Bloomberg BNA

Medical Devices Law & Industry Report™

Value-Based Contracting: A (Critical and Solvable) Rubik's Cube for Manufacturers

BY DONIELLE MCCUTCHEON AND TREVOR WEAR

In recent years—as a result of statements made by the President and others in his administration, government initiatives, and the increasingly competitive healthcare market that is focused on value-based (rather than fee-for-service) arrangements—medical device manufacturers have experienced an interest in responding to this change in environment by offering customers arrangements that involve performance-driven, outcomes-based, or risk-share concepts rather than traditional sales and discount arrangements. However, medical device manufacturers who wish to showcase the benefits of their newest innovation, or who simply want to stand out in a crowded field by pursuing such novel arrangements, face challenges in implementing these arrangements given the current (and rigid) legal framework under the federal healthcare fraud and abuse laws, in particular, the federal Anti-Kickback Statute ("AKS"),[1] which were enacted and implemented decades before this current industry shift. The AKS is particularly relevant to value-based arrangements because it is a very broad, intent-based statute that prohibits medical device manufacturers from providing anything of value (*e.g.*, discounts and services) to their customers with the intent to induce such customers to make referrals or recommendations for the manufacturer's products that may be reimbursed by a federal healthcare program ("FHCP"), such as Medicare or Medicaid.

Given the government's drive to transition its FHCPs toward reimbursement regimes that are based on performance-driven, outcomes-based, and risk-share concepts, the government needs to modernize the existing healthcare fraud and abuse laws to more fully accommodate the government's healthcare agenda, the changing healthcare environment, and industry practices. It seems unfair of the government to establish waivers and other safe harbors that apply only in the narrow context of the government's specific initiatives, *e.g.*, the Medicare Shared Savings Program, and not more broadly to other commercial arrangements, when value-based arrangements are beneficial to healthcare as a whole. As further explained below, such changes

Donielle McCutcheon is an associate in Sidley Austin's Chicago office. Her practice focuses primarily on healthcare regulatory, compliance, and fraud and abuse matters. Donielle regularly advises medical device manufacturers on a wide variety of issues, including coverage and reimbursement, sales and marketing practices, clinical trials, relationships with providers, and transparency reporting pursuant to the federal Physician Payment Sunshine Act and similar state laws.

Trevor Wear is a partner in the Chicago office of Sidley Austin LLP. He is a healthcare lawyer with more than fifteen years of experience in healthcare administration and law. Trevor's practice covers much of the healthcare industry, although he devotes much of his time to counseling pharmaceutical and medical device manufacturers on fraud and abuse and other compliance matters and on coverage, reimbursement, and other strategic issues, both in the U.S. and abroad.

[1] 42 U.S.C. § 1320a-7b(b).

need not be dramatic. In fact, a few tweaks to the current regulatory structure would have a significant impact on the types of arrangements that manufacturers could more readily execute with customers. However, recognizing that any meaningful regulatory change would take significant time and that the industry's value-based focus is not going away, we also offer below considerations that manufacturers should keep in mind when evaluating and pursing such arrangements under the current legal framework.

The Government's Value-Based Initiatives

Based, in part, on the view that fee-for-service reimbursement systems ''contribute to waste in health care by encouraging unnecessary utilization and fragmented, poor quality care,''[2] the government has implemented a number of value-based initiatives. For example, the Centers for Medicare and Medicaid Services (''CMS'') Innovation Center was established by the Affordable Care Act (''ACA'') with the express purpose of ''test[ing] innovative payment and service delivery models to reduce program expenditures . . . while preserving or enhancing the quality of care.''[3] The Innovation Center solicits input from interested parties and selects models based on a variety of criteria, including reducing costs and improving quality of care.[4] One Innovation Center initiative is the Bundled Payments for Care Improvement (''BPCI'') initiative, which consists of four models that categorize patient services into episodes of care.[5] Medicare's reimbursement practices differ by model, but generally, Medicare pays hospitals based on episodes of care, rather than on a fee-for-service basis, and depending on the model, the hospital can receive further payments if its care is delivered at a lower cost than CMS estimates.[6] Another Innovation Center model is the Comprehensive Care for Joint Replacement program, which ''hold[s] participant hospitals financially accountable for the quality and cost of'' a hip or knee joint replacement surgery and recovery by comparing the hospital's actual fee-for-service expenses for the episode against Medicare's episode price and issuing an extra payment to the hospital or requiring that the hospital repay Medicare for any difference.[7] The Secretary of the Department of Health and Human Services (''HHS'') has authority to waive certain requirements under the Medicare and Medicaid programs to facilitate these innovative initiatives.[8] These initiatives are part of the Obama administration's goal of tying 50% of Medicare payments to quality and value through alternative payment methods by 2018.[9] CMS reports that it is actively analyzing data from these initiatives with the aim of, among other things, identifying quality and process improvements.[10] The data gleaned from these programs will likely lead to broader implementation of bundled and episode-based payment methodologies under FHCPs.

