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## *Conflict of Interest*

### **Final ‘Sunshine’ Rule Will Increase Industry Burdens, Boost Transparency, Attorneys Say**

**T**he health care industry can expect an increase in administrative burdens as a result of the physician payment “sunshine” final rule, which was released Feb. 1, but patients will gain a greater level of transparency into industry transactions, health care attorneys told BNA.

Kirk Nahra, an attorney with Wiley Rein, Washington, said the final rule will create significant burdens for various components of the health care industry.

“At the end of the day, there is a real question as to whether the positive value of this transparency (particularly given all of the other fraud-related restrictions on the kinds of payments involved here) is worth the additional burdens and potential risks for certain kinds of activities [such as research] that may benefit the health care system and patients overall,” Nahra said.

The Centers for Medicare & Medicaid Services released the final rule, which implements Section 6002 of the Affordable Care Act, a provision that requires manufacturers of drugs, devices, and other medical supplies to report certain payments provided to physicians or teaching hospitals. Data collection starts in August under the final rule. CMS is scheduled to post the data publicly Sept. 30, 2014.

The information that will be made publicly available includes information about physician ownership or investments in applicable manufacturers and group purchasing organizations (GPOs).

The final rule was published in the Feb. 8 *Federal Register* (78 Fed. Reg. 9,457).

In addition to increasing administrative burdens for the health care industry, Wiley Rein’s Nahra also said it was uncertain whether patients will find the transparency information useful, “or whether most patients will know or care about the information.”

He also said there was a concern that the information will be used primarily by lawyers seeking to challenge relationships between physicians and drug and device manufacturers.

**Costs Versus Benefits.** Kirk Ogrosky, an attorney with Arnold & Porter, Washington, and former deputy chief of the Fraud Section in the Department of Justice’s Criminal Division, also told BNA that the burdens imposed by the final rule may exceed the benefits.

“Unfortunately, the final rule’s burdens on industry creates a structure where the cost appears to far outweigh the potential benefit,” he said.

Ogrosky said he was concerned that patients would not be fully capable of utilizing the transparency information in a productive manner, and he said the information might discourage patients from getting necessary treatments.

“I hope that CMS takes great strides to help explain the import of the data, since it is potentially putting people at risk at great cost to industry,” Ogrosky said.

**Improved Transparency.** Kathleen McDermott, an attorney with Morgan, Lewis & Bockius LLP, Washington, acknowledged that there will be implementation challenges for both the health care industry and CMS. She added, however, that overall, the final rule will benefit the public.

“These regulations will not cause patient harm,” McDermott said. “Transparency generally is a benefit to the public and patients.”

She said the final rule took into account many industry comments and CMS has committed to a frequently-asked-questions process that has been helpful in the past with certain state agency transparency compliance.

McDermott said implementation challenges will include how detailed the disclosures are.

“There is always a question on whether the granularity of these disclosures really advances meaningful disclosure,” she said. “Patients do not care about pizza and bagels and buffets any more than prosecutors do.”

McDermott also said there could be a “potential negative concern for protecting research initiatives.”

**Teaching Hospital Provision Lacks Clarity.** Laurence Freedman, an attorney with Patton Boggs LLP, Washington, told BNA that the final rule was helpful in clarifying some of the transparency requirements facing the health care industry.

For example, Freedman said that moving the implementation date to August 2013 “helps give industry time to review the rule, train compliance officers and their sales team, and prepare for data collection and reporting requirements.”

However, Freedman said he was concerned about the lack of clarity surrounding reporting payments to teaching hospitals, noting that the final rule includes no

list of teaching hospitals, and no way for a manufacturer to determine if a client is part of a complex teaching hospital.

“If this is not clarified, this could have a [detrimental effect on] research and patient care,” Freedman said.

Freedman also said the final rule includes “no reasonable way for a manufacturer to identify indirect payments to covered entities when the manufacturer is unaware of such payment.”

BY JAMES SWANN

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*The final rule (CMS-5060-F) is at <http://www.gpo.gov/fdsys/pkg/FR-2013-02-08/pdf/2013-02572.pdf>.*

*A CMS fact sheet on the rule is at <http://op.bna.com/hl.nsf/r?Open=wpiy-94htpd>.*