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Impact of Value-Based Health Care on the Medical Device Industry: Three Takeaways From the Case for Transformation

Introduction: The Case for Transformation

In the world of fee-for-service health care, most medical devices were sold to hospitals or other health care providers for use in the diagnosis or treatment of patients. Except in the case of durable medical equipment, health insurers rarely paid for the devices separately. Historically, the principal aim of the medical device maker was to provide a quality product at a price point that would still allow the purchaser to derive a profit in connection with the procedure in which the device was used. The device maker had little need to concern itself with the other costs of the procedure, or with whether the procedure improved the patient's quality of life. Those were the concerns of the physician, the hospital, and the post-acute care providers, such as inpatient and outpatient rehabilitation facilities.

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The increasing focus on Value-Based Health Care (VBC) creates a paradigm shift for medical device companies as VBC aims to make providers increasingly accountable for positive patient outcomes by conditioning some part of the providers' payments on such outcomes. The initial and more straightforward VBC parameters have included reduced rate of infection or re-hospitalization for complications from the surgical implantation of a cardiac or orthopaedic device. Increasingly, however, VBC goes well beyond these parameters and seeks to measure the longer-term effects of a patient's recovery, including whether the intervention leads to an enhanced quality of life.

For example, the Medicare Shared Savings Program (MSSP) is a voluntary program that encompasses four tracks in which gainsharing is available for each track, and two-sided risk-sharing and prospective payments are phased in depending on the track.¹ Health care providers, principally hospitals and physicians, join an accountable care organization (ACO) where they agree to share in a single payment for qualifying procedures. ACO participating providers are paid on a fee-for-service basis during the performance year and are eligible for gain (or risk) sharing based on the ACO's overall performance against cost and quality metrics. MSSP quality has two elements – successful reporting and actual performance; during year 1 of an ACO, the reporting thresholds are minimal, and require only complete and accurate reporting across all required measures, with performance against specific benchmarks phased in over subsequent years.² For the 2017 performance year CMS specified 31 measures across four domains: patient/caregiver experience, care coordination/patient safety, preventive health and at-risk population.³

¹ See Centers for Medicare & Medicaid Services, "Medicare Shared Savings Program Quality Measure Benchmarks for the 2016 and 2017 Reporting Years" (Dec. 2016), <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/MSSP-QM-Benchmarks-2016.pdf>

² *Id.*

³ *Id.*

Similarly, Medicare's voluntary Bundled Payment for Care Improvement initiative offers four potential care models to health care providers that enter into payment arrangements in which the provider is accountable for financial and performance outcomes for Medicare beneficiaries.⁴

During the Obama administration, the Center for Medicare and Medicaid Innovation (CMMI) created several more far-reaching programs in which participation was to be mandatory for providers treating specified conditions.⁵ The fate of mandatory programs through CMMI is somewhat uncertain due to President Trump's antipathy towards the Affordable Care Act,⁶ as well as the stated opposition of Secretary of Health and Human Services Tom Price to mandatory programs of this kind.⁷ However, while Secretary Price has delayed the start date of new mandatory bundled payment programs, as yet none have been terminated and in his congressional hearings spoke favorably about limited scope pilot and voluntary programs. Moreover, there is broad consensus among industry stakeholders that both public and private VBC initiatives should continue.⁸

Faced with this new reality, medical device makers confront new challenges and new opportunities. As payers impose financial risk on providers for delivering better long-term outcomes, device makers will be faced with cost pressures making profitability from device sales alone more difficult to achieve. The winners in this environment must learn to work with customers to control costs and improve patient outcomes. Answering this challenge presents new opportunities, as companies increasingly are sharing downside risk with their customers in connection with the performance of their products, acquiring or creating consulting or management capabilities in order to offer customers a complete solution to the procedures in which their devices are used, and even vertically integrating by investing in the health care delivery system. This is uncharted waters for many if not most device companies, requiring the development of new expertise and also navigating new legal and regulatory hurdles.

