

POINT OF VIEW

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HOW TO SUCCEED IN VALUE-BASED, PATIENT- CENTERED HEALTHCARE

A BRIEFING FOR MEDICAL DEVICE COMPANIES

AUTHORS

J. David Campbell, Partner
Terry Stone, Partner
Peter Gilmore, Partner

U.S. healthcare is in the midst of unprecedented change as players across the value chain move from today's complex, costly, and fragmented fee-for-service model to a new value-based, patient-centered approach that keeps both the cost and quality of care in sharp focus.

The passage of the Affordable Care Act in 2010 accelerated the pace of change. The act called for the creation of accountable care organizations—more than 520 of which have already entered the market. It directed the Department of Health & Human Services to pilot various bundled reimbursement models, and roll out the successful ones in 2016. There is little doubt that these models will reshape not only Medicare but also commercial markets. (See Exhibit 1.)

At present, we expect at least 30 percent of U.S. patients to receive care in value-based models by 2016, at which point the pace of change will accelerate again. By 2025 value-based care delivery will account for 70 percent of

total healthcare spend, population health managers (PHMs) will play a dominant role, and various forms of capitation and bundled payments will effectively replace fee-for-service. Over the same period, Oliver Wyman predicts that U.S. healthcare costs will fall by more than \$7 trillion, with \$1 trillion in value migrating among health industry players—including new players attracted from retail, technology, and other adjacent industries.

Patients will be treated differently, industry players will be reimbursed differently, and a whole new set of risks and opportunities will emerge for pharmaceutical and diagnostics companies, prescription benefit managers (PBMs), drug distributors, life science data players—and of course medical device companies. How will a device company succeed in this new market?

THE NEW HEALTHCARE MARKET FOR MEDICAL DEVICE PLAYERS

At the heart of this new market will be three tree trends re-shaping the industry.

Bundled reimbursement will dominate. Bundled reimbursement is payment based on the expected cost of a clinically defined episode of care, sometimes described as “a middle ground” between fee-for-service and capitation. (See Exhibit 2.) Oliver Wyman foresees a dramatic increase in bundled reimbursement for facilities, physicians, and device companies across a range of care episodes. Medicare seeks to expand bundled reimbursement into

Exhibit 1: Medicare’s four bundled reimbursement models

MODEL 1

RETROSPECTIVE ACUTE CARE HOSPITAL STAY ONLY

The episode of care is defined as the inpatient stay in the acute care hospital. Medicare will pay the hospital a discounted amount based on the payment rates established under the Inpatient Prospective Payment System used in the original Medicare program. Medicare will continue to pay physicians separately for their services under the Medicare Physician Fee Schedule. Under certain circumstances, hospitals and physicians will be permitted to share gains arising from the providers’ care redesign efforts. Participation will begin as early as April 2013 and no later than January 2014 and will include most Medicare fee-for-service discharges for the participating hospitals.

MODEL 2

RETROSPECTIVE ACUTE CARE HOSPITAL STAY PLUS POST-ACUTE CARE

The episode of care will include the inpatient stay in the acute care hospital and all related services during the episode. The episode will end either 30, 60, or 90 days after hospital discharge. Participants can select up to 48 different clinical condition episodes.

MODEL 3

RETROSPECTIVE POST-ACUTE CARE ONLY

The episode of care will be triggered by an acute care hospital stay and will begin at initiation of post-acute care services with a participating skilled nursing facility, inpatient rehabilitation facility, long-term care hospital or home health agency. The post-acute care services included in the episode must begin within 30 days of discharge from the inpatient stay and will end either a minimum of 30, 60, or 90 days after the initiation of the episode. Participants can select up to 48 different clinical condition episodes.

MODEL 4

ACUTE CARE HOSPITAL STAY ONLY

CMS will make a single, prospectively determined bundled payment to the hospital that would encompass all services furnished during the inpatient stay by the hospital, physicians, and other practitioners. Physicians and other practitioners will submit “no-pay” claims to Medicare and will be paid by the hospital out of the bundled payment. Related readmissions for 30 days after hospital discharge will be included in the bundled payment amount. Participants can select up to 48 different clinical condition episodes.

chronic disease management, and has indicated it expects bundled reimbursement to account for 75 percent of spending by 2018. It is hard to envision a device that will be unaffected, let alone a device company. As large employers and centers of excellence also explore opportunities to use bundled reimbursement, it is clear that the reimbursement landscape will change radically.

