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## **Will Pressures in Medical Manufacturing Reach Your Production Floor?**

by Tom Sommer

Manufacturers in the healthcare industry are facing a mix of cost and pricing pressures, from government regulations to changes in how hospitals pay for their goods. The solution? Companies will have to work smarter and more efficiently to keep up.

Makers of medical devices and equipment are feeling the squeeze. Research published last year by Emergo Group, a consulting firm for the medical device industry, revealed that pricing pressure is a big concern for these companies. About one-third of executives said pricing pressure is a top challenge facing their business. Among companies with 250 or more employees, 61 percent said pricing pressure was among the biggest challenges.

Where is the pressure coming from? Some starts at the top, with government regulation. Perhaps the biggest example is the medical device excise tax enacted in 2013 as part of the Affordable Care Act. The 2.3 percent tax has led 43.5 percent of companies to adjust their operations in some way, by raising prices, investing less in research and development, lowering production costs, or reducing their employee headcount, according to Emergo. In a 2015 survey by the Advanced Medical Technology Association, nearly half of companies said they would consider reducing employment further if the tax remained in place.

However, companies recently got a temporary reprieve—in December, when Congress passed a bill that put a moratorium on the tax. It's set to return on January 1, 2018.

“The medical excise tax moratorium, while a great thing in itself, does not give companies the long-term direction they need to be able to manage their companies with financially sound practices,” says Maria Shepherd, president of Medi-Vantage, a medical device marketing and business strategy firm. “They have to operate to the worst-case scenario, which is that the medical device excise tax will be back again in two years.”

Then there are the costs of complying with the FDA's requirements for Unique Device Identifiers (UDIs). As companies implement these changes by the deadlines—with the latest being in 2020—they could spend anywhere from \$100,000 to \$100 million on their efforts, according to a report from BoozAllen, a technology consulting firm.

Every regulatory change and requirement adds costs, but small companies will feel the biggest pinch, says Shepherd. “The impact of the UDI requirements will be more costly for smaller medical device companies than it will be for larger medical device companies,” she says.

It's no surprise that regulations and taxes levied on the medical device industry would impact manufacturers. However, other changes to the healthcare landscape may also impact companies all the way to the ground level.

The organizations that buy medical equipment are changing the way they do business, and hospitals nationwide are looking to trim costs. Deloitte recently reported that value-based care will be the biggest trend for hospitals over the next decade. What's more, in a recent survey from the American College of Healthcare Executives, hospital CEOs said financial challenges are their top concern. As they continue to implement healthcare reform, 78 percent are looking to reduce operating costs, while 66 percent are working on value-based purchasing.

Cuts to Medicaid and Medicare reimbursement were also key concerns, as budget reductions continue to squeeze hospitals. For example, this year's federal budget extends a two percent drop in Medicare payments to physicians and hospitals.

Hospitals in some states face additional cuts. For instance, Connecticut's 2016 state budget includes a \$68.9 million reduction in reimbursement to Medicaid providers and an increased tax on hospitals.

When looking to save money, hospital execs around the country are taking a hard look at medical device costs. More and more hospitals are using value analysis committees—groups that evaluate medical products on their effectiveness and price. In 2012, 64 percent of hospitals reported using value analysis committees, according to researchers from GfK Custom Research and Einstein Healthcare Network in Philadelphia. In their latest survey, 100 percent of hospitals used value analysis committees to evaluate new products under consideration. The research showed that a product's price was the most important part of the committee's assessment of value, over factors such as patient experience.

As hospitals look to spend less on devices, devicemakers may need to spend more money on studies and marketing materials that physicians can take to value analysis committees, says Shepherd. Those materials should include evidence that the products have unique features that can improve outcomes, reduce costs, or both.