Data will play a key role in the transition to VBC, particularly data aggregation and de-identification services, the use of predictive analytics, and the sharing of data to improve quality of care and clinical outcomes. Those medical device companies that are already in a position to offer valuable data expertise and analytic capability to providers will benefit the most. Of course, the increased reliance on data presents a number of challenges – under HIPAA, under state laws regarding personal information, and under pre-existing contractual restrictions. Device makers must assess how they can use, disclose, and share this data with their customers and even internally between their device-focused units and their service-focused units.

From our vantage point in advising some of the companies at the forefront of this transformation, we offer a few important take-aways for next generation medical device makers in the world of VBC.

Take-away #1: Device Makers Will Become Risk-Bearers

Often the first and easiest step for a device maker is to start sharing the risk of patient outcomes with its customers. In the world of the expensive, implantable devices that are widely used in the Medicare population – particularly

⁴ See generally Centers for Medicare & Medicaid Services, "Bundled Payments for Care Improvement (BPCI) Initiative: General Information" (Apr. 6, 2017), <https://innovation.cms.gov/initiatives/bundled-payments/>.

⁵ See, e.g., 80 FED. REG. 73274 (Nov. 24, 2015) (lower extremity joint replacement bundles); 82 FED. REG. 180 (Jan. 3, 2017) (acute myocardial infarction and coronary artery bypass graft bundles; modifications to lower extremity joint replacement bundles).

⁶ Shannon Muchmore, "GOP May Try to Hobble CMS Innovation Center," MODERN HEALTHCARE (Nov. 7, 2016).

⁷ Henry Powderly, "Tom Price Says CMMI "Off Track," Hints at Changes to Programs," HEALTHCARE FINANCE (Jan. 24, 2017).

⁸ See, e.g., Letter from Payors and Provider Organizations to Pres. Donald J. Trump and Vice President Michael R. Pence (Jan. 27, 2017); Press Release, Health Care Transformation Task Force, Major Health Care Players Unite to Accelerate Transformation of U.S. Health Care System (Jan. 28, 2015); Bruce Japsen, *UnitedHealth, Aetna, Anthem Near 50% Value-Based Care Spending*, FORBES (Feb. 2, 2017).

electrophysiological cardiac products and metal bone and joint replacements – these customers tend to be hospitals, though as procedures migrate to the outpatient setting, ambulatory surgical centers may have a more prominent role.

The most straightforward example of risk sharing is some kind of repayment to the customer if the device fails to perform as promised. Here the customer value proposition is easy to understand. For example, in 2014, St. Jude Medical began offering to pay hospitals a 45% rebate on the net price of cardiac resynchronization therapies if a lead revision was needed within the first year of implantation as a result of four specified factors.⁹ Similar programs have been offered by other device manufacturers over the last several years, some of which may be based not only on a failure of product performance, but also on a failure of the episode of care to produce a certain outcome, such as reduction in the incidence of re-hospitalization.

Perhaps most interesting is the situation where the device maker is willing to go at full or partial risk for its payment based on whether the hospital gains or loses money from the procedure due to an outcomes-based bundled payment from the health insurer.¹⁰

As the risk sharing becomes more elaborate, so do the business challenges. Does the device maker have adequate data to predict how its device will perform? Even more challenging is whether the data can appropriately predict the likelihood of complications that might arise through no fault of the product? This requires good data analytics as well as carefully drafted contracts to measure the risk.

What may be more challenging are the legal compliance issues. At what point would the device maker become a risk-bearing entity under state insurance laws? At what point would its involvement in treatment protocols raise concerns under laws regulating the corporate practice of medicine? Is it possible to protect against the potential for enhanced liability for personal injury?