Similarly, the ACA established the Medicare Shared Savings Program, which permits groups of providers to collaborate in providing care for Medicare fee-for-service beneficiaries through Accountable Care Organizations (''ACOs'') and to receive certain shared savings that may result from the coordinated care.[11] In connection with this program, Congress has permitted the HHS Secretary to waive requirements of specific fraud and abuse laws as necessary to facilitate the ACOs.[12] Accordingly, on November 2, 2011, CMS and the HHS Office of Inspector General (''OIG'') jointly published an interim final rule establishing specific waivers and acknowledging the tension between the ACA's value-based initiatives and the pre-existing fraud and abuse laws: ''the Secretary has determined . . . that it is necessary to waive certain provisions of the Physician Self-Referral Law, the Federal anti-kickback statute, the Gainsharing [Civil Monetary Penalty], and the Beneficiary Inducements [Civil Monetary Penalty] in some circumstances to carry out the Shared Savings Program.''[13] The rule established five waivers to address different circumstances, such as a pre-participation waiver applying to the start-up phases of an ACO, a broad waiver that applies to ACO-related arrangements during the ACO's participation under the Shared Savings Program, and a waiver applying to the distribution and use of shared savings payments earned under the Program.[14] On October 29, 2015, CMS and OIG finalized the Medicare Shared Savings Program waivers with the exception of the waivers of the application of the Civil Monetary Penalty law provision relating to ''gainsharing,'' as the HHS Secretary determined that this was no longer necessary in light of legislative changes that occurred after the publication of the interim final rule.[15] According to CMS, as of April 2015, the Medicare Shared Savings Program included 404 Shared Saving Program ACOs and 7.3 million assigned beneficiaries in 49 states plus Washington, D.C. and Puerto Rico.[16]

---

[2] OIG, Management Challenge 2: Transitioning to Value-Based Payments for Health Care, https://oig.hhs.gov/reports-and-publications/top-challenges/2013/challenge02.asp.

[3] Pub. L. No. 111-148, 124 Stat. 389 (codified at 42 U.S.C. § 1315a (2012)).

[4] 42 U.S.C. § 1315a(a)(3) & (b)(2). *See also* CMS, Model Design Factors, http://innovation.cms.gov/Files/x/rfi-websitepreamble.pdf.

[5] CMS, Bundled Payments for Care Improvement (BPCI) Initiative: General Information, http://innovation.cms.gov/initiatives/bundled-payments/.

[6] *Id.*

[7] CMS, Comprehensive Care for Joint Replacement Model, http://innovation.cms.gov/initiatives/ccjr/.

[8] 42 U.S.C. § 1315a(d)(1).

[9] Press Release, CMS announces additional participants in pilot project to improve care and reduce costs for Medicare, Aug. 13, 2015, https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2015-Press-releases-items/2015-08-13.html.

[10] *See, e.g.*, CMS, BPCI Fact Sheet, https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2015-Fact-sheets-items/2015-08-13-2.html. In fact, in February 2015, the agency published report detailing the first year of the BPCI. LewinGroup, CMS BPCI Initiative Models 2-4: Year 1 Evaluation & Monitoring Annual Report (prepared for CMS), Feb. 2015, https://innovation.cms.gov/Files/reports/BPCI-EvalRpt1.pdf.

[11] Pub. L. No. 111-148, 124 Stat. 395 (codified at 42 U.S.C. § 1395jjj (2012)).

