The Journal of Healthcare CONTRACTING

Providing Insight, Understanding and Community

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In the Public Eye

Government report on pricing confidentiality stirs the pot, causing some to question well-worn pricing techniques.

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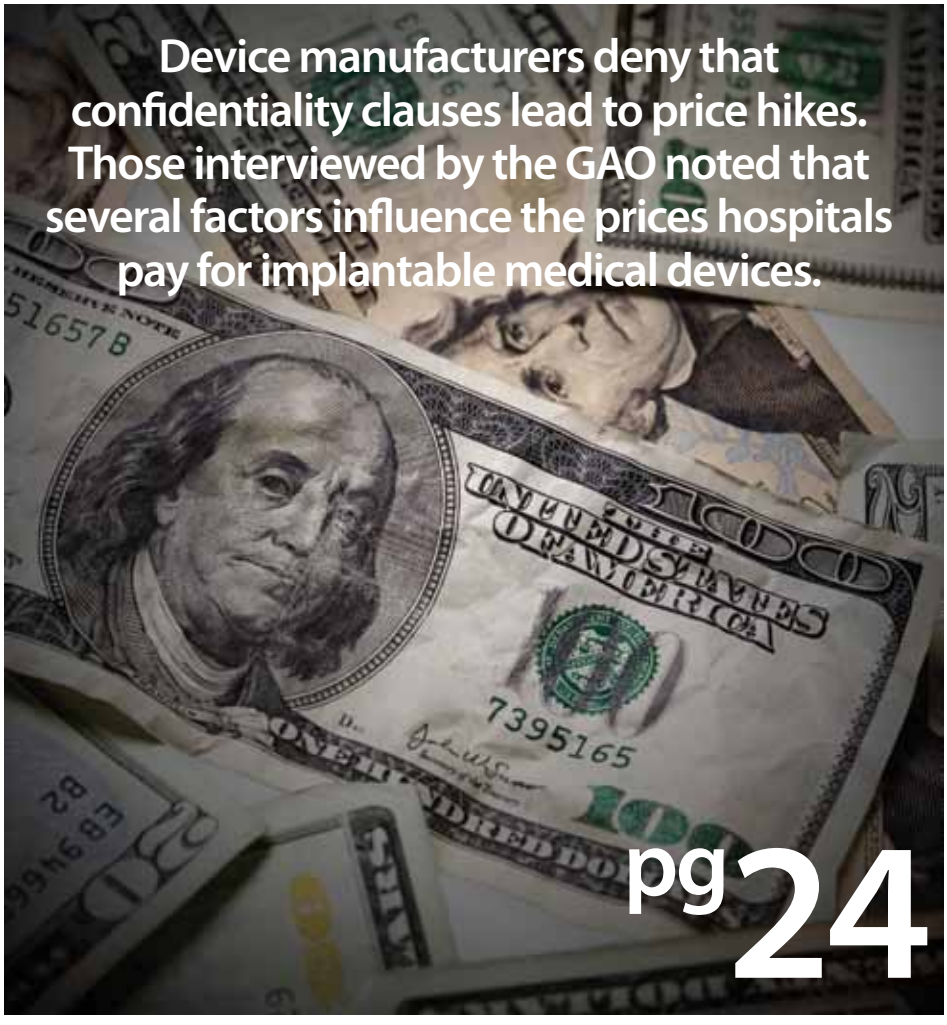

John Pritchard

The Savings Chase

Is a model based on measuring demonstrated savings sustainable?

The old adage rings true today, that desperate times call for desperate measures. The present results of these desperate measures involve drastic supply chain initiatives and counting every dollar possible toward the lofty goal of demonstrated savings.

I have the good fortune to talk to our nation's most progressive supply chain leaders every day. When we are discussing their initiatives and priorities, almost without fail they will mention what their goal this year is in demonstrated savings and where they are in the pursuit of that goal. It is very common for me to hear "I have a demonstrated savings goal of $50 million, and I am on track for over $60 million."

It seems like chasing the line item savings to achieve demonstrated savings has become a thundering mantra. I wonder if increasing the quality of outcomes and enhancing patient experience aren't getting lost in the mix.

Whether you love or hate reform, the basic principles of it – decreasing cost, increasing quality and enhancing patient experience – are appropriate and necessary for improving the state of the U.S. healthcare system.

I have great faith that our nation's hospital and IDN leaders will embrace these tenants of reform, not because it is law, but because it is good for their organization, their community and their patients. In the near future, most everything a provider organization does internally and externally will be measured on these three initiatives.

I look forward to the day when I speak to a progressive supply chain leader and in addition to the savings they have mustered they can quote how their systems and processes have also increased the quality of outcomes and enhanced the patient experience.

Thanks for reading this issue of *The Journal of Healthcare Contracting*!

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Front Row Seat

Healthcare delivery fascinates Michael Regier. Now, with a pivotal Supreme Court decision months away, he's reminded why.

Michael Regier

Michael Regier has been attract-ed to healthcare delivery ever since working for a law firm in Chicago with a large healthcare practice. To him, healthcare delivery "is where all the circles of the Venn Diagram come together," that is, where clinical, ethical, technological, financial and other issues converge.

But never has he been more fascinated by healthcare delivery than today. And with good reason. After all, at press time, the U.S. Supreme Court was preparing to hear arguments about the constitutionality of the Patient Protection and Affordable Care Act (ACA) of 2010 – the healthcare reform law. And then there are the upcoming congressional and presidential elections.

Regardless of how the Supreme Court rules, or who wins the elections, a series of events is about to unfold that will test the mettle of lawmakers and the public as they continue to reshape the healthcare delivery system. And Regier will have a front row seat.

Regier is senior vice president of legal and corporate affairs, general counsel and compliance officer for VHA Inc. In this position, he is responsible for the company's public policy office, which is based in Washington, D.C. He also oversees legal services, public relations and corporate communications, risk management

and office services, as well as VHA's business ethics and compliance program.