The area creating the most significant challenges for device makers is the Federal health care programs' anti-kickback statute. In our earlier example, St. Jude offered to absorb some of the costs associated with certain forms of post-implantation device failure. Current safe harbors, such as the warranty or discount safe harbors, may protect this relatively straightforward form of risk sharing where the financial consequences are ultimately determined by device performance, rather than broader clinical or quality outcomes.¹¹

Of course, the more complicated the risk share, the greater the challenge in structuring an arrangement that either meets a safe harbor or that may be treated positively under a facts and circumstances analysis. For example, what if a program offers to pay the customers' costs of the replacement procedure, or any losses resulting under a value-based contract with a payor? Such an offer does not seem unreasonable from a business point of view, but likely would not qualify as a warranty because the warranty safe harbor prohibits payments that exceed the cost of the item itself.¹² If the amount paid included cash payments or supplying one good without charge would it be viewed as encouraging the purchase of another, thus not meeting the discount safe harbor either.¹³

Although safe harbor compliance is not necessarily a requirement for a creative sale arrangement, the potential for the payments to be viewed as inducements counsels in favor of caution. For example, a medical device maker would be well-advised to develop accurate documentation of the purposes of the arrangement, as well as any safeguards or other elements that have previously been viewed positively in relevant HHS-OIG advisory opinions. It is undeniable that there is inherent tension between the desire to enter into creative arrangements designed to encourage value-

⁹ St. Jude Medical, 2014 Disease Management Prospectus: Chronic and Acute Decompensated Heart Failure at 17 (2014), https://www.sjm.com/~media/LandingPage/focus/HF_Prospectus_Brochure_06_FINAL_RGB_US-2001186BEN.ashx.

¹⁰ See Jaimy Lee, "Devicemakers Explore Risk Contracts with Hospitals," MODERN HEALTHCARE (Dec. 6, 2014).

¹¹ 42 C.F.R. § 100.952(g).

¹² *Id.*

¹³ *Id.* at § 100.952(h).

based initiatives and also to demonstrate that such arrangements are permissible under current law and guidance. For example, would OIG support an initiative under which the manufacturer might receive no payment absent a certain result, and only share in the upside of a customer's profitable episode of care?

Interestingly, regulations implementing the MSSP provided limited waivers of the anti-kickback statute (and the Stark law) for financial arrangements among the participants in an ACO.¹⁴ Unfortunately, however, similar waivers do not yet exist, however, for the other bundled payment programs adopted by CMMI. To address this issue, earlier this year the principal trade associations for the device and pharmaceutical industries petitioned the HHS Office of Inspector General for new safe harbor regulations that would protect risk-sharing arrangements similar to these.¹⁵

The importance of the device maker to the success of VBC programs through risk-sharing will continue to drive the market in this direction. Hopefully, HHS will adapt to these new circumstances in ways that do not cramp these developments.

Take-away #2: Device Makers Will Become Consultants and Managers

A second, and perhaps more progressive, step along the VBC continuum is for device makers to think "beyond the device" and embrace a service-focused model by becoming consultants and episode managers for their provider or payor customers. In addition to data, device manufacturers possess a valuable combination of product expertise and disease state knowledge that can be leveraged to offer services that improve outcomes and reduce costs.

This change represents a seismic shift in the existing product-focused paradigm and presents a wide variety of opportunities as well as legal and compliance risks for device makers. In considering the business and legal implications of these arrangements, a key question for device makers is how to manage the purchase of services versus the purchase of products as device makers pursue providing services such as operating room and hospital efficiency optimization as well as care coordination management.

Consulting and episode management models can take many forms, from providing services in-house to partnering with third-party consulting and software companies. A few well-publicized real-world examples are discussed below.

One example is the provision of operating room assistance to hospitals and ambulatory service centers through a technology-based solution, such as that offered by Smith & Nephew's strategic business unit Syncera. Syncera offers hospitals software that allows the hospital to access, analyze, and manage real-time data related to instrument utilization during surgery. This data empowers operating room administrators to identify the instruments an individual surgeon uses during a specific procedure, assemble and prepare the instrument trays accordingly, and train the operating room staff using interactive, visual layouts of each tray. This offering streamlines operating room prep, thereby reducing overall costs, creating more value for customers, and differentiating themselves at the same time.¹⁶

Stryker Corporation's 2011 acquisition of Marshall Steele & Associates provides a second example that embraces hands-on consulting services. Marshall Steele was a stand-alone consulting firm, initially focused on operating room efficiencies, and later expanded to offer a larger suite of efficiency-oriented services to hospitals, physicians, and payors. Stryker rebranded the business as Stryker Performance Solutions and now offers customized implementation

¹⁴ 80 Fed. Reg. 66,726 (Oct. 29, 2015).

