published online.

If the dispute is not resolved in time, and experts say with such a short window some arguments are likely to remain unresolved, the disputed amount will still be published, with a flag denoting that it has been disputed by the recipient.

"There's, frankly, not a lot of time to do it," said Brian Dunphy of Mintz Levin Cohn Ferris Glovsky & Popeo PC.

Physicians had urged CMS not to publish disputed data. The agency rejected that request, saying it would create an incentive for doctors to dispute payments solely in order to block them from public view.

Doctors had also wanted CMS to publish the recipient's version of the correct payment amount alongside the manufacturer's, or to publish some sort of rebuttal from the recipient. But CMS ultimately said only the manufacturer's data will be represented in disputed cases.

"The result of that dispute is what should be ultimately reported. Then patients can make a fair judgment," said Shari Erickson, vice president for governmental and regulatory affairs for the American College of Physicians, which lobbied CMS on these issues.

The doctors' concerns snowball when one considers that CMS does not plan to update the database more than once a year. If a doctor and drugmaker, for example, cannot resolve a dispute in the 60-day window before publication, the drugmaker's version of the payments will be published, as disputed. Even if the parties reach a resolution quickly thereafter, the information will likely not be updated until the next year.

CMS took pains to make clear that, in large part, its hands are tied by statutory deadlines and limited resources.

Although CMS agreed that it should update the database more frequently, the agency said it did not have the resources to do so. The statute, part of the Patient Protection and Affordable Care Act, requires an update at least once a year.

"It's not often the agency says, 'We're sympathetic,'" said Jason Caron of McDermott Will & Emery LLP.

Caron said that in order to get the changes they want, doctors would have to go back to Congress for a legislative fix — a daunting proposition when the lobby is focused on replacing Medicare's sustainable growth rate and protecting Medicare from cuts during deficit reduction talks.

Some doctors had also called on CMS to get involved in mediating disputes. But again the agency demurred, saying it does not have the resources to do so. Instead, regulators said they would monitor the number of disputes, with an eye out for manufacturers with a high rate of disputes, especially disputes that go unresolved.

Some experts sought to temper the doctors' fears. Caron pointed out that the manufacturers have plenty at stake in getting their numbers right. They must attest to their submissions, which carries legal implications, and could face penalties for inaccurate or incomplete information. Their reputations among doctors could also be affected by a high rate of bad submissions.

"Everybody's reputation is on the line. Everybody wants to get it right," Caron said.

Kathleen McDermott, a partner at Morgan Lewis & Bockius LLP, argued that patients actually prefer a doctor who's prominent in research activities.

"Patients like it when their doctors are involved with industry on education, research and innovation. They like their doctors to be experts," she said. "Patients are not negative on these relationships as long as they know about them."

--Editing by John Quinn and Katherine Rautenberg.

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