Prior to joining VHA in June 2007, he served as senior vice president, legal affairs and general counsel for the Seton Family of Hospitals in Austin, Texas, since 1995. Before joining Seton, he practiced law in Chicago for 10 years.

Since September 2010, Regier has hosted "Focus on Reform," a bimonthly broadcast from Washington, D.C., that aims to help VHA members and others understand and prepare for the impact of healthcare reform.

Never a more important decision

"I'll never say 'never,' but it is hard for me to imagine that there will be a Supreme Court decision in my career that will be more important than this one," he says. The Court has a lot on its plate, as it will explore three primary issues related to the healthcare reform law:

- The so-called "individual mandate," which requires most citizens and legal residents to maintain health insurance or pay a financial penalty, beginning in 2014. (Those who fail to meet certain minimum income levels will qualify for federal subsidies.) The federal government maintains it has the authority to require U.S. citizens to purchase health insurance or pay a penalty, under the Constitution's "commerce clause." But challengers (which, in the Supreme Court case, is a consortium of 26 states) argue that the government lacks the constitutional authority to require citizens to buy a product from a private entity. If the Court rules that the individual mandate is unconstitutional, it will then determine whether the rest of the ACA must be overturned, or whether it can stand without the mandate.
- The expansion of the Medicaid program to all citizens and certain legal residents with incomes up to 133 percent of the poverty level. The Court has been asked to decide whether the law's Medicaid expansion is constitutional, and whether the federal government has the right to cut off state funding for non-compliance.
- The potential application of the Anti-Injunction Act, a federal statute dating from 1867, which generally provides that statutes that impose penalties may be challenged in litigation only when the penalties are actually imposed. At least one federal appeals court relied on this Act in declining to rule on the constitutionality of the individual mandate at this time. Should the Court conclude that the Anti-Injunction Act applies, any claims involving the constitutionality of the mandate could be delayed until 2015, when the first penalties are scheduled to kick in.

"I don't see any good set of consequences coming out either way," says Regier, referring to the Court case. "Let's say the Court strikes the law in its entirety. We still have the light at the end of the tunnel – which is a train, that is, the rate of increase in healthcare spending. We as a society are still going to have to do something to address that."

Under this program, hospitals that perform well on quality measures relating to clinical processes of care and to patient experience of care, or those making improvements in their performance on those measures, would receive higher payments. The program would apply to payments for discharges occurring on or after Oct. 1, 2012.

If the law is struck down…

Should the Court strike down the law, it would unleash a chain of events that could unravel many programs already underway, says Regier. Some examples:

Value-based purchasing. Under this program, hospitals that perform well on quality measures relating to clinical processes of care and to patient experience of care, or those making improvements in their performance on those measures, would receive higher payments. The program would apply to payments for discharges occurring on or after Oct. 1, 2012. The financial incentives would be funded by a

reduction in the base operating DRG payments for each discharge, which will be 1 percent in FY 2013, rising to 2 percent by FY 2017. The Deficit Reduction Act of 2005, signed by President Bush, set the wheels in motion for value-based purchasing, notes Regier. Although CMS proposed a value-based purchasing system in a report delivered to Congress in 2007, CMS needed separate statutory authority to implement the system – which it got, in the Affordable Care Act. Were the law to be struck down, however, progress toward value-based purchasing might stop.

Accountable care organizations. The Affordable Care Act created the Medicare Shared Savings Program, under which ACOs would allow providers to share in savings achieved by coordinating patient care across all sites of care, inpatient and outpatient, and by providing higher quality care. In December 2011, the Department of Health and Human Services announced that 32 healthcare organizations would participate in a Pioneer Accountable Care Organization initiative. A decision striking down the Affordable Care Act would also strike the statutory authority for both the Pioneer ACO program and the Medicare Shared Savings Program.

The Center for Medicare and Medicaid Innovation, a new organization at the center of many key initiatives currently undertaken by CMS, could itself be a casualty of a Supreme Court decision striking down the Affordable Care Act, says Regier. The Innovation Center's current initiatives include the Partnership for Patients and the Health Care Innovation Challenge grant program.

"The implications are tremendous," says Regier. "Providers have had a real struggle just to keep pace with implementation [of the Affordable Care Act] and the uncertainty associated with it. But if there's a giant red 'do-over' button with the Supreme Court decision, it could be tremendously difficult for providers from a planning perspective."

"Providers have had a real struggle just to keep pace with implementation [of the Affordable Care Act] and the uncertainty associated with it. But if there's a giant red 'do-over' button with the Supreme Court decision, it could be tremendously difficult for providers from a planning perspective."

– Michael Regier

If the law is upheld…

Even if the court upholds the constitutionality of the law, complications will ensue, says Regier. For example, the Affordable Care Act requires states to certify that they can run health insurance exchanges, but a number of states are not ready to do so, and some have refused to participate. (As of March 2012, 13 states had established exchanges and five more had signaled their plans to do so, according to the Kaiser Family Foundation. But six states had shown no significant planning activity, and two states – Louisiana and Arkansas – had announced plans to stop pursuing a state-based exchange.)

"We may have a major catch-up by some states," says Regier. "Still, that's probably a better scenario for providers. Personally, I think it would be better for the industry and the country if the Court upholds the statute, because I have more confidence in our ability as a nation to improve legislation that is imperfect than to start from scratch."

Regardless of what the Supreme Court decides, there's still a lot of action to be played out in the court of public opinion. And that begins with Congress. On this score, Regier has some serious questions.

Hyper partisan atmosphere

"There seems to be a hyper partisan atmosphere now, in which the objective seems to be preventing the other guy from accomplishing anything, rather than seeing if we can influence what the other guy is thinking in order to get to a place that we both want," he says. "We need that latter type of thinking if we want to meet the challenges our country is facing."