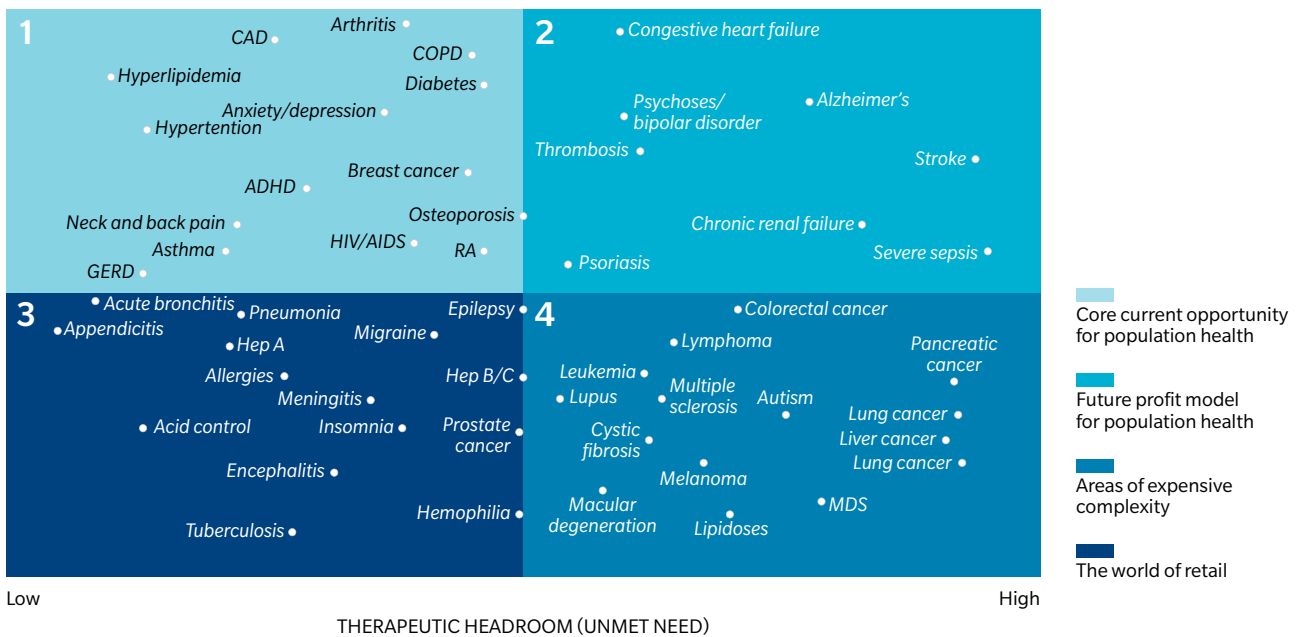
Bundled reimbursement will require medical device companies to think beyond their own products and economics and focus on the economics of the entire episode of care and beyond. Device companies—with new partners, capabilities, and offerings—will not only compete with each other for customers, but with facilities and physicians for reimbursement sharing.

There will be new opportunities (and needs) to create value in certain disease areas.

Different disease areas have different profiles in the context of value-based healthcare. PHMs will be looking for ways to improve costs and outcomes, and this will affect the way they evaluate drugs, devices, and other health interventions. Exhibit 2, for example, illustrates a useful way of grouping disease areas by unmet medical need and total cost of care for the whole population. Each quadrant requires a different approach from PHMs. In Quadrant 1, for example, treatment costs for the population are high, mostly because the conditions are common, but there is relatively little unmet need. In this set of diseases, PHMs tend to focus on eliminating waste and inconsistencies in care delivery. In contrast, the diseases in Quadrant

Exhibit 2: Disease area cost-unmet need matrix

TOTAL COST OF CARE



3 are so rare that they don't offer sizable opportunities for population-level savings—but at the level of the individual patient they are areas of high expense and complexity to PHMs. PHMs have not yet focused on applying care models to these diseases to reduce total cost or improve outcomes. As overall costs per patient continue to increase, standards of care will emerge, and PHMs will focus on the costs of drugs, diagnostics, and devices.

PHMs remain committed to finding new and innovative ways to control cost and quality of care for diseases in Quadrant 1, and increasingly Quadrant 2. Device companies' innovation is similarly concentrated, with roughly 50 percent of device trial programs focused in Quadrant 1 and an additional 30 percent in Quadrant 2. In contrast, however, pharmaceutical companies have deprioritized these quadrants. Pharma has set its sights on niche, high-unmet-need disease areas found in Quadrant 3, with almost 40 percent of all pharmaceutical and biotech development programs focused there, compared to only about 10 percent of device trials. Why this difference? Has the device industry over-focused on diseases where CMS's explicit mandate to negotiate device costs may hurt profit and growth, or has pharma moved into areas requiring unheard-of levels of innovation? Device companies must not only be confident in where they focus their innovation, but also be confident they have strategies for succeeding there.

