

Self-referral, anti-kickback changes: What doctors should know

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Andis Robeznieks

Senior News Writer

The U.S. Department of Health and Human Services (HHS) has released final rules pertaining to efforts to reform regulations related to physician self-referral and the anti-kickback statute (AKS). The reforms aim to advance the transition to value-based care and improve patient-care coordination.

Medicare's physician self-referral law, often called the "Stark Law," has not been significantly updated since it was enacted in 1989—a time when most health care services were primarily paid for on a fee-for-service basis. Since then, both Medicare and the private sector have created many value-based health care delivery and payment systems aimed at addressing the substantial cost growth linked to a volume-based system.

These efforts were generally supported by the AMA as necessary to support better care coordination.

"The Stark Law and anti-kickback statute can have a negative impact on the ability of physicians to assist with coordination because they inhibit collaborative partnerships, care continuity, and the engagement of patients in their care," Patrice A. Harris, MD, MA, said last fall, when she was the AMA's president.

"In certain circumstances, physicians are prohibited from employing care coordination strategies on behalf of our patients," added Dr. Harris, now the AMA's immediate past president. "Instead, patients, in addition to dealing with the physical and emotional aspects of a disease or condition, often find themselves having to coordinate their own care in a fragmented and siloed system."

"Dual regulatory environment"

The AMA commented on proposed self-referral and AKS reforms last December and is developing formal comments on both of the rules.

Meanwhile, it has issued a summary of key issues that indicates several recommendations from the AMA were followed. It also appears, however, that legislative remedies may be needed to achieve the rules' intended results.

“The differences between the two final rules create a dual regulatory environment, where a value-based arrangement could meet the requirements for protection under one law but not the other, which could hinder the transition to a value-based health care delivery and payment system,” the AMA summary states.

The Centers for Medicare & Medicaid Services (CMS), in its final rule on physician self-referral, notes that its reforms “are aligned in nearly all respects” with final value-based definitions on the AKS that were put forth by the HHS Office of Inspector General (OIG), but the agency acknowledged there is an issue.

The CMS rule clarifies that the two sets of regulations “include intentional differences that allow the anti-kickback statute to provide ‘backstop’ protection for federal health care programs and beneficiaries against abusive arrangements” that are “intended to induce or reward referrals.”

This serves to balance the need for parties seeking to develop and implement value-based arrangements that avoid the strict liability referral and billing prohibitions of the physician self-referral law, while ensuring enforcement action can be taken against parties engaging in intentional kickback schemes, according to CMS.

Due to the complexities, however, the AMA summary “strongly recommends consultation with health care counsel experienced in the federal Stark Law and the AKS, as well as the applicable state’s fraud and abuse laws” before taking action on the rules.

Changes to physician self-referral

The rule creates new permanent exceptions to the Stark Law for value-based arrangements.

CMS followed AMA recommendations regarding new definitions for the terms “target patient population” and “designated health services.”

CMS finalized a new exception to protect arrangements involving the donation of certain cybersecurity technology and related services, including certain cybersecurity hardware donations.

In response to AMA advocacy, CMS declined to limit the types of donors protected under this exception; instead, the Final Rule protects all donors. Given the complexity of cybersecurity,

donations may also include training services, such as training a physician's staff on how to use the cybersecurity technology, how to prevent, detect, and respond to cyber threats, and how to troubleshoot problems with the cybersecurity technology. Physicians and their staff may also be provided access to a donor's primary technology help desk (to report cybersecurity incidents, for example).

CMS, however, declined to follow the advice of the AMA and others providing comment to create exceptions specifically for rural and small physician practices entering value-based arrangements.

Anti-kickback safe harbor changes

The AKS rule finalizes and modifies existing safe harbors and creates new ones.

The OIG finalized three new value-based arrangement safe harbors that were generally narrower than the Stark exemptions and aim to protect certain payments among individuals. They vary in terms of the type of remuneration that can be provided, the level of financial risk the parties assume, and the types of safeguards required to satisfy the safe harbor.

Several business entities were declared ineligible to use value-based safe harbors, including: drug manufacturers, distributors and wholesalers; pharmacy benefit managers; and several others. A limited pathway, however, was carved out for certain medical device manufacturers and durable medical equipment companies to participate in protected care coordination arrangements that involve digital health technology.

A safe harbor was established to protect furnishing certain tools and support to patients that serve to improve quality, health outcomes and efficiency in value-based enterprises.

The OIG also expanded allowable mileage for patient transportation in rural areas and patient transportation from inpatient facilities post-discharge.