¹⁵ Ropes & Gray, *Drug and Device Makers Suggest Anti-Kickback Safe Harbor Clarifications to Encourage Value-Based Health Care Arrangements* (March 17, 2017), <https://www.ropesgray.com/newsroom/alerts/2017/03/Drug-and-Device-Makers-Suggest-Anti-Kickback-Safe-Harbor-Clarifications.aspx>.

¹⁶ Press Release, Smith & Nephew, *Smith & Nephew Acquires Interactive Software Technology to Drive Supply Chain Optimisation and Improve Savings for Syncera™ Customers*, PR Newswire (May 6, 2015).

programs and data analytics solutions to help improve quality outcomes, patient satisfaction, and profitability. Other device makers have taken the approach of partnering with rather than acquiring consultant companies.¹⁷

A third example, the Depuy Synthes Geriatric Fracture Program, takes more of an episode management approach. The program provides a holistic approach to treating patients from the time they arrive in the emergency department through discharge. The program is comprised of components that complement CMMI mandatory episode payment programs (*i.e.*, opportunity assessment, implementation support, program materials, and performance dashboard), thereby especially assisting hospitals enrolled in these programs.¹⁸ Benefits to hospital customers also include improving patient care through early surgical intervention within 24 hours of fracture, management of comorbidities, evidence-based care pathways, prevention of delirium and early supported discharge.

For each of these models, there are a variety of value-based payment opportunities available to device makers. For example, a device maker could use a bundled payment for each episode of care, with certain minimum quality-related thresholds. The device maker payment could also be built upon a combination of a bundled payment for each episode, with goals related to quality, efficiency, and patient satisfaction serving as bonus benchmarks. In other words, a baseline payment amount would be supplemented if the service improves care quality, streamlines efficiency, and results in high rates of patient satisfaction. Additionally, the device maker could work with hospitals to design and establish gainsharing initiatives to incentivize physician participation.

Unlike the simple product performance risk-sharing approach, the main business challenge presented by offering a consulting service may be convincing provider customers that the device maker can be a qualified and honest broker. The legal and regulatory challenges include those that arise under a pure risk-sharing product sale model, though often to a greater extent: state insurance/risk-bearer laws, corporate practice of medicine, increased potential liability for patient harm and compliance with state and federal restrictions on the use and disclosure of patient-identifiable information and other kinds of data. Especially challenging may be the identity crisis over whether the company is now in the service business or whether the services are just a “value-ad” to sell more product. The latter approach is fraught with the potential for anti-kickback liability.

Device makers may deploy a variety of strategies to address these challenges. Especially important will be resolving the device/service identity crisis in favor of treating the consulting business as its own profit center. Key challenges include separateness of the business, reluctance of existing product customers to trust/use the consulting service, and to ensure sufficient independence to avoid the anti-kickback concerns that could arise if the services are viewed simply as a way to sell more devices.

Take-away #3: Device Makers Will Vertically Integrate by Investing in Health Care Providers

Moving beyond consulting, actual ownership of health care providers (whether through a joint venture or outright acquisition) offers medical device makers a further step towards facilitating positive patient outcomes. Potential investment targets may include ambulatory surgical centers, rehabilitation centers, physical therapy providers, specialty physician practices (*i.e.* orthopedic or interventional cardiology), or even an entire integrated hospital or clinic.

For example, in April 2015 Medtronic announced its acquisition of Diabeter, a diabetes clinic and research center based in the Netherlands that is one of the largest independent specialist centers for children and adolescents with

¹⁷ For example, in 2015, Boston Scientific strategically aligned with TogetherMD (a health analytics software company) and MedAxiom (a cardiovascular consulting company) to improve outcomes and reduce costs of cardiovascular care delivery. In 2016, Boston Scientific developed a cloud-based, digital health solution with Accenture to provide insights into care coordination and patient population health patterns.

