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Final Stark Rule Makes Room for 'Imperfect Performance,' Has VBC Exceptions Like OIG's

By Nina Youngstrom

CMS has finalized its overhaul of the Stark Law regulation with new and revised exceptions that give hospitals a better shot at avoiding or repairing the sort of technical noncompliance that may cause big overpayments or false claims allegations. The regulation, which was published in the Dec. 2 *Federal Register*,[1] created a new limited remuneration exception and modified a special rule for temporary noncompliance, while revamping the definitions of fair market value, commercially reasonable, and volume or value of referrals, which are pillars of many common Stark exceptions.

At the same time, CMS and the HHS Office of Inspector General (OIG), in a companion regulation,[2] found a way they're comfortable with loosening the reins of the fraud and abuse laws to advance value-based care (VBC). New Stark exceptions and safe harbors to the Anti-Kickback Statute shield three types of "value-based arrangements" with relative degrees of compliance obligations depending on their financial risk. The regulations should be compared side by side, because the Stark exceptions are not a mirror image of the safe harbors, said attorney Limo Cherian, with K&L Gates in Chicago. She sees providers walking through new value-based doors if they don't have to take much risk.

"These are really fundamental changes," said attorney Neal Shah, with Polsinelli in Chicago. "Compliance processes probably will be different. If you determine a payment shouldn't have been made, you may have many new tools to deal with it." Sometimes that will free hospitals from self-disclosure or repayment of millions of dollars to Medicare for procedural errors. However, it comes through in the rule that CMS will continue to be conservative about not changing things in a way that creates vulnerability to fraud and abuse, Shah said.

The Stark Law bars Medicare payments for designated health services (DHS) referred by physicians who have a financial relationship with the entity providing the DHS, unless an exception applies. Virtually all the changes in the new regulation take effect Jan. 19, with the exception of some provisions on group practices.

In terms of Stark exceptions, the regulation clarified the definitions of commercially reasonable, fair market value, and volume or value of referrals. CMS now says commercially reasonable means "the particular arrangement furthers a legitimate business purpose of the parties to the arrangement and is sensible, considering the characteristics of the parties, including their size, type, scope, and specialty." Even if nobody profits, the arrangement may still be commercially reasonable. That's big news because CMS is saying an arrangement can be commercially reasonable even if it results in losses. That seems to strike a blow at the premise of False Claims Act lawsuits that contend hospitals violated the Stark Law when they accepted losses on physician practices in exchange for their referrals.