[12] 42 U.S.C. § 1395jjj(f) (2012).

[13] CMS and OIG, Medicare Program; Final Waivers in Connection With the Shared Savings Program; Interim Final Rule, 76 Fed. Reg. 67992, 67993 (Nov. 2, 2011).

[14] *Id.* at 67993.

[15] CMS and OIG, Medicare Program; Final Waivers in Connection With the Shared Savings Program; Final Rule, 80 Fed. Reg. 66726 (Oct. 29, 2015).

[16] *See* CMS, Medicare Shared Savings Program Fast Facts (April 2015), https://www.cms.gov/Medicare/Medicare-Fee-for-

   ISSN 1935-7230

Overview of Manufacturer Initiatives

Medical device manufacturers' customers, typically hospitals and other providers, are often subject to the government's growing number of value-based reimbursement initiatives. Additionally, the products manufactured by medical device companies are usually paid for by FHCPs through packaged or bundled reimbursement models. For these reasons, and in light of the myriad of government value-based and risk-sharing initiatives, medical device manufacturers should be (and several forward-thinking manufacturers are) developing novel contracting strategies that align with and leverage these performance-driven concepts. Such contracting strategies offer manufacturers a way to negotiate with customers on something other than greater discounts and rebates, and they can take many forms. For example, there are two basic models for manufacturer risk-share offerings. Under the first model, the ''downside'' model, the manufacturer agrees to return a portion of the product purchase price to the customer in the form of a rebate if the customer fails to achieve certain expected cost savings or clinical performance goals through the use of the manufacturer's product. Under the second model, the ''upside'' model, in exchange for reduced upfront pricing on a product, the customer will remit additional payment to the manufacturer (perhaps even in an amount that results in the customer paying the full, undiscounted amount of the product), if the customer achieves certain cost savings or clinical performance goals, or both. These arrangements may or may not involve the manufacturer also providing information and analysis designed to improve the function of the customer's clinical or cost control systems, *e.g.*, care pathway development and episode-based performance analysis. Under some contemplated arrangements, the manufacturer may also provide services in the form of on-site assessments and implementation support, which, in many cases, are intended to ensure the customer realizes improved results through the use of the manufacturer's technology. For purposes of illustration, a manufacturer may offer a large hospital system a significant discount on one of its medical technologies that is used in the hospital inpatient setting and has been proven to reduce patients' length of hospital stay associated with certain admissions, under an agreement that requires the customer to make additional payment to the manufacturer, if the customer achieves reduced inpatient stays for the applicable admissions as a result of the arrangement with the manufacturer.

Other value-based or risk-share arrangements include, for example, contracting arrangements where the manufacturer offers a customer a ''per procedure'' bundled fee on all of the devices needed in the service related to a particular Diagnosis Related Group (''DRG''). For example, this might include all of the devices needed for a total joint replacement. Similarly, a manufacturer may offer a customer a cap on the amount the customer will spend with respect to certain procedures if the customer agrees to almost exclusively use the manufacturer's products for the selected procedure. Pursuant to other arrangements, a customer may only pay for a product if the patient has a positive response to the therapy. Like those discussed above, these arrangements may also involve a service component, such as a requirement that the customer provide certain data to the manufacturer or that the manufacturer analyze certain aspects of the customer's operations and make cost-savings recommendations, which better ensures that the performance or outcomes goals of the arrangement will be met.

Misalignment with Current Legal Framework

While it is clear that many medical device manufacturers are ready and willing to implement (and a number of manufacturers have already implemented, albeit in a more limited fashion) these novel arrangements that align incentives across the industry and are responsive to the government's stated goals of moving toward value-based healthcare, there is misalignment between the policy goals and programs and the underlying legal framework, which potentially creates risk for medical device manufacturers exploring these arrangements.