One casualty of the hyper partisanship might have been former temporary CMS Administrator Donald Berwick,

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who stepped down in December 2011 after 17 months on the job. Partisan wrangling meant he never received a Senate confirmation hearing.

"I personally think it's a crying shame when someone who has the professional expertise and the passion of Don Berwick is unable to be confirmed to lead an organization like CMS," says Regier. "If you sat down and looked over the last 10 to 15 years in healthcare and said, 'Name the five individuals who have done the most to improve quality and safety,' Don Berwick as leader of [the Institute for Healthcare Improvement] would have been near the top of everyone's list." At CMS, Berwick revitalized the agency and rebuilt a sense of pride and esprit de corps, he says. "Dr. Berwick was someone the career staff saw as not only caring about patients and providers, but also about the work the agency did and the people who did it."

The irony of the partisan wrangling is that on many issues, Republicans and Democrats are not that far apart. In fact, points out Regier, many of the provisions that the Republicans decry were, in fact, originally proposed on that side of the aisle.

The irony of the partisan wrangling is that on many issues, Republicans and Democrats are not that far apart. In fact, points out Regier, many of the provisions that the Republicans decry were, in fact, originally proposed on that side of the aisle. The current Medicare Acute Care Episode (ACE) bundled payment demonstration, for example, was launched by the Bush Administration. The concept of value-based purchasing was championed by HHS Secretary Michael Leavitt, also in the Bush Administration. State-based insurance exchanges and the ability to purchase insurance across state lines were part of John McCain's platform when he ran for president in 2008. And in 2006, as governor of Massachusetts, Mitt Romney signed into law a health reform bill that required almost everyone to buy insurance – that is, an individual mandate.

"A lot of the tools in the Affordable Care Act that are aimed at the delivery system came out of the Republican side of the aisle," says Regier. "Whether the Republicans would embrace some of those elements again if the statute were to be struck down, I don't know."

Regardless of what happens on the Republican side of the aisle, developments on the Democratic side could unravel at least some provisions of the healthcare reform law, should the Supreme Court uphold its constitutionality, says Regier. In fact, some unraveling has already taken place.

In October 2012, for example, HHS Secretary Kathleen Sebelius announced that the CLASS Act would be scrapped, because it wasn't financially feasible. The Community Living Assistance Services and Supports program (CLASS Act) was a voluntary insurance program that would have provided benefits for community living services for people who became functionally disabled and required long-term services and supports, so long as they had been paying premiums for at least five years.

Another casualty might be the Independent Payment Advisory Board, points out Regier. The IPAB was to be a group appointed by the Comptroller General, charged with making coverage decisions and determinations of Medicare and Medicaid. If certain federal spending targets were projected to be exceeded, the board was to have to ordered mandatory spending reductions in Medicare.

"It's this provision that was largely vilified, with people talking about death panels," he says. "It has become extremely controversial." So controversial, in fact, that the Obama Administration itself has eased off the pedal. (In early March, the House Energy and Commerce Committee supported legislation to repeal the IPAB, a decision applauded by the American Medical Association, among others.) This despite the fact that former Office of

Management and Budget Director Peter Orszag once had called the IPAB one of most important elements of the Affordable Care Act.

What happens after the election?

Regier is curious – and perhaps a little apprehensive – about what will happen following the November elections, and before the next presidential term begins in January. "We will have gone through a brutal Republican primary, an incredibly aggressive and probably – for the electorate – unpleasant presidential campaign. And then a lame duck session."

For healthcare providers, that lame duck session represents a particular period of risk, for a number of reasons, he says.

First, the Bush tax cuts are scheduled to expire at the end of the year. "A lot of people don't want that to happen, and even the Administration is willing to consider an extension of the cuts for the middle class," he says. The federal government may turn around and seek ways to recoup those lost revenues – perhaps through Medicare and Medicaid reimbursement cuts.

Second, the failure last fall of the bipartisan Congressional Joint Select Committee to find more than a trillion dollars in deficit reductions means that automatic spending cuts will go into effect in 2013. Some of that money will come out of defense, but much will come out of domestic programs, including Medicare and Medicaid.

"I think for providers, a lot of the action may end up happening in the lame duck session after the presidential election," says Regier.

Then, come January, when the next presidential term begins, more surprises might unfold, says Regier. "I think the real dramatic change could come in a scenario where the president wins re-election; the Senate shifts to Republican hands, though not by a large enough margin to override a presidential veto; and the House remains in Republican hands."

President Obama has already indicated some willingness to work with Republicans, as witnessed by his discussions with House Speaker John Boehner last summer, when the two came close to an agreement on how to deal with the debt crisis and raise the debt ceiling. The talks – which would have cut spending by as much as $3.5 trillion – broke down. But as a lame duck president, Obama might feel freer to work with Republicans without fear of reprisal from his own party or the electorate, says Regier.

"So I actually see a scenario for more significant change in the nearer term if the president wins reelection."

One more piece of the puzzle remains to be fit – the medical device excise tax. The Affordable Care Act gave the Internal Revenue Service the authority to impose a 2.3 percent excise tax on the sale of any taxable medical device by a manufacturer, producer or importer, beginning in January 2013. The tax is projected to generate $20 billion over 10 years, and is intended to be the medical manufacturing community's "contribution" to healthcare reform.

"There's no question it's one of the more important funding sources for the Affordable Care Act," says Regier. "That's the political dilemma for those who would seek to repeal it – doing so would add to the deficit. If you're going to do that, where will the money come from that would have been raised through that excise tax? There are no easy answers to that."

It seems healthcare delivery defies easy answers. But maybe that's what makes it so interesting. **JHC**

"I think for providers, a lot of the action may end up happening in the lame duck session after the presidential election."

– Michael Regier

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The 84,000-square-foot Integrated Distribution Center helps North Shore-Long Island Jewish improve service, cut costs

When Pinak Shah joined North Shore-Long Island Jewish Health System in 2007, his responsibility was clear: Centralize the supply chain of this large and growing IDN.

