

Reproduced with permission from BNA's Health Care Daily Report, 168 HCDR, 8/29/18. Copyright © 2018 by The Bureau of National Affairs, Inc. (800-372-1033) <http://www.bna.com>

Medical Device Makers Eager to Weigh in on Anti-Kickback Law

Medical device manufacturers are optimistic the Trump administration will change anti-fraud policies to allow greater company participation in formal arrangements that coordinate care for patients.

Industry representatives and attorneys told Bloomberg Law they see an opportunity in the Department of Health and Human Services' recent request for information (RIN:0936-AA10) for public comments, asking how the HHS can foster care coordination by modifying or adding safe harbors to the anti-kickback statute, such as making prices for devices contingent on whether patients improve.

Industry group AdvaMed sees the anti-kickback statute as the "top deterrent to more companies getting engaged in value-based arrangements," Terry Chang, associate general counsel and director of medical and legal affairs, told Bloomberg Law Aug. 27. AdvaMed represents about 300 medical device manufacturers, including Medtronic plc, Baxter International Inc., and Abbott Laboratories.

The anti-kickback criminal statute bars "knowing and willful" payments for patient referrals involving Medicare- and Medicaid-covered items and services. Medicare is a major player in the U.S. medical devices market.

New Technologies There's a sense that the existing safe harbors don't take into account new medical device technology, Laura Weidenfeld, a health-care attorney at Jones Day, told Bloomberg Law Aug. 27. Weidenfeld is a former trial attorney with the Department of Justice's civil division working on health-care fraud.

The anti-kickback law is a criminal law, and the safe harbors are provisions specifying payment and business practices that wouldn't be treated as criminal offenses. The Aug. 24 action by the HHS's inspector general's office to seek comments is part of a larger effort from the Trump administration toward value-based care.

The question of potential barriers to integrated care from the anti-kickback statute is typically focused on doctors, so it's important that the HHS is asking the questions of other members of the health-care industry, Troy Barsky, a health-care attorney with Crowell & Moring LLP in Washington, told Bloomberg Law Aug. 24.

Comments are due Oct. 26. This request for information follows RFIs from the administration on topics including the physician self-referral law, known as Stark after its sponsor.

Push From Manufacturers AdvaMed and the Pharmaceutical Research and Manufacturers of America, the leading industry group for brand drug companies, have been pushing changes to the anti-kickback statute since the Affordable Care Act was created, Thomas Bulleit, a health-care attorney at Washington-based Ropes & Gray, told Bloomberg Law Aug. 24.

This RFI is a "step in the right direction in addressing key regulatory barriers to value-based contracts. Value-based contracts for prescription medicines have the potential to lower costs for patients and the health-care system," a PhRMA spokesperson told Bloomberg Law Aug. 27.

Medical device manufacturers have been "made hopeful by this RFI that they may see some new changes," Weidenfeld said. They've been talking with the inspector general's office.

The RFI is separate from an annual solicitation of new safe harbors that the HHS's Office of Inspector General is required to carry out each year, Chang said.

There has been a tension between the Trump administration's push for value-based care and the focus of fraud and abuse regulations on fee-for-service care, Weidenfeld said. The administration is aware of that and trying to do something about it, she said.

Medical device makers try to fit their coordinated care efforts under existing safe harbors, but they were designed for fee-for-service models and don't easily fit into these arrangements, Chang said.

Models from the innovation center at the Centers for Medicare & Medicaid Services have given fraud and abuse waivers to hospitals and physicians who engage in value-based arrangements, but those waivers have excluded device and drug manufacturers.

Preventing Fraud "The issue has been how to make the changes narrow enough to promote better health outcomes without facilitating . . . payments for referrals," Bulleit said.

A potential safeguard against paying for referrals could be asking device or drug manufacturers to accept financial risk for patient outcomes, Barsky told Bloomberg Law. The RFI specifically asked about that, and it follows the Medicare agency's push for sharing in financial risk in the most recent Medicare Shared Savings Proposal rule.

Medical device companies are interested in taking on risk because the physicians they serve want them to do so, Chang said.

AdvaMed has proposed that any arrangements made would be set up in writing upfront before any value is exchanged as a protection against fraud, Chang said.

Cybersecurity The RFI also asks if there are barriers that could prevent or limit donating or subsidizing of cybersecurity and if there is any potential for fraud or abuse.

Cybersecurity is a common issue that Barsky is hearing about now. Providers are worried that having all their electronic medical information on a common platform without a common cybersecurity strategy puts them at greater risk for a hack. There are safe harbors for sharing electronic health records, but not for sharing cybersecurity strategies.

It's important that providers "be able to communicate safely," Weidenfeld said, and that the administration encourage providers to deploy cybersecurity.

There is a safe harbor for hospitals to provide physician offices with electronic health record technology to facilitate care, Bulleit said. The RFI looks at potentially allowing hospitals to do the same thing with cybersecurity measures.

BY SHIRA STEIN

To contact the reporter on this story: Shira Stein in Washington at sstein@bloomberglaw.com

To contact the editor responsible for this story: Brian Broderick at bbroderick@bloomberglaw.com