Value-Based Care Stark Law Exceptions and Anti-Kickback Safe Harbors

Value-based Care

CMS and OIG worked closely to evaluate comments on the proposed regulations and to make consistent changes in the final rules. But, the final value-based care rules do not fully align due to the public policy considerations of the underlying statutes.

Stark Law. Under the Stark Law, CMS created three new compensation exceptions for (1) value-based arrangements with full financial risk for the cost of all patient care (such as, capitation or global budget payments); (2) value-based arrangements with meaningful downside risk to the physician (*i.e.,* not less than 10% of total value of payments to the physician at risk); and (3) value-based arrangements (regardless of the level of risk taken).[1] The exceptions address both the growing trend away from traditional fee-for-service arrangements and toward payments based on the value of the care provided and the specific risks of value-based payment models. The exception for value-based arrangements, regardless of risk level, does include a commercially reasonable standard, but the other exceptions calling for more risk assumption do not include a commercially reasonable standard. None of the new exceptions include typical Stark compensation standards for set-in-advance, consistent with fair market value, or determined in a manner that does not take into account the volume or value of referrals or other business generated. Instead, all of the exceptions require that the payments: (1) must be for or the results from the value-based activities undertaken by the recipient for patients in the target population and (2) must not be an inducement to reduce or limit medically necessary items or services to any patient.

Definitions key to understanding the scope of the new exceptions include a *"value-based purpose"* which is any of the following: (1) coordinating and managing the care of a target population; (2) improving the quality of care for a target population; (3) appropriately reducing the costs to or growth of expenditures of payors without reducing the quality of care for a target patient population or (4) transitioning from more traditional fee-for-service payment mechanisms to mechanisms based on quality of care and control of costs of care for a target patient population. A "*Value-based Enterprise*" ("*VBE*") means 2 or more VBE participants collaborating to achieve a value-based purpose; each of which is a party to a value-based arrangement; that have an accountable body or person responsible for the financial and operational oversight of the VBE; and that have a governing

[1] 42 C.F.R. Section 411.357 (aa).

document that describes the VBE and how the VBE participants intend to achieve its value-based purpose.

Anti-Kickback Statute. In finalizing the three safe harbors for a "*Value-based Enterprise*" ("*VBE*"),[2] OIG aligned in many respects with the CMS approach to the Stark exceptions for key definitions, terminology and structure described above. The VBE safe harbors protect: (1) care coordination arrangements; (2) value-based arrangements with substantial downside financial risk; and (3) value-based arrangements with full financial risk.

But, there are important differences. For example, the care coordination arrangements safe harbor protects on in-kind remuneration. Further, OIG established a list of entities that are *ineligible* under the VBE safe harbors including pharmaceutical makers, distributors and wholesalers; PBMs; lab companies; compounding pharmacies; a medical device distributor or wholesaler; and, with limited exception under the care coordination safe harbor only, medical device or medical supply manufacturer or wholesaler and most DMEPOS seller or renter.[3] Another important difference is that OIG added an additional safe harbor for outcomes based payments with outcomes measures based on clinical evidence or credible medical support.[4]

[2] 42 C.F.R. Section 10001.952 (ee), (ff), and (gg).
[3] 42 C.F.R. Section 1001.952 (ee) (13).
[4] 42 C.F.R. Section 10001.952 (d)(2).