(L t r): Steve Inacker, Cardinal Health; Phyllis McCready, North Shore-LIJ; Anthony Caprio, Cardinal Health; Donna Drummond, North Shore-LIJ; Pinak Shah North Shore-LIJ; Gene Tangney, North Shore-LIJ; Lou Mayle, Cardinal Health; and Jonathan Driscoll, Cardinal Health.

North Shore-LIJ had already taken a step in that direction several years prior to his arrival, when it centralized procurement in conjunction with an ERP implementation. But the IDN took a big next step in December 2011, when its newly constructed Integrated Distribution Center, or IDC, went live with seven of the IDN's 14 hospitals. Four more were implemented in March 2012, with the remaining three scheduled to follow by the end of 2012.

The decision to open its own distribution center in Bethpage, N.Y., on Long Island, was a logical one. "When we merged hospitals – and this is a normal healthcare scenario – we realized we needed to standardize products, so [our clinicians] would achieve similar clinical outcomes throughout the system," says Shah, who is senior director, supply chain operations, Integrated Distribution Center. But to enforce standardization, the supply chain team needed to exercise some controls to ensure that nothing was coming through the back door. "You need a building to control that," he says.

Optimize the supply chain

Building a distribution center made sense from a financial and logistics perspective, he says. First, it would give the IDN the opportunity to work directly with manufacturers and reduce distribution fees (though it should be noted that Cardinal Health is a major player at North Shore-LIJ). Second, it would allow the IDN to optimize its supply chain. Without a central distribution point, multiple hospital sites were receiving identical products from manufacturers, he points out. But having a distribution center would allow the IDN to buy in bulk, realizing some volume discounts. For the manufacturer, it would reduce the amount of labor required to pick and ship boxes of the same product to multiple locations. "That can be optimized and can come back as a savings," points out Shah.

North Shore-LIJ had another consideration in mind when envisioning the IDC – disaster management. In case of emergencies, such as the H1N1 pandemic of a couple of years ago, the IDN wanted to centrally stock all emergency items, so it could monitor expiration dates,

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says Shah. In the case of a natural or man-made disaster, the IDN could direct needed supplies to the areas that needed them, to ensure the safety of staff, patients and the community.

Cardinal Health – one of the IDN's two med/surg distributors prior to the start of the project – became North Shore-LIJ's partner during the construction phase, says Shah. "We wanted them to be part of the mix, to share their knowledge with us." The result was what Shah calls a "hybrid design," bringing the best of Cardinal Health's expertise and North Shore-LIJ's experience.

20 hours a day

The IDC itself is 84,000 square feet. It has eight inbound/outbound dock doors, and is a seven-day-a-week, 20-hour-per-day operation. It is temperature-controlled, has full generator backup, and features Crown Equipment material handling equipment, InfoLink wireless technology and a Rite-Hite Wheel-Lok dock safety system. The facility includes a cross-dock staging area as well as a high-dollar security cage, in addition to bulk racking, shelving, and carton-flow and hand-stacking areas. Altogether, it contains more than 13,000 inventory storage locations. The facility has a staff of 62 people in the front office and warehouse, many of whom came to the center from the IDN's hospitals.

High-volume med/surg products are shipped to the IDC by Cardinal, while manufacturer-direct items arrive from the vendors. "It's a hybrid model," says Shah. Through cross-docking, items that used to be delivered directly to individual hospitals are handled through the center, with exceptions made for items that require special handling and storage, such as frozen tissue.

The distribution center employs the AIMS inventory management system from Arlington Heights, Ill.-based Witron, the same system employed by Cardinal Health in its warehouse facilities. Warehouse personnel use a voice-directed warehouse picking system from Wexford, Pa.-based Lucas Systems. Wearing headphones, the warehouse workers are directed to the correct picking location by an automated voice; the voice also responds to information the associates speak back.

Inventory reduction

After the items are picked and packed, they are shipped in totes directly to North Shore-LIJ's facilities by Penske Logistics. "We felt the transportation piece was very complicated, and it had to be optimized on the backhaul portion," says Shah. "We felt that outsourcing would bring more expertise [to the operation]." Though the trucks and drivers are Penske's, the trucks carry the IDN's logo.

The distribution center opened with 2,000 unique items, and is expected to hold about 5,500 by the end of 2012.

The distribution center opened with 2,000 unique items, and is expected to hold about 5,500 by the end of 2012. By standardizing items and consolidating inventory, the IDN has been able to reduce systemwide inventory substantially.

Next up? Expanding the reach of the Integrated Distribution Center into North Shore-LIJ's many non-hospital facilities. "That's where we'll try to go in the next wave," says Shah. **JHC**

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For Northeast Purchasing Coalition, LLC, it's very much about balance. "We utilize a healthcare value equation in our clinical discussions to ensure we consider both the financial information and clinical input," says Pamela L. Scagliarini, vice president, supply chain management, Yale New Haven Health System, who is responsible for the service provider contract with Northeast Purchasing Coalition (NPC). The equation? "Health care value = Health outcome/cost."

Pamela L. Scagliarini

The coalition was formed in January 2011, with the mission to "leverage the power of clinical networking and integrate evidence-based practice with strategic sourcing to deliver the best overall value," says Scagliarini. "We have recently added Fletcher Allen Partners to NPC and are now 29 members strong. We represent 78 hospitals across the region. As is the case with most organizations, it is important to ensure that growth of the NPC advances [its] overall mission and adds value to the member owners of the coalition. It is also critical that potential new membership aligns closely with our desire to have high levels of clinical engagement, which ultimately supports our collective ability to deliver on our commitments to the market."

