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HHS Unveils Plan For Kickback, Stark Law Changes

By Adam Lidgett

Law360 (October 9, 2019, 8:09 PM EDT) -- The U.S. Department of Health and Human Services on Wednesday floated a proposal for new Anti-Kickback Statute safe harbors that would shield coordinated-care arrangements among health care providers, and also a proposal to ease Stark Law restrictions on physician referrals.

HHS announced two proposed rules that related to the AKS, which bars anyone in the health care realm from taking a payment in exchange for referrals or making and payment to get a referral, and the Stark Law, which discourages physicians from making referrals that benefit them financially. The Centers for Medicare and Medicaid Services drafted the Stark Law rule and the Office of Inspector General for HHS drafted the Anti-Kickback Statute rule.

According to HHS, the proposals would give "greater certainty [to] health care providers participating in value-based arrangements and providing coordinated care for patients" and would provide more compliance leeway to health care providers.

"These proposed rules would be a historic reform of how health care is regulated in America," Eric Hargan, the deputy HHS secretary, said in a statement. "They are part of a much broader effort to update, reform and cut back our regulations to allow innovation toward a more affordable, higher quality, value-based health care system, while maintaining the important protections patients need."

Under the proposed AKS rule, there would be new safe harbors available, including one for those involved in arrangements meant to enhance "quality, health outcomes and efficiency," according to HHS, with others covering value-based care arrangements that take on serious financial risks.

HHS said under the proposals, specialty doctors and primary care practices would be able to share data analytics tools to benefit shared patients. Under the proposals, hospitals would be able to give cybersecurity software to doctors if the physicians refer patients there, HHS said, and doctors and hospitals could work together better when patients are discharged.

Health care providers have been eagerly awaiting the pair of proposed rules that would support coordination of care among different providers. The coordination is intended to improve outcomes and reduce costs, and the rules are expected to make anti-fraud laws less hazardous.

The OIG in August 2018 acknowledged that various entities — including providers, insurers and

drugmakers — have been urging it to loosen the reins on next-generation models of care, which often contain financial incentives that could be construed as kickbacks.

"It gives us a little more clarification on what types of financial relationships are going to qualify for the exceptions and therefore don't present a problem under the law," Morgan Lewis & Bockius LLP partner Donna S. Clark said of the Stark Law proposal.

Morgan Lewis associate Jacob Harper told Law360 on Wednesday that for the past decade there has been a steady move away from the volume-based health care payment model to a more value-based one.

"It's a pretty substantial step forward in terms of making value-based payment a common aspect of every health care provider's business," Harper said, regarding the AKS proposal.

--Additional reporting by Jeff Overley and Emily Field. Editing by Stephen Berg.

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