¹⁸ Christina Farup, “How to Be a Trusted Partner in Episodic Hip Fracture Procedures,” MEDICAL DEVICE & DIAGNOSTIC INDUSTRY DEVICE TALK (Nov. 8, 2016).

Type 1 diabetes.¹⁹ Medtronic operates Diabeter as part of its Diabetes Services & Solutions business units and is Medtronic's first entry into diabetes integrated care models.²⁰ The company advertises that Diabeter providers retain their independence in clinical decision-making, therapy and brand choice of medical technology.²¹

Investment in a health care provider may be attractive because of the perceived ability to directly standardize and manage care. Instead of being limited to data aggregation and predictive analytics to make recommendations for care, overseeing the execution of care protocols and clinical pathways would give medical device makers with direct access to data the ability to redesign pre-operative and post-operative care based on previously identified best practices. Unlike consulting, investment does not necessarily require a medical device maker to be device-agnostic and overcome customer concerns regarding product selection; however, for some types of investments (such as an ASC, where other manufacturers' products may also be clinically relevant) provider resistance to perceived infringement in device selection may continue to be a challenge.

Once a medical device maker actually crosses into the health care provider space, the medical device maker itself would become responsible for positive patient outcomes. Investment in health care providers is replete with the same regulatory and compliance pitfalls applicable to health care providers. For example, ownership would give the medical device maker additional ability to identify the devices to be used in a procedure; however concepts of physician professional judgment and patient autonomy may interfere with the ability of a medical device maker to implement care protocols uniformly, even if the protocols are based on sound scientific and statistical evidence. Similarly, there is the possibility that a medical device maker could incur direct medical malpractice liability, rather than the more limited liability for a defective device, if patient outcomes are suboptimal.

The anti-kickback legal territory is even more uncharted. The government has historically expressed concern when product sellers "lock up" a referral stream through financial relationships with providers. Although HHS-OIG has provided guidance in the context of joint ventures and contractual arrangements (such as practice management) there is currently little if any guidance as to how regulators would view referrals within a vertical ownership scenario.²² One current precedent is in dialysis therapy providers. Of course, unlike orthopedic or cardiac implantable devices in an ASC or hospital setting, access to a dialyzer is the main component of the patient's treatment, instead of being a component that is used in a surgical procedure. So one can more easily see how device maker ownership of the provider inevitably dictates choice of the device. Nevertheless, a vertically controlled, branded operation could mitigate concerns previously expressed by regulators with regard to management of a health care provider's operations since the medical device maker would bear direct clinical and financial responsibility for the success of its products and protocols.

Conclusion: The Way Forward

Even as Congress and the Trump Administration consider major changes to the Affordable Care Act, the health care industry's momentum towards VBC seems unlikely to diminish. Absent a major change in direction, medical device makers should prepare for the increasing prevalence of customer expectations for solutions that favor better

¹⁹ See Press Release, Medtronic, Medtronic Acquires Diabeter, Innovative Diabetes Care Provider, Medtronic Newsroom (Apr. 2, 2015); see also Jens Deerberg-Wittram & Laura Lüdtkke, The Boston Consulting Group, Diabeter: Value Based Healthcare Delivery in Diabetes (Sept. 2016).

²⁰ *Id.*

²¹ *Id.*

²² See Office of Inspector General, "Special Advisory Bulletin: Contractual Joint Ventures" (Apr. 2003) at 2. Common elements of potentially problematic arrangements include: (i) expansion of a provider into a new line of business that is dependent on referrals from the provider's existing business, (ii) a lack of management and capital commitment by the owner to the new business, (iii) the fact that, but for the arrangement, the supplier would be a competitor in the same business, (iv) the provider and supplier both share in the economic benefit of the new business, and (v) aggregate payments to the supplier that vary with the volume or value of referrals. *Id.* at 3-4.

outcomes, and more cost-effective care management, over procedure volume. The good news is that forward-thinking device makers already have begun addressing the business and legal challenges, leading the way to help the industry position itself to succeed in the world of VBC.