From an AKS perspective, given the breadth of the statute, there are a number of statutory exceptions and regulatory safe harbors to protect arrangements in the marketplace that the government wants to encourage but that would otherwise implicate the law (*e.g.*, discounts and warranties), but the more innovative, cost-saving arrangements that the industry should be moving towards do not often fit well within the currently available exceptions and safe harbors. Specifically, a trilogy of recent enforcement actions involving pharmaceutical manufacturers[17] have left many in the industry wondering whether it is now the government's view that discount arrangements that involve a service or performance component fall outside the AKS discount safe harbor, despite the fact that such a position would be a significant departure from longstanding government guidance. Given that many of these novel arrangements include the provision of data and/or consulting services, which are often tied to the discounts and rebates offered by the manufacturer and may also include discount or rebate triggers that are tied to something other than product purchases (*e.g.*, a patient health outcome), many are concerned that the government might fail to recognize discount safe harbor protection for such arrangements.

Further, similar to the government programs discussed above, much of the cost-saving achieved under these risk-share and value-based programs is due to the manufacturer bundling a suite of items and services and offering the entire package at a reduced price to the customer. However, the ''same methodology'' limitation under the AKS discount safe harbor, which limits bundled discounts only to arrangements where the items or services at issue are ''reimbursed by the same [FHCP] using the same methodology,''[18] also creates a

Service-Payment/sharedsavingsprogram/Downloads/All-Starts-MSSP-ACO.pdf.

[17] *See, e.g., U.S. ex rel. Lisitza and Krammerer v. Johnson & Johnson*, Nos. 07-10288, 05-11518, Compl. of the U.S. (D. Mass Jan. 15, 2010); *U.S. ex rel. Lisitza and Krammerer v. Johnson & Johnson*, Nos. 07-10288, 05-11518, Transcript of Motion to Dismiss, at 25, 27, 59-60 (D. Mass Oct. 7, 2010); *see also U.S. ex rel. Banigan and Templin, et al. v. Organon*, No. 1:07-cv-12153-RWZ, 3rd Am. Compl., (D. Mass. Sept. 7, 2010); *see also U.S. v. Novartis Pharmaceuticals Corp.*, No. 1:11-cv-08196-CM, Amended Complaint-in-Intervention (S.D.N.Y. Jan. 8, 2014).

[18] *See* 42 C.F.R. § 1001.952(h)(5)(ii).

hurdle for manufacturers, as these arrangements often tie together products and services that are used in different procedures or different settings, which makes compliance with this safe harbor requirement challenging.

While usually addressable, many manufacturers also struggle with how to make the price concessions under these arrangements transparent to the FHCPs, consistent with the reporting and disclosure requirements under the discount safe harbor.

Manufacturers may also look to structure their innovative arrangements to satisfy other AKS safe harbors, such as the personal services, equipment rental, or one of the managed care safe harbors, but it is often difficult to design an arrangement that meets all of the technical elements of any safe harbor, and the government has previously advised that ''multi-purpose'' arrangements will need to be structured so that each purpose meets a safe harbor.[19]

Given the severe penalties under the AKS, and the related liability under the False Claims Act, it is no surprise that many manufacturers have been reluctant to implement these arrangements, and as a result, the healthcare system fails to realize the potential efficiencies and cost-savings that can be achieved. While there are existing value-based and risk-share arrangements that are structured to comply with current law, absent a modification to the legal and/or regulatory regime, it is likely that many manufacturers will continue to refrain from proceeding with such arrangements or will resign themselves to implementing only limited versions of such arrangements, leading to lost cost-saving opportunities for the system, minimal improvement in patient care, and, very likely, fewer sales for manufacturers.

A Possible Legal or Regulatory Fix?

While we believe that value-based and risk-share arrangements can be designed to comply with current law, they can be further encouraged and even more readily adopted, if adjustments are made to the current regulatory structure. Addressing the legal challenges manufacturers face in implementing value-based and risk-share arrangements would not require an overhaul of the healthcare fraud and abuse laws. Rather, as the government has already done with respect to its own programs, namely the CMS Innovation Center and Medicare Shared Savings Program, the government could simply implement limited waivers to the existing fraud and abuse laws and regulations to provide additional flexibility to manufacturers. Another possible consideration is for OIG to issue a new safe harbor under the AKS for certain value-based arrangements among industry stakeholders. Specifically, such a safe harbor could resemble other safe harbors and permit arrangements where, among other things, (i) the terms of the arrangement are set forth in a written agreement executed between the parties, (ii) all remuneration exchanged between the parties is documented and reviewable by the government upon request, (iii) the arrangement is consistent with current standards of medical care and protects against both inappropriate reductions in services and overutilization, (iv) written disclosure of the arrangement is provided to all patients whose care may be affected by the arrangement, and (v) no reimbursement is sought from a FHCP for any ancillary services offered in connection with the arrangement. Such an approach would align with many of the safeguards articulated by OIG in the numerous advisory opinions the agency approved with respect to gainsharing between hospitals and providers.[20] Like other existing safe harbors, this safe harbor could be narrowly tailored to permit only those arrangements that present a low likelihood of fraud and abuse.