Some hospitals also tap consulting firms to help them reduce costs. "The goal of the ACA was to bend the cost curve," says Charles Neikam, Vice President of Supply Chain Management at Inova Health System. "Each year reimbursement is being reduced which is causing hospitals to reduce costs to stay profitable." How has Inova adjusted? In 2013, they began working with Premier Performance Partners, a healthcare consulting firm, to reduce their supply spend by \$40 million so that they could be competitive by 2014. They met the goal in 2014 and implemented supply cost savings of \$15 million in 2015. "Unfortunately the appetite for cost savings will only increase as each year the curve gets bent further," says Neikam. "We also face stiff competition and our competitors are under the same constraint."

Inova has worked on providing surgeons across their system with products and services that would help them be more cost effective and competitive, Neikam says. And there's more on the horizon: "In January we implemented savings in Endo Mechanicals and have initiatives in the pipeline with Food Service, Cardiac Rhythm Management Devices and Drug Eluting stents to name a few," he says.

They used plenty of data to make their decisions. "We gave each company a chance to present their products to the surgeons and then we followed up with the companies and surgeons until everyone was satisfied they understood the landscape," says Neikam. They analyzed multiple data sets to make sure they were confident in the numbers they presented to the surgeons, and stakeholders were educated on the advantages of the different product offerings and price points. "With the surgeons' help, we

implemented savings of \$2.5 million, and it did not require the surgeons to have to switch from their current preference,” says Neikam.

Group purchasing organizations are also putting pressure on the prices devicemakers can charge for their products. The Healthcare Supply Chain Association reports that about 72 percent of purchases made by hospitals now go through group purchasing organizations. Market research firm IBISWorld recently reported that as the influence of group purchasing organization grows, prices of medical and surgical supplies will grow at just 0.8 percent through 2017.

Prices for some equipment are even falling. The average price paid by hospitals and other provider organizations fell over the past year for six of the top 10 supply items purchased in October 2015, the most recent month for which data were available at press time. These include implantable pacemakers, acetabular shell hip implants, femoral knee implants, humeral shoulder implants, drug-eluting stents, and cochlear implants, according to the Modern Healthcare/ECRI Institute Technology Price Index.

To keep costs low, some hospitals and industry players are even trying creative new strategies. In August, *Medical Device and Diagnostic Industry* reported that Dublin-based Medtronic is entering risk-based contracts with some hospitals. The idea is that the manufacturer will be penalized if a device doesn't deliver the expected outcome. Devicemakers would be wise to pay attention to this trend, says Shepherd. Risk sharing could be costly in the short-term but lead to better quality and innovation in product design in the long-term, she says.

In other cases, hospitals may be looking to make the devices they already own last longer. Refurbishing is a growing area in the medical device market, according to a recent report by Markets and Markets, which estimates that the market for refurbished medical equipment will reach \$9.37 billion by 2019. That's a compound growth rate of 12.5 percent from 2014 to 2019. This could lead to fewer purchases of new equipment, a potential squeeze on manufacturers.

Even when hospitals do buy new equipment, reimbursement rates from insurers can pose a challenge.

The Centers for Medicare and Medicaid Services will pay suppliers less per unit for many pieces of durable medical equipment in 2016 compared to 2015, according to a fee schedule released late last year. For example, in the contiguous United States, average payments for the purchase of a walker will drop by 26 percent and 24 percent in urban and rural areas, respectively.

Manufacturers should be prepared for reimbursements from Medicare and Medicaid to continue to fall, says Shepherd. The effects are expected to trickle all the way down to manufacturers, reducing the prices they can sell devices for.

Even private insurers are holding devicemakers to an increasingly high bar, says Shepherd. “Insurers want the same thing that hospitals want—evidence of improved outcomes for the payment or reduced cost for the hospital and therefore reduced costs for them,” she says. Various departments in medical device companies, from R&D, marketing, and more may need to spend increasing time and resources to make sure devices are attractive to insurers.

How can you prepare for the cost pressures ahead? In a 2014 report, consulting firm Accenture noted that at many top medical devicemakers, spending on research and development outpaced revenue. One

of their recommendations was to “devote rigorous attention to improving R&D, supply chain and back office operations.”