Solidarity and savings

For NPC members, the advantages of joining a purchasing coalition are clear. "The savings are higher than expected and the collaboration and unity of the members is more solid than I would have expected in the short time we have been together," says Scagliarini. "I attribute this to the quick savings we were able to attain and the agreement on the fact that we must deliver on our commitments to the market. In addition, we embrace each initiative as a learning process. As each initiative unfolds, it represents a new

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set of challenges that we openly discuss, and we agree on both member expectations as well as our expectation of the supplier community. We have become a stronger unit as a result of our first-year challenges."

Indeed, the coalition's strong unity and ability to remain focused on its goals has enabled it to consider a broad range of products early on. "Our top three initiatives from a savings perspective have been office supplies, prefilled syringes and trocars," says Scagliarini. "As you can see, these represent a variety of product categories: a non-clinical commodity driven through our supply chain leaders; a clinical preference product line that has required both nursing and pharmacy input; and a product [that has required] our physicians [to] provide the clinical recommendations. The majority of our first-year initiatives [have been] in the clinical preference category."

"As an owner of the NPC, it is our responsibility to spend the resources of both the dedicated staff and the member organizations' clinicians wisely."

– Pamela L. Scagliarini

In the first year alone, the coalition has netted over $14.7 million in savings, which is far ahead of its $9 million target, she points out. "This savings represents a 12 percent savings over 27 initiatives. Our targets for 2012 are more aggressive from a savings perspective, as well as the number and type of initiatives. We have a contract plan spanning commodity, clinical preference, physician preference, capital and purchased services.

"Our process is clear," she continues. "We go to the market together with commitment. If an organization within the NPC cannot participate in an initiative, that decision is made early in the process. Our members, inclusive of the clinicians, have [had] more clarity on their roles and responsibilities and how they interact with the decision-making process as the year has progressed. We were developing the process as we began operations in early 2011 and, therefore, we were all learning as we went. The leadership of NCP's executive director, Kathy Galullo, has been critical in facilitating us through difficult issues, which ultimately has strengthened the coalition."

The process

NPC's operations committee, a group of supply chain executives, meet monthly in person to make decisions on initiative analysis, contract strategy and contract award, according to Scagliarini. The operations committee meetings provide an opportunity to obtain clinical updates from the NPC clinical director, Paula Jurewicz, RN, and the NPC physician advisor, Maxwell Laurans, MD, she explains. "Paula facilitates the clinical advisory committee and its subcommittees, and Dr. Maxwell Laurans facilitates the physician advisory group and M.D. subject matter expert groups. These updates and recommendations are carefully considered in our voting process. We are fortunate to have a set of supply chain leaders who consider the short-term benefits of each of our strategy decisions, the longer-term effect of our actions on the overall market and our strength as a coalition, and most importantly, [their] effect on clinical care." The contracting effort is facilitated by VHA and Novation, with support from Yale New Haven Health System (YNHHS), she adds. YNHHS also facilitates the clinical and physician effort.

Although NPC typically includes its GPO in the process, "this is not a limitation," notes Scagliarini, who points out that the NPC membership decides which suppliers will be considered in a competitive review, based on market information, service-level experience, and product breadth and depth. "There is efficiency associated with enhancing an existing base GPO agreement, which needs to be carefully weighed with the market dynamics, product quality and breadth attributes of all suppliers in making this decision," she says. "As an owner of the NPC, it is our responsibility to spend the resources of both the dedicated staff and the member organizations' clinicians wisely."

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Best interests

Through strong communication, NPC ensures the interests of its member facilities are considered, and that their needs are met. The coalition's engagement process includes supply chain, physicians, clinical subject matter experts and hospital executives. "We have established a set of advisory committees, subject matter expert committees and liaisons that provide clinical input regarding engagement strategy, product evaluation type, subject matter expert feedback and formal clinical recommendations," says Scagliarini. "It is the responsibility of the NPC staff to broadly communicate within the structure of committees and liaisons, and the responsibility of the supply chain leaders to further deliver the message and solicit feedback within the organization."

Regardless of the coalition's smooth operation, it is not immune to the challenges of obtaining physician and staff buy-in. "The difficulty ranges based upon the product type and how advanced each organization is in driving change," Scagliarini explains. "If an organization has a robust value analysis process, the NPC initiatives slot into the current process more easily. If not, then the NPC process has served, in many organizations, as the base for the development or improvement of a value analysis process surrounding the initiatives. In addition to physicians and staff, the level of executive buy-in and involvement at each organization can significantly affect our ability as a group to commit. The NPC actively communicates to the executive sponsors regarding initiative updates, barriers and overall progress to goals to seek their support. Organizations with more active executives have higher levels of staff and physician involvement, leading to better buy-in."

That said, through collective leverage and commitment as a group, NPC "has seen benefits to the overall cost of healthcare and specifically our organizations," she continues. "Both the awarded supplier and the coalition members drive cost out and/or improve their revenue stream."

"Personally, there is great satisfaction in bringing an idea from concept to realization," she says. "This type of development initiative requires you to pull upon different skills sets that are required in running your own internal operation. Refining these skills is personally rewarding [and provides] benefits to Yale New Haven Health System."

"Personally, there is great satisfaction in bringing an idea from concept to realization."

– Pamela L. Scagliarini

Looking ahead

As good as it is for NPC, it can always get better, notes Scagliarini. "There are always areas of improvement, which is what drives us to be better at what we do," she says. For one, the NPC staff is focused on improving how the clinical engagement process can interact more fluidly with the supply chain decision making process, she points out. This will require the coalition "to seek as much evidence as available to support our initiatives," she says. "Improvement on this front will allow us to move more quickly in the realization of bottom line savings and ensure we are delivering high-quality products and services to our organization.

"I envision that we will expand our scope [over the next several years] to include other areas of spend more deeply, as well as provide guidance regarding utilization of products. In the near term, we are assessing the viability of pharmaceuticals, purchased services and capital. I also envision that each of [the] hospitals and health systems will continue to improve their own value analysis process as a by-product of the work that is coordinated through the NPC."

