



CMS NEWS

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CMS Announces Historic Changes to Physician Self-Referral Regulations
Unprecedented additions to regulations that interpret “Stark Law” opens avenues for healthcare providers to ensure patients receive highest quality of care

Today, the Centers for Medicare & Medicaid Services (CMS) finalized changes to outdated federal regulations that have burdened health care providers with added administrative costs and impeded the health care system’s move toward value-based reimbursement. The Physician Self-Referral Law, also known as the “Stark Law,” generally prohibits a physician from sending a patient for many types of services to a provider that the physician owns, is employed by, or otherwise receives payment from—regardless of what that payment is for. The old federal regulations that interpret and implement this law were designed for a health care system that reimburses providers on a fee-for-service basis, where the financial incentives are to deliver more services. However, the 21st century American health care system is increasingly moving toward financial arrangements that reward providers who are successful at keeping patients healthy and out of the hospital, where payment is tied to value rather than volume.

Concerns regarding the Stark rule’s bureaucratic barriers to value were one of the top concerns raised by providers when CMS held listening sessions in 2017 as part of its “Patients over Paperwork” initiative. The millions of dollars and hundreds of hours of time spent complying with the administrative burden of the rule were cited as a significant burden which impeded patient care. With providers taking on the accountability for the total cost of care for their patients, the risks regarding self-referral have changed. However, ambiguities in the Stark law have frozen many providers in place, fearful that even beneficial arrangements might violate the law, which can come with dire and costly consequences. This has resulted in healthcare providers spending millions of dollars complying with arcane regulations instead of putting those dollars toward patient care. It has also impeded the move toward value, not just in Medicare, but across all payers, including Medicaid and private health plans.

“When we kicked off our Patients Over Paperwork initiative in 2017, we heard repeatedly from front-line providers that our outdated Stark regulations saddled them with costly administrative

burden and hindered value-based payment arrangements,” said CMS Administrator Seema Verma. “That sound you hear is the mingled cheers and exclamations of relief from doctors and other health care professionals across the country as we lift the weight of our punishing bureaucracy from their backs.”

With this final rule, CMS is ensuring the regulations interpreting the Stark Law allow for changes that will help modernize the healthcare system. The rule finalizes many of the proposed policies from the notice of proposed rulemaking issued in October 2019, including:

- Finalizing **new, permanent exceptions for value-based arrangements** to that will permit physicians and other health care providers to design and enter into value-based arrangements without fear that legitimate activities to coordinate and improve the quality of care for patients and lower costs would violate the physician self-referral law. This supports CMS’ broader push to advance coordinated care and innovative payment models across Medicare, Medicaid, and private plans.
- Finalizing **additional guidance on key requirements of the exceptions to the physician self-referral law** to make it easier for physicians and other health care providers to make sure they comply with the law.
- **Finalizing protection for non-abusive, beneficial arrangements** that apply regardless of whether the parties operate in a fee-for-service or value-based payment system – such as donations of cybersecurity technology that safeguard the integrity of the health care ecosystem.
- **Reducing administrative burdens that drive up costs** by taking money previously spent on administrative compliance and redirecting it to patient care.

Unless otherwise specified in the rule, all of the provisions in this rule will go into effect 60 days from the rule’s display date in the Federal Register.

Overall this rule will result in better access and outcomes for patients by creating clearer paths for the providers that serve them to do so through enhanced coordinated care arrangements. We have crafted the exceptions to this rule to be narrowly tailored to allow for value based care coordination. At this time, we have retained the strong patient protections from the original law to clearly prohibit referrals that are based solely on financial incentives to the provider. This means patients can be assured that any referrals for care their provider recommends should be based solely on what is in the best interest of the overall health of the patient and not what is most lucrative for the provider.

More information on the final rule may be found at <https://www.federalregister.gov/public-inspection/2020-26140/medicare-program-modernizing-and-clarifying-the-physician-self-referral-regulations>

For more information, please visit: <https://www.cms.gov/newsroom/fact-sheets/modernizing-and-clarifying-physician-self-referral-regulations-final-rule-cms-1720-f>

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