

Report on Medicare Compliance Volume 30, Number 24. June 28, 2021 Value-Based Stark Exceptions, Safe Harbors Are Put in Play; Hospital Gives App to M.D.s

By Nina Youngstrom

Six months after new regulations cleared the way for value-based arrangements (VBAs) with far less fear of violating the Stark Law and Anti-Kickback Statute (AKS), health care organizations are contemplating how to put them to use and in some cases pulling the trigger. There's a lot of interest in capitalizing on three new exceptions for value-based care in the revised Stark Law^[1] and similar safe harbors under the AKS,^[2] which took effect Jan. 19, attorneys said.

"We are looking at them in the context of things like clinical co-management and gain sharing, and I am looking now at the management of difficult-to-transfer patients," said attorney Larry Vernaglia, with Foley & Lardner in Boston. "That's the playground for the new value-based enterprises and safe harbors."

One arrangement that recently came to life falls under the Stark exception for VBAs and another new safe harbor for patient engagement tools and supports, according to attorneys Robert Miller and Charles Oppenheim, with Hooper Lundy & Bookman PC in Los Angeles. Under the arrangement, a hospital gives physicians an app for patients with a particular diagnosis. Because the physicians were reluctant to chip in for the app, the arrangement doesn't qualify for a corresponding safe harbor for value-based care that requires physicians to have some skin in the game. Otherwise, though, the arrangement captures the benefits of the path that has been paved for value-based care in the recent regulations from CMS and the HHS Office of Inspector General (OIG), Miller and Oppenheim said.

"This is a good illustration for using VBE [value-based enterprise] exceptions and frameworks," Oppenheim said. "It looks complicated and elaborate, and you envision yourself having to invest a small fortune, but it doesn't have to be that complicated." They pulled it off without having to form a new entity in an agreement that was memorialized in a few pages. "You can have a governing body, committee or one of the parties responsible for monitoring patient outcomes and making sure the goals are satisfied," Miller noted. It's too early to say whether the VBA's objectives are being achieved, but the attorneys are optimistic.

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