Pam Scagliarini is the vice president, supply chain management at Yale New Haven Health System (YNHHS). Supply chain management includes strategic sourcing (contracting and procurement operations), corporate supply chain analytics, the system-wide value analysis committee structure, and the site-specific operations of materials management, linen and forms. She is also responsible for the management of supply chain operations at the YNHHS network member facilities, as well as the service provider contract for the Northeast Purchasing Coalition, LLC, and contracting and regional clinical engagement for VHA, inclusive of physician preference products. **JHC**

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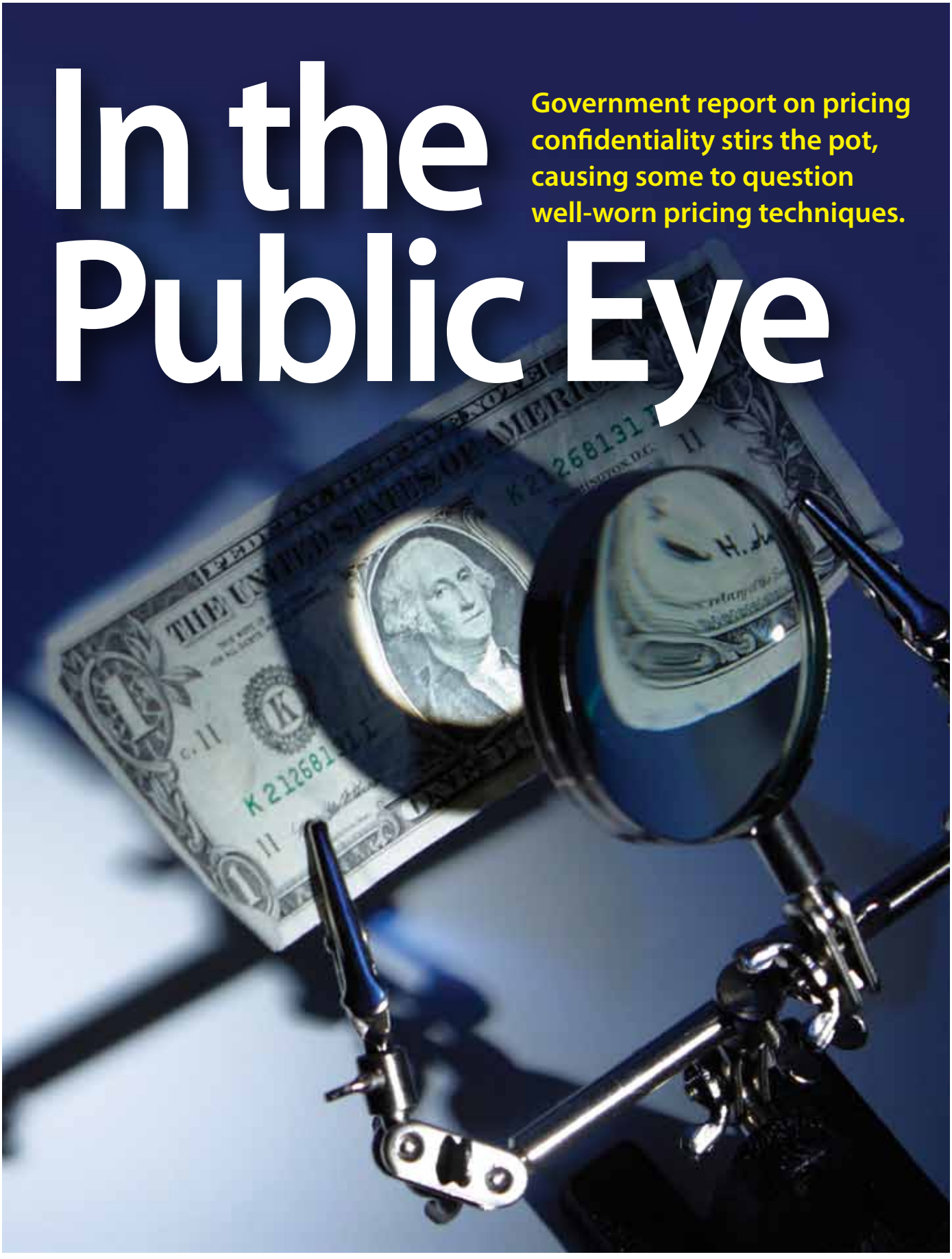
 *Calculations based on these sources; sample calculations available upon request. 1. Computers, Informatics, Nursing: September/October 2009, Volume 27, Issue 5, pages 318-323, Connected Care: Reducing Errors Through Automated Vital Signs Data Upload, Smith, Laura B. MSN, RN; et al. 2. Automated Vital Sign Documentation for Medical Surgical Units: Saving Time and Increasing Accuracy: Fact or Fairytale?, Meg Meccariello, RN MS; Jennifer Johnstone, RN MS, Presented at The Nursing Management Congress 2008 Las Vegas, NV. 3. Vital signs measurement frequency estimates from "Lippincott's Textbook for Nursing Assistants: A Humanistic Approach to Caregiving," Pamela J. Carter, 2007, page 292. 4. Hospital beds (most recent) by country estimates from NationMaster.com, www.nationmaster.com/graph/hea_hos_bed-health-hospital-beds. 5. Population, Source: U.S. Census Bureau, Population Division.

In the Public Eye

Government report on pricing confidentiality stirs the pot, causing some to question well-worn pricing techniques.



Greg Wieder won't sign 'em. "We won't do business with a company that insists on that." But others will, figuring they can still find ways to access pricing databases and share pricing info with their surgeons and other clinicians. Meanwhile, vendors appear to keep pressing the issue, although some are of the opinion that in today's information-rich society, it's pointless to try to keep pricing behind the curtain.

"I don't see how I can keep pricing confidential anyway," says Wieder, director of materials management at Wentworth-Douglass Hospital in Dover, N.H. Insurers are demanding it, surgeons are demanding it, even patients are demanding it.