Considerations for Working under the Current Regime

Recognizing that a legal fix, if implemented, will take some time, there are a number of considerations medical device manufacturers should keep in mind as they evaluate such arrangements, including those listed below. However, each arrangement requires a case-by-case analysis to ensure the arrangement is structured to align as closely as possible with existing law and guidance.

- Structure the arrangement to fit within an available AKS exception or safe harbor, which could mean, for example, defining the value at issue as a discount or rebate tied to the purchase of the product that meets the discount safe harbor, even if the discount or rebate is triggered by a clinical or economic outcome.
- Include robust ''compliance with laws'' language in the applicable agreement, including a provision that preserves the provider's independent clinical judgment and protects the best interest of patients, in part, to address potential corporate practice of medicine issues and tort theories of liability, as well as healthcare fraud and abuse concerns.
- To the extent the contemplated arrangement will include the provision or receipt of ancillary data, analysis, or other service components that are directed to the customer, consider designing such aspects of the arrangement as a separate service arrangement, consistent with the AKS personal services safe harbor.[21]
- Arrangements that involve, or could be perceived as involving, switching (*i.e.*, transitioning from a competitor's product to the manufacturer's product) should be carefully considered, particularly if the manufacturer's product is more expensive and/or less clinically appropriate for certain patients.
- Consider the inclusion of robust audit rights to permit the manufacturer to validate the accuracy of any data or other information provided under the arrangement, and where such audit rights exist, exercise the right when and if there are questions or concerns about the data and performance under the arrangement.
- Consider launching the arrangement on a pilot basis, particularly if this is the first such arrangement entered into by the manufacturer, that pro-

[19] OIG, Anti-Kickback Provisions; Final Rule, 56 Fed. Reg. 35952, 35957 (July 29, 1991).

[20] *See, e.g.*, OIG Ap. Op. No. 07-21 (Dec. 28, 2007); OIG Ap. Op. No. 05-1 (Jan. 28, 2005), OIG Ad. Op. No. 01-1 (Jan. 11, 2001).

[21] 42 C.F.R. § 1001.952(d).

  MELR ISSN 1935-7230

vides a means for the manufacturer to get out of the arrangement after a specified time period in case there is any issue from a compliance, business or other perspective.

- Depending on the arrangement, a manufacturer may wish to seek an advisory opinion from OIG. This was the approach many took with respect to gainsharing arrangements prior to OIG's 2014 proposed rulemaking in which the agency stated that gainsharing arrangements were not an enforcement priority for the agency unless the arrangement lacked sufficient patient and program safeguards.[22]

- Evaluate other legal considerations, including, but not limited to, laws impacting product promotion, insurance, and patient privacy.

There is strong momentum throughout the industry to transition to value-based compensation for healthcare items and services. This is something that payors (particularly, the government) are demanding and others in the industry are expecting. Medical device manufacturers are not exempt from this industry-wide shift. While there are legal hurdles that the government should address, the healthcare industry is already moving to value-based arrangements, in large part, at the hands and encouragement of the government. Therefore, to compete successfully in this evolving industry, medical device manufacturers should carefully consider whether such arrangements make sense for them, given their products and customers, and evaluate how best to implement value-based and risk-share arrangements in a manner that meets their business objectives and minimizes the potential fraud and abuse risk.

[22] OIG, Revisions to Safe Harbors Under the AKS, and Civil Monetary Penalties Rules Regarding Beneficiary Inducement and Gainsharing; Final Rule, 79 Fed. Reg. 59717, 59729 (Oct. 3, 2014).