Original equipment manufacturers (OEMs) can also reduce cost by relying more heavily on contract R&D and manufacturers, a growing trend in the industry, says Shepherd. It is often faster and cheaper for medical device companies to outsource these functions. But, don’t expect innovation from contract R&D and manufacturers. They work to specifications the medical device company must provide. In a recent white paper, Sparton Corporation noted that OEMs are outsourcing more of their engineering and putting more responsibility for third-party validation on contract manufacturers.

Streamlining can also help. “We have adapted our model to support systems that now include the entire continuum of care,” says Doug Golwas, senior vice president of corporate sales at Medline. Their dedicated sales teams are trained in the specific needs of each care point, and their distribution centers have the capacity and capability to logistically serve the entire continuum out of one point, he says.

One example is a large integrated delivery network on the East Coast, says Golwas. “They recently purchased a network of primary care providers and the supply chain executive wanted to be able to serve his hospitals, ASC’s and PO’s with one distributor to improve operational efficiency,” he says. Medline tailored a solution for the system to expand service to the non-acute care points. “Once we had consolidated the number of distributors from 3 to 1, we went to work with the customer to manage pricing and standardization of products across the continuum of care,” says Golwas.

Among all manufacturers, labor costs are also a challenge. In a 2014 study by Accenture, 61 percent of manufacturers said it’s difficult to hire the skilled workers they need. That can result in increased overtime costs and other expensive ramifications.

For healthcare manufacturers, that doesn’t have to be a problem. Contingent labor can help manufacturers reduce labor costs while maintaining the highest level of quality. “One proven way to help stem costs is to optimize labor through the use of contingent or temporary labor, that way manufacturers only use what they need, exactly when they need it,” says Steve Sawin, president and CEO of Operon Resource, the leading provider of temporary labor and workforce solutions for healthcare product manufacturing companies.

Operon Resource Management, the only known staffing firm certified to ISO 13845, provides medical and life science manufacturers with temporary labor. Workers are screened, trained, oriented and prepared for the job before their first day..

“The challenge of using contingent labor to manage labor fluctuations in this industry is to assure that the workers understand the unique requirements and are ready to make a contribution on the floor,” says Sawin. Medical products are made in compliance with stringent standards. “If the workers are not ready, or the manufacturer has to spend too much time preparing them, then they miss out on market opportunities,” he says.

Like the medical device industry, the pharmaceutical industry isn’t immune to cost pressure. For one, the price to develop new drugs keeps trending upward. In 2014, researchers at Tufts University found that it costs an average of \$2.6 billion to develop a new prescription drug. In 2003, that figure was \$1.044 billion, adjusted for inflation. That’s an increase of 145 percent between the two studies.

Labor costs are also increasing in this sector. A report from the Bureau of Labor Statistics shows that unit labor costs in pharmaceuticals and medicines rose 3.7 percent per year from 1987 to 2013, then another 5.2 percent from 2013 to 2014, the latest year for which data are available.

There could be more pressure on the horizon, as leading candidates in the presidential race have suggested strategies to bring down drug prices. In September, Hillary Clinton outlined multiple proposals aimed at reducing drug prices for consumers if she is elected. One example: Consumers could import drugs from other countries with strong safety standards. Multiple GOP candidates have also discussed drug pricing at campaign stops. Potential changes may well be in line with public perception. In a Kaiser Health poll published last summer, 72 percent of people said the prices of prescription drugs are unreasonable.

As the market changes, companies are finding ways to adapt. By implementing cost-saving solutions, industry players are working hard to cope with the pressures that squeeze them today and loom on the horizon.

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*See published article in Medical Device and Diagnostics Industry Magazine, <http://www.mddionline.com/blog/devicetalk/will-pressures-medical-manufacturing-reach-your-production-floor-03-09-16>*