In the public eye

Confidentiality clauses are back in the public eye, thanks in large part to a federal government report published in January, which blamed such clauses for huge variations in hospital prices. What remains to be seen is whether the attention will garner more than a couple of TV news blurbs.

The report, which was requested by U.S. Senator Max Baucus, a Montana Democrat who chairs the Senate Finance Committee, found that "substantial variation" exists in the prices hospitals pay for the items studied – total knee implants, primary total hip implants, coronary drug-eluting stents, automated implantable cardioverter defibrillators, and cardiac resynchronization therapy defibrillators.

"This report makes clear that too little information is available about the costs of implantable devices," said Baucus, in a statement following the release of the report. "It raises serious concerns over the prices hospitals and Medicare are forced to pay for implantable medical devices. Until we find a meaningful way to report prices that helps contain rising costs, this problem will only grow.

"The lack of available data makes it extremely difficult for Medicare and hospitals to get a full sense of the cost problem. We simply have to find smart ways to curb rising costs, preserve quality care and save taxpayer dollars, and getting more information about the cost of implanted medical devices is a strong first step. One solution could be for hospitals that treat Medicare beneficiaries to report and share device pricing information with the Centers for Medicare and Medicaid Services."

> **"This report makes clear that too little information is available about the costs of implantable devices."**
>
> **– Max Baucus, U.S. Senator**

Lawsuits

Confidentiality agreements have been a fact of life for contracting executives for years, particularly with physician-preference items. But they flared into the public consciousness eight years ago.

In August 2004, Guidant Corp. (now Boston Scientific) filed a lawsuit against Aspen Healthcare Metrics, a MedAssets company, on the grounds that prices paid by hospitals for Guidant's cardiac rhythm devices were confidential, that hospitals do not own such data, and that Aspen had no right to collect or disseminate it. Aspen responded that Guidant's pricing information was readily available within the industry and in certain industry publications, and that physicians could obtain Guidant cardiac-rhythm-management pricing even when they were not employed by the hospital or subject to confidentiality agreements with Guidant. In May 2006, the two companies reached a settlement, the terms of which were confidential.

Also in May of that year, ECRI Institute, which has published its PriceGuide pricing database since 1996, filed suit against Guidant, asserting its right to continue publishing pricing data collected from hospitals. Speaking at the time, ECRI President and CEO Jeffrey Lerner, Ph.D., called it a First Amendment issue. The two sides settled in November 2007. Once again, the terms were confidential.

Though Medicare does not directly pay hospitals for implantable devices, the agency uses data from cost reports and claims to help it establish prospective payment rates.

At the time, the confidentiality/transparency issue was so hot that Senators Charles Grassley and Arlen Spector introduced "The Transparency in Medical Device Pricing Act" in October 2007, which would have required device manufacturers to report the average and median sales prices for implantable devices on a quarterly basis as a condition of participation in Medicare, Medicaid or the State Children's Health Insurance Program. The legislation went nowhere.

Today, confidentiality clauses remain part of the healthcare contracting process, according to those with whom the *Journal of Healthcare Contracting* spoke.

"They're very pervasive," says Joseph Volpe, vice president, supply chain, Wheaton Franciscan Healthcare, Glendale, Wis. "They're part of just about every contract we see." Volpe believes vendors ramped up their insistence on confidentiality following the ECRI and Aspen lawsuits. "Everybody interpreted those suits as Guidant winning," he says.

Granted, confidentiality clauses in contracts for general commodity-type contracts are waning, says Volpe. He believes that the economic slowdown has cooled vendors' insistence on them. "They may put the clauses in, but many will accept modifications that will take some of the teeth out of them," he says. That said, vendors of physician-preference items are still adamant that confidentiality clauses remain intact.

Why is the government interested?

Though Medicare does not directly pay hospitals for implantable devices, the agency uses data from cost reports and claims to help it establish prospective payment rates. It was the rapid climb in costs for implant-related procedures that drew the attention of the feds last year, prompting the U.S. Government Accountability Office (GAO) investigation.

From 2004 through 2009, Medicare expenditures for such procedures increased from about $16 billion to $20 billion, reported the GAO. "While cardiac and orthopedic procedures accounted for nearly all [implantable-medical-device-] related expenditures, orthopedic procedures accounted for most of the increase in such expenditures during our period of study. A substantial portion of this amount may be attributable to the cost of the devices themselves, but exactly how much is unknown, in part, because hospitals purchase the IMDs and Medicare does not track IMD prices or how much individual hospitals pay for them."

Among the 31 hospitals that submitted data to the GAO, the difference between the lowest and highest price reported for a particular automated implantable cardioverter defibrillator (AICD) model was $6,844. The difference between the highest and lowest price reported for another AICD model was $8,723. The median prices across the four AICD models ranged from $16,445 to $19,007.

It was more difficult to compare prices for orthopedic implantable devices because of the greater variation among device configurations, said the report's authors. "However, the data on orthopedic implants reported by hospitals and GPOs – which may not capture all discounts and rebates – provided some evidence of substantial price variation." For instance, one hospital reported spending about $4,500 for a specific primary total hip construct in 2010. In comparison, a GPO provided information showing that one of its members paid about $8,000 for the same device construct, or 78 percent more. Similarly, a GPO provided data on two of its member hospitals that purchased the same primary total knee construct. One hospital paid about $5,200, while the other paid about $9,500, or 83 percent more.

Dr. Gregory Hickman's goal is to avoid narcotic-based pain control and its potential consequences whenever possible. He succeeds by practicing Regional Anesthesia, "which also gets patients quickly and more comfortably out of the surgery center, opens up beds and makes nurses available to take care of more patients."

