

## Medical Device Makers Object to Payment Reporting in Opioid Bill

By Shira Stein

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- Sunshine provision of opioid package would require reporting payments to nurse practitioners and physician assistants
- Medical device makers say new requirements for them wouldn't help combat opioid epidemic

Medical device makers are worried a bill that would require them to publicly disclose payments made to nurse practitioners and physician assistants would increase their regulatory burden without increasing transparency for opioid prescriptions.

The bill (S. 2891), introduced by Sen. Chuck Grassley (R-Iowa), is part of a larger package of 70 bills to combat the opioid epidemic the Senate passed Sept. 17 and would also require drugmakers to make the disclosures. The House and Senate are working on a compromise version of the package that both chambers are expected to vote on in the next two weeks.

The bill is intended to increase the transparency of payments by drugmakers to practitioners who have the ability to write prescriptions and reduce opioid prescriptions.

"Medical devices are wholly separate from opioids, which are a pharmaceutical product. While we support the existing Sunshine law, we do not believe this provision will provide the public with meaningful information and device companies will bear a significant compliance burden," Scott Whitaker, president and CEO of AdvaMed, said in a statement Sept. 17. AdvaMed represents about 300 medical device manufacturers, including Medtronic plc, Baxter International Inc., and Abbott Laboratories.

Nurse practitioners and physician assistants are becoming increasingly important in primary care, especially with their ability to write prescriptions. A 2010 Health Affairs study found that nurse practitioners provided care equivalent to that provided by physicians.

The bill would expand an open payments program run by the Centers for Medicare & Medicaid Services that was created by a physician payments "sunshine" provision of the Affordable Care Act. The program is intended to give the public a look at the financial relationships between industry and physicians.

Drug and device manufacturers are required to report all payments they make to physicians and teaching hospitals, which can include lunches, consulting fees, and plane tickets.

“Without full transparency, pharmaceutical companies can operate under the cover of darkness, possibly using gifts and payments to influence the prescribing practices of medical professionals like nurse practitioners and physicians assistants,” Sen. Richard Blumenthal (D-Conn.), a co-sponsor of the bill, said in a statement May 22. “That’s why it is absolutely essential that pharmaceutical companies disclose gifts and payments made to additional health care providers who prescribe opioids and other drugs—not just doctors.”

The bill would require drug and device makers to collect this information beginning in 2019 and report it in 2020. The bill would also apply to clinical nurse specialists, certified nurse anesthetists, and certified nurse-midwives.

### **Debate About Concerns**

“Of course medical device companies don’t like having to report the money and perks they give to healthcare providers. But Ohioans deserve to know their doctor or nurse is making decisions in their own best interest—not the best interest of the drug and device companies providing kickbacks,” Sen. Sherrod Brown (D-Ohio), said in a statement to Bloomberg Law. Brown is not considering making changes to the bill.

AdvaMed’s concerns are not about this specific bill, they are more about sunshine provisions in general, an aide from Sen. Blumenthal’s office told Bloomberg Law.

AdvaMed is “talking with policymakers to make sure they understand the ramifications of this language,” Matt Wetzel, assistant general counsel at AdvaMed, told Bloomberg Law Sept. 19. AdvaMed hopes the House will look more closely at the bill while it is working out a compromise with the Senate.

Keeping the reporting requirements for drug and device manufacturers uniform may be a reason Congress is including devicemakers in the bill, Wetzel said.

Tracking interactions with physicians is a significant undertaking, Wetzel said. The bill would require even more work by adding nurse practitioners and physician assistants.

### **Program Problems**

AdvaMed wants Congress to fix issues with the open payments program before adding more tracking requirements.

The database the CMS maintains on health-care providers has some errors in the data, which makes complying with the open payments program more difficult, Wetzel said.

The CMS depends on practitioners to update their information with the agency, so sometimes the data isn’t accurate or up-to-date, Wetzel said. This can lead to inconsistencies between the data drug and medical device makers submit to the agency and the agency’s data.

The payment categories the CMS uses don’t match with the medical device industry’s code of ethics, Wetzel said.

Medical device makers are not allowed to give gifts to providers, but any miscellaneous payments are categorized as such. This can be misleading to the public, Wetzel said.

There is also a loophole in the open payments regulations that allows physician-owned distributors to not disclose their payments, Wetzel said. Physician-owned distributors sell implantable medical devices and are owned by physicians.

AdvaMed wants to make sure transparency by drug and device manufacturers is “effective and meaningful,” Wetzel said.

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