Consider the cost data in Exhibit 3 for three device-related episodes of care. For a Quadrant 1 or Quadrant 2 condition like hypertension or congestive heart failure, cost pressures will be key. For these device-related episodes of care, a surgical center negotiating a 5 percent cost reduction with a device company would be numerically comparable to negotiating a 43 to 118 percent savings in the costs of health care providers for the two cardiac conditions.

Exhibit 3: Cost breakdown of three device procedures

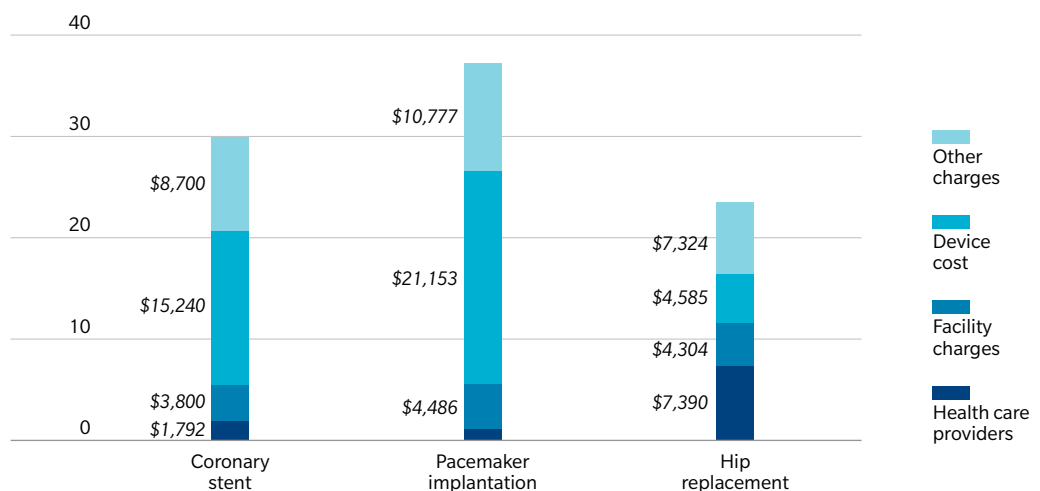
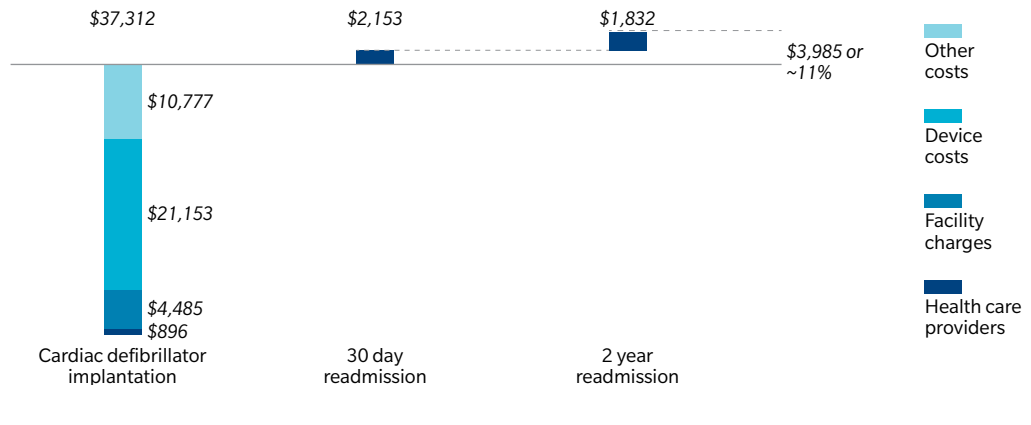


Exhibit 4: Cardiac defibrillation implant and readmission costs



In a new environment of bundled reimbursement, how will the current set of innovation investments play out? A payer seeking a 5 percent value improvement in the bundled world is probably indifferent as far as where the value comes from—have investments in innovation been made with a “bundled” mindset? Offerings “beyond the device” will become an important way to build value. The economic units of U.S. healthcare have long been visits, days, procedures, and the like. Offerings that improve cost and quality but require “additional” reimbursement have been rare. Oliver Wyman believes beyond-the-device offerings will become more and more important as device firms look to differentiate themselves in the new cost and quality market. In some cases, they will take the form of added services. Because ACA is reducing payments to hospitals with high readmission rates, Medtronic, for example, announced its intention to focus on heart failure readmission and spent \$200 million to acquire Cardiocom, a disease management and patient monitoring company. Together they are creating an offering with the potential to save clients as much as 11 percent of their defibrillator implantation costs. (See Exhibit 4.) Other companies, meanwhile, are exploring ways to share financial risk with their hospital and physician customers through guarantees and other structures. How will device and other health companies reconsider their innovation investments?

