

OIG Proposes Significant Changes to Anti-kickback Statute Safe Harbors to Support Value-Based Arrangements

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In recent years, the U.S. health care system has embraced many models of care reimbursement, such as gain-sharing, capitation and outcomes-based pricing, which predicate payments to providers, payors or manufacturers on clinical or economic outcomes. These "value-based arrangements" seek to incentivize economy and efficacy throughout the supply chain. Value-based arrangements may require the exchange of value by involved parties, either in the form of in-kind resources, such as shared-care coordinators, or technology, such as data analytics tools, or by making payments, such as to reward physicians for successful participation in a gainsharing program or to adjust the pricing of a drug or device in light of clinical outcomes.

For some time now, the industry has complained that the Federal Anti-kickback Statute constrains these relationships by calling into question the legality of transfers of value inherent to the arrangements. In response, the Office of Inspector General (OIG) has released a [proposed rule](#) that would add a suite of additional safe harbors to the Federal Anti-kickback Statute as well as modify existing safe harbors.

The proposed new safe harbors would not protect arrangements involving pharmaceutical or durable medical equipment manufacturers, suppliers or distributors or, indeed, a host of other players (for example, OIG states that it is considering excluding pharmacists and pharmacy benefits managers (PBMs) from participation in these arrangements), and, instead, focus mainly on providers and patients. Apparently because of a desire to include manufacturers of digital and remote monitoring devices, and because of definitional difficulties, medical device manufactures, however, are not specifically excluded at present, although OIG is considering excluding some or all device manufacturers under the final rule. The proposed amendments to the existing warranty safe harbor, however, may be useful to manufacturers seeking to protect value-based arrangements. Also, OIG indicates that it is considering "future safe harbor rulemaking to address specifically tailored protection for value-based and outcomes-based contracting for ... manufacturers."

Below, we review some of the key changes that would be worked by this proposal.

New Safe Harbors Encourage Collaboration between Providers and Payors

Three of the proposed new safe harbors address remuneration exchanged between participants in qualifying value-based arrangements, specifically remuneration paid by payors or providers pursuant to value-based arrangements targeting a specific "target patient population." Under one of these safe harbors—the care coordination safe harbor—only "in-kind, non-monetary remuneration," is protected. Under the remaining two, qualifying payments are permitted, but at least some of the involved providers must assume downside financial risk from a payor, in order for the arrangement to qualify for protection.

These proposed safe harbors utilize the concept of a "value-based enterprise" (VBE), which is a network of two or more individuals and entities that collaborate, via a commercially reasonable written arrangement to achieve one or more value-based purposes, and which is ultimately responsible for conducting the safe-harbored arrangements

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under its "auspices." The VBE would form an "accountable body" to ensure that the participants have a legitimate role in the VBE and in VBE arrangements, that VBE participants are not participants in name only and, particularly, "to ensure that value-based arrangements are aligned with at least one value-based purpose and not misused for purposes that raise program integrity concerns." The OIG has solicited comments on the parameters and scope of the VBE's obligations and responsibilities.

The OIG also specifically solicits comments on whether the definition of target patient population should be limited, for example, to patients with a chronic condition. This and other significant definitional issues including whether an activity must be evidence based, and what that means, obviously could have a material effect on the scope and utility of these safe harbors.

Additional Protection for Patient Support Tools & Local Transportation

As well, the proposed rule includes safe harbor protection for provider-recommended patient support tools, excluding cash or cash equivalents furnished by VBE participants to patients under certain conditions. The proposed rule expands the patient local transportation safe harbor and would work corollary changes to the Civil Money Penalties Act.

Amendment to Personal Services Safe Harbor

With the stated goal of adding flexibility regarding outcomes-based payments to providers, such as shared savings payments, shared losses payments, gainsharing payments, pay-for-performance payments, or episodic or bundled payments made to providers by their employers, the OIG proposes to amend the personal services and management contracts safe harbor to eliminate the requirement that aggregate compensation be set in advance, and substitute the requirement that a methodology for calculating compensation be set in advance.

In a long awaited move, the proposed changes also eliminate the requirement that contracts specify the schedule, length and charge for sporadic, part-time services offered by an agent. However, as with the new safe harbors, OIG proposes to exclude from the allowed outcomes-based payments, "any payments made, directly or indirectly, by a pharmaceutical manufacturer; a manufacturer, distributor, or supplier of DMEPOS; or a laboratory. Such payments would also exclude any payment that relates solely to the achievement of internal cost savings for the principal." The OIG is also considering excluding payments made by pharmacies (including compounding pharmacies), PBMs, wholesalers and distributors.

Amendment to Warranty Safe Harbor

Potentially of use to manufacturers, the rule adjusts the definition of "warranty" (as used in the warranty safe harbor) to, among other things, encompass both items and services so long as the items and services are reimbursed under the same payment (raising an interesting question as to whether the term "same methodology," as used in the discount safe harbor, is intended to connote something other than "under the same payment"), and provides protection for warranties for one or more items and related services.

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CONTACT

Please contact us if you would like assistance in drafting comments to these proposed rules, which will be due 75 days after the rule is formally published in the Federal Register, or have questions about how they might impact your business if enacted.



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