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The Transformative Possibilities of the Value-Based Fraud & Abuse Reforms

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In what is likely the most substantial fraud and abuse rulemaking in over a decade, the U.S. Department of Health and Human Services (HHS) Office of Inspector General (OIG) and Centers for Medicare & Medicaid Services (CMS) published on November 20, 2020, long-awaited final rules changing the regulations addressing the Anti-Kickback Statute (AKS) and Civil Monetary Penalties for Beneficiary Inducements (CMP),[1] and the Physician Self-Referral Law (Stark Law),[2] respectively. Commercial payers have played a significant role in the shift to value and the AKS final rule references a study finding that payers that adopted value-based payment models "reduced health care costs by an average of 4.6 percent, improved provider collaboration, and created more impactful member engagement."[3] The final rules significantly reduce barriers for payers and providers to continue to collaborate and innovatively move towards increased risk sharing and other value-based care models.

A new three-tiered Stark Law exception for value-based arrangements and three similar but non-identical AKS safe harbors are generally viewed as the most critical parts of the final rules. For payers, this is doubly so, as the value-based changes should affect payer agreements and arrangements downstream of payer agreements, in each case reducing regulatory barriers to innovative value-based payment models. This increased flexibility appears to reflect a significant opportunity for payers and their downstream providers to pursue bolder value-based arrangements and may constitute a significant tailwind to the evolution away from pure fee-for-service arrangements.

Both rules were part of the HHS Regulatory Sprint to Coordinated Care and are the culmination of a multi-year effort that began with CMS and OIG issuing requests for information in September 2018 and issuing proposed rules in October 2019.[4] The final rules will become effective on January 19, 2021, the day before the Biden administration is sworn into office. Given the generally positive reception from stakeholders and longstanding interest in modifying the Stark and AKS regulations to permit greater utilization of value-based reimbursement, it is not expected that the incoming administration will seek to significantly change these final rules.

Stark Law Value-Based Exception

In finalizing the new exception, CMS touts that it boldly "depart[s] from the historic exceptions to the [Stark Law] in order to facilitate the transition to a value-based health care delivery and payment system."[5] The three tiers of the exception are based on the level of risk borne by the parties to the arrangement, i.e., full financial risk, meaningful downside financial risk (softened in the final rule to a 10% threshold from the proposed rule's 25% threshold[6]), and care coordination arrangements with no or lower risk. Greater flexibility is provided for higher-risk arrangements on the assumption that such arrangements inherently have disincentives to at least partially curb overutilization.

The value-based arrangements exception is built on a series of interwoven definitions such as "value-based activity," "value-based arrangement," "value-based enterprise (VBE)," "value-based purpose," "VBE participant" and "target patient population."[7] The definitions are necessarily formal as CMS and OIG strived to capture a broad universe of potential arrangements between varied types of parties. Yet, straightforward arrangements can readily satisfy the definitional thresholds.

For example, imagine a physician-hospital arrangement—that happens to be downstream of a payer-hospital arrangement focused on high-value care—in which the hospital incented a physician group to enhance the quality of care to surgical patients, including through the postoperative phase, with a goal of improving outcomes such as reducing readmissions. In this example, the payer-hospital arrangement itself likely would not have implicated the Stark Law, but the downstream physician-hospital arrangement would generally need to satisfy a Stark Law exception. Here, the "value-based enterprise" would simply be the miniature 'network' of the hospital and the physician group (as governed by the contract between the parties), the "value-based purpose" would be to improve the quality of care to surgical patients, and the "value-based activity" could be the physicians group's efforts to develop and adhere to redesigned care protocols. Under this new exception, the hospital and physician parties would have greater flexibility in structuring the compensation payable to the physician group, as, for example, the parties would not need to satisfy—at least for Stark Law purposes—the element of 'fair market value,' which does not always cleanly fit into the value-based context. Through the hospital having such enhanced flexibility in aligning incentives in its physician contracting, it might be more willing to enter into a bold value-focused arrangement with the payer in the first instance, as the hospital can now likely be more confident in its ability to perform well under the arrangement with the payer.

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