The complexity of certain diseases like Alzheimer’s, multiple sclerosis, and bipolar disorder make it difficult to standardize care delivery and therapeutic intervention. PHMs find it challenging to improve cost and quality of care in these areas, which creates real opportunity for innovators with deep disease area understanding and technological know-how. Despite this apparent opportunity, few device companies have made the move to offerings beyond their own products. Offerings like Medtronics’ are the exceptions, not the rule.

What will be the next partnerships to improve care and value? What is their potential? Who are the right partners, and how will the savings occur?

WINNING MODELS FOR THE MEDICAL DEVICE AND LIFE SCIENCE SECTORS

For device companies, alone or partnering with others, the key to winning in the value-based healthcare market will be replacing the transactional, unit-cost model with integrated solutions that improve cost and quality. Companies must look beyond their traditional business models to solve PHM and consumer needs along three critical dimensions shown in Figure 5:

1. Health technologies and services that improve outcomes, patient experiences, and/or cost of treating diseases
2. Participation in more effective and efficient delivery of healthcare
3. Financial products, including ownership of health outcome risk, that ultimately right-size total cost of care

Distinct choices of which quadrants and episodes of care to target for innovation will drive a device company to refine its innovation strategy. The choice between population health advantages versus innovation to address unmet need will have deep implications. The right mix of enablement, delivery, and financing will create new device company business models. Two examples of such different business models are illustrated below.

Quadrant 1 diseases—Core current opportunity for population health. In the upper-right quadrant—in areas like hypertension, lipid management, and type 2 diabetes—device companies can create value by becoming a “category owner” that helps PHMs achieve target outcomes with whatever drug, diagnostic, or device does the best job—even a competitor’s. Given their exposure to real-world patient-level data, device companies are well positioned to provide objective guidance to PHMs on achieving superior efficacy at the lowest cost. We believe service and intermediary players—PBMs, distributors, and specialty pharmacies—are also well positioned given their exposure to the full set of therapeutic options offered and a perceived lack of bias toward any one particular option. This would position them well to move away from unit-cost contracting models to payment-for-outcomes arrangements leveraging multiple therapeutic portfolios.

Exhibit 5: New business model elements in the value-based market

HEALTH ENABLEMENT	HEALTHCARE DELIVERY	HEALTH FINANCING
What are the possibilities for LS innovators and service providers to move from a technology provider only to an integrator of broader health technology solutions?	What role could LS innovators and service solution to enhance the quality and cost-effectiveness of the healthcare delivery?	What opportunities are available for LS innovators and service providers to participate more fully in the way healthcare is paid for and cost is managed?

Quadrant 3 diseases—Expensive complexity. As we look at diseases in the bottom right quadrant—metastatic and chronic cancers, chronic inflammatory diseases, and rare genetic disorders—the combination of relatively small patient populations and care largely based in drug therapy gives life science innovators an advantage in medical understanding and patient intimacy. The expensive complexity associated with these conditions suggests PHMs will be challenged to manage outcomes and per-patient cost. Life science companies, by contrast, are well positioned to become efficient, total “care owners,” delivering care and taking responsibility for the financial risks associated with these patient.

Is your device company prepared to emerge from being a provider of products to a combined health enablement, healthcare delivery, and health financing enterprise?

TAKING THE FIRST STEP

Medical device executives should ask themselves these crucial questions:

Will your company compete in disease areas with high cost pressure? If so, are you confident your innovation plans will deliver? If not, does the disease area offer sufficient alternative benefits to deliver the growth you need? Have you reached these conclusions based on old-system observations or new?

What are the economics of care most important to your business? How will the new health system change these economics? What new offerings would create the most advantage in these areas? Will your company develop them, acquire them, or partner to obtain them? As you consider outcomes, does your company understand the risk inherent in the episode of care? Are you able to take it on?

Abundant opportunity exists for medical device and other life sciences companies in the new, value-based U.S. market. But companies will need to embrace the new market changes; given PHM needs and innovation investment patterns, the opportunity to compete beyond the product itself, and the need to exploit both these options to win in the new bundled reimbursement environment, device companies will need to ask and answer where they want to compete, how they want to compete, with what offerings, and with what partners. Executives giving the same answers to “how will you compete” as they have in the recent past are unlikely to have really wrestled with the changes, and are instead likely to wrestle with the impact on their business.

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ABOUT THE AUTHORS

J. David Campbell and Peter Gilmore are partners in Oliver Wyman's Health & Life Sciences practice. They can be reached at david.campbell@oliverwyman and peter.gilmore@oliverwyman, respectively.

Terry Stone is managing partner of Oliver Wyman's Health & Life Sciences practice. She can be reached at terry.stone@oliverwyman.com.

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