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Drug and Device Makers Suggest Anti-Kickback Safe Harbor Clarifications to Encourage Value-Based Health Care Arrangements

In response to the annual solicitation by the Office of Inspector General ("OIG") of the U.S. Department of Health and Human Services ("HHS") for developing new, and modifying existing, safe harbors to the anti-kickback statute,[1] drug and device makers, and related trade groups, have responded with proposals to provide additional clarity around value-based health care.

The letters suggest both modifications to existing safe harbors (particularly the warranty, discount, and personal services safe harbors) and development of new safe harbors geared directly toward value-based arrangements. Although in the past OIG rejected a proposed modification of the discount safe harbor that would have allowed explicitly for bundled sales of capital and disposable items at a single purchase price,[2] the industry's movement toward value-based health care may suggest that these proposals will receive more sympathetic treatment.

Warranty Safe Harbor

Under the current warranty safe harbor, manufacturers and suppliers can offer a payment under a warranty to cover replacement of their own faulty product, as long as the payment does not exceed "the cost of the item itself."[3] In addition, manufacturers can offer "competitive replacement agreements," under which one manufacturer replaces another manufacturer's defective item that was covered by a warranty. Both the buyer and seller must meet certain disclosure obligations.

In its letter, the Advanced Medical Technology Association ("AdvaMed") proposes changes that (i) expressly would allow product sellers to warrant that their product will produce a clinical outcome, and (ii) would expand the expenses that may be reimbursed beyond just the cost of the product itself. AdvaMed's letter suggests that greater clarity may be needed for an arrangement where a medical device company offers a bundle of items and services to a hospital for a fixed price to achieve a specific clinical outcome, and provides a warranty for that outcome by paying a rebate if the outcome is not achieved.

AdvaMed's letter proposes a new "value-based warranties" safe harbor to provide greater clarity to new arrangements. The proposed safe harbor would incorporate many of the same disclosure obligations as the existing warranty safe harbor, but would make explicit that the arrangements covered under the safe harbor include not just items, but "value-based services." In the alternative, AdvaMed proposes removing the limitation under the existing warranty safe harbor that the warranty may only pay for the cost of the item itself, to allow, for example, payment for follow-up care or clinical outcomes related to the original item.

1 42 U.S.C. § 1320a-7b; 81 Fed. Reg. 95551 (December 28, 2016).
2 OIG Semiannual Report, App. G (April 1, 2004–September 30, 2004).
3 42 C.F.R. § 100.952(g).

Discount Safe Harbor

The current discount safe harbor[4] protects discounts, defined as reductions in the amount a buyer is charged based on an arms'-length transaction. Certain items explicitly are *not* discounts, including cash payments, supplying one good without charge to induce purchase of another (except under certain circumstances), and services provided in accordance with a personal or management services contract. The safe harbor contains a number of disclosure requirements for different types of entities that might be involved in a discount arrangement.

Both the AdvaMed letter and a letter from the Pharmaceutical Research and Manufacturers of America ("PhRMA") propose a new safe harbor based on the discount safe harbor that expressly would allow for (i) price adjustments based on achievement of a measurable clinical or cost outcome and (ii) services to be bundled with a product.

In the alternative, AdvaMed proposes modifying the discount safe harbor to protect value-based arrangements (defined as arrangements where there is a value-based price adjustment conditioned on, or calculated based on, one or more clinical and/or cost outcomes that are associated with the reimbursable items or services being sold) explicitly. PhRMA also suggests a number of additional clarifications to the existing discount safe harbor, such as broadening the definition of buyers from the three existing defined categories of buyers to include other potential buyers, such as payors; clarifying the disclosure requirements for each potential entity in a transaction (*e.g.*, simplifying disclosure requirements, which currently are different for each category of buyer and clarifying whether a seller is responsible for ensuring that a buyer meets the disclosure obligations); and clarifying whether it is permissible for sellers to condition rebates on buyers' performance of certain services (currently, the discount safe harbor states, without perfect clarity, that services provided in accordance with a personal or management services contract are not discounts).

Personal Services Safe Harbor

The personal services safe harbor[5] currently protects personal or management services provided under certain terms, including a written agreement, duration of not less than one year, fair market compensation, and aggregate compensation set in advance.

AdvaMed's letter points out the difficulty that the concept of "fair market value" creates for value-based arrangements, where a significant part of the value may be the outcome. The letter notes that the personal services safe harbor is ill-equipped to address services provided under a risk-based compensation model, where the compensation is tied to outcome and therefore the amount to be paid is not set in advance. Similarly, PhRMA notes that services may change as the buyer's needs change during the arrangement. Both suggest revising the personal services safe harbor to address these issues.

Value-Based Payment Safe Harbor

Taking a more conceptual approach, a letter from a leading medical device company notes that innovative value transfer arrangements differ substantially from arrangements contemplated under existing safe harbors, because the value being exchanged by the parties may not be monetary. Instead, the value may be in kind, such as care coordination, data analytics, and other technology solutions, which do not fit neatly under traditional applications of the existing safe harbors. For example, it may be difficult to determine fair market value for newly established cost efficiency or patient outcomes goals, as well as who derives the benefit from the arrangement. The company proposed that a new safe harbor designed around innovative value transfer arrangements would better enable companies to partner with providers to create value-based healthcare programs. In developing this new safe harbor,

4 42 C.F.R. § 100.952(h).
5 42 C.F.R. § 100.952(d).

the company suggests guiding principles of shared financial risk, transparency, and protection of clinician/patient choice.

Other Proposals

Managed Care. PhRMA suggests clarifying the circumstances under which a drug manufacturer that has a rebate agreement with a health plan or pharmacy benefit manager ("PBM") qualifies for protection under one of the managed care safe harbors.[6] For example, in the safe harbor for price reductions by contractors assuming "substantial financial risk" under managed care arrangements, PhRMA proposes additional text that payments based on clinical, cost, or utilization outcomes could be a payment methodology that puts a contractor at "substantial financial risk," reasoning that this would encourage the types of risk-sharing arrangements designed to be protected under this safe harbor.

PBMs. A pharmaceutical company's letter underscores the increasingly large role PBMs play in the healthcare system, and how they contribute to the efficient negotiation and administration of relationships between pharmaceutical manufacturers and health plans. The manufacturer proposes a new PBM safe harbor to ensure clarity in the relationship between pharmaceutical manufacturers and PBMs, particularly around PBM administrative fees. The new safe harbor would ensure that administrative fees are structured so that they do not improperly incentivize PBMs to refer certain items (through formulary inclusion or other controls) or reward higher priced drugs. Suggested principles include transparency; fair market value fees; fixed administrative fees, not percent of list price; separate negotiation of administrative fees and formulary decision-making; and separation from other PBM business lines. In the alternative, the manufacturer suggests modifying the group purchasing organization safe harbor to reference PBMs.

Adherence; Data Analytics. A pharmaceutical manufacturer also proposes new safe harbors to protect programs encouraging patient adherence to medication, and providing data and data analytics solutions.

Together, these letters demonstrate significant interest by the drug and device maker community in partnering with providers to support the shift from volume to value-based health care delivery, and underscore the important role that OIG can play in clarifying the landscape and promoting these arrangements. Industry will be watching closely to see whether OIG chooses to act on any of these proposals.

[6] 42 C.F.R. § 100.952(m), (t), (u).