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Why the variation? The GAO suggested three reasons:

- **Physician preference.** "Physicians, though typically not involved in price negotiations, often express strong preferences for certain manufacturers and models of implantable medical devices."
- **Lack of volume discounts.** "To the extent that physicians insist on using the device of their choice, the hospital misses opportunities to obtain volume discounts from manufacturers."
- **Confidentiality clauses.** "Confidentiality clauses barring hospitals from sharing price information make it difficult to inform physicians about device costs and thereby influence their preferences."

Device manufacturers deny that confidentiality clauses lead to price hikes. Those interviewed by the GAO noted that several factors influence the prices hospitals pay for implantable medical devices.

GPOs react

"The GAO report confirms what GPOs, hospitals, long-term-care providers, and anyone on the front lines of patient care and healthcare cost-containment see every day," said Healthcare Supply Chain Association President Curtis Rooney in a statement. "Medical device pricing secrecy decreases competition, limits the ability of hospitals and their GPO partners to effectively negotiate for medical products and services, and artificially drives up healthcare costs, leaving hospitals, Medicare and American taxpayers to foot the bill.

"The $200 billion medical device industry is able to leverage its army of salespeople to drive unnecessary utilization and further enforce contractual 'gag clauses' to keep prices a secret, which gives device makers a virtually unchecked ability to drive up costs for hospitals and Medicare," continued Rooney. "Because hospitals are unable to discuss price with the physicians who typically choose which products to use, hospitals have become third party payers."

Baucus, who requested the report as part of an ongoing effort to identify opportunities for savings in federal health programs, said the next step should be to find a way to increase transparency, which, he believes, would help contain costs and preserve high-quality care.

Are confidentiality clauses to blame?

Device manufacturers deny that confidentiality clauses lead to price hikes. Those interviewed by the GAO noted that several factors influence the prices hospitals pay for implantable medical devices. "They pointed to marketplace dynamics – the degree of competition within a local market and the market power of hospitals purchasing the devices – as key influences. Additionally, they noted that the support offered by manufacturers, such as device servicing agreements and training, as well as the terms and length of the contract itself, play a role in price negotiations. Finally, the manufacturers told us that the extent to which changes in device technology improve patient care affects what hospitals pay for IMDs."

Some contracting executives aren't buying it.

"I did some work relative to price transparency," says Wieder, who uses the VHA PriceLYNX comparative pricing database. "What I found was dispiriting. We were paying $1,200 more for pacemakers than some other organizations. When I investigated it, [vendors would say], 'You're too small, you don't have as much volume,'" he says. "But that didn't make any sense to me, only because I couldn't believe it was costing more to produce my pacemaker than somebody else's."

Wieder says he had an epiphany when shopping for a camera for his son this past winter. "I found I could get the same one at the same price everywhere.

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"I thought, 'If Nikon has the same price point, why don't these manufacturers have the same price point for all the hospitals they sell to?'"

Vendors take exception to his logic, says Wieder. "They're going back to the old Adam Smith rule of supply and demand. But I call it old business practices. The world has become flat because of computerization and information systems." Medicare and Medicaid, as well as private payers, have impressive data-collection skills. "They are going to start asking questions like, 'Why are we paying one hospital [for procedures] more than another, based on the product cost?'"

Business as usual?

Not all contracting executives are as dead set against signing confidentiality agreements as Wieder. And that's causing heartburn in some quarters.

"Some of our members aren't even aware of the problems [presented by] confidentiality agreements," says Amerinet Vice President of Contracting Dale Wright. "They think it's standard practice. But we're trying to educate them that this is not necessarily how business is or should be done. We're saying to them, 'Don't handcuff yourself.'"

Confidentiality clauses, which prohibit supply chain executives from sharing pricing with their agents, consultants, sometimes even the doctors who practice in their IDNs, "only serve one entity – the supplier," says Wright. "If you think about commerce in general, where else would you go to a store and not know what you're paying, or what the market is worth out there?"

"Novation and VHA are not supportive of confidentiality," says Nik Fincher, vice president, analytics sales, VHA. "In my experience, when I see somebody get trapped into that, and told they are getting a great price and shouldn't let anyone else see it, you'll find just the opposite has happened. There are enough of those stories around so that you have this general acceptance in the supply chain that confidentiality is not a good thing.

"We have seen in our LYNX products time and time again: When you look at the entities you would expect to get the best pricing, that has not been the case. It still appears that, more than keeping a secret, the best way to get the best price is to give the supplier as much business as you can and maximize contract usage."

Comparative databases

Like Volpe, Lori Graham, surgical purchasing manager for Wayne Memorial Hospital, Goldsboro, N.C., sees confidentiality clauses on almost every contract she sees. "They're across the board – implants, instruments, equipment, disposables, reusables." Even distributors are stipulating that the IDN keep secret their fees, she points out.

Seldom do the clauses explicitly prohibit Graham from sharing Wayne Memorial's pricing with surgeons or other clinicians, she says. "It's more, 'You are not to share our pricing,' and I've taken that to mean, don't share it with other facilities or suppliers."

Despite these obstacles, Wayne Memorial has found a way to access

"Some of our members aren't even aware of the problems [presented by] confidentiality agreements. They think it's standard practice. But we're trying to educate them that this is not necessarily how business is or should be done."

– Dale Wright, Amerinet, Vice President of Contracting

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1. López-Huertas HL, Polcari AJ, Acosta-Miranda A, et al. Metallic ureteral stents: a cost-effective method of managing benign upper tract obstruction. *J Endourol.* 2010;24(3):483-485.

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benchmarked pricing – in this case, the Premier OrthopedicFocus and SpendAdvisor products, as well as the ECRI PriceGuide – and use it to save money on implant purchases. The information is blinded, meaning Wayne Memorial doesn't know the prices that individual hospitals and IDNs are paying, nor do other participating facilities know what Wayne Memorial is paying.

Vendors have suggested that pricing databases are unreliable, because they can't reflect rebates, volume discounts, etc. And supply chain executives do seem to take them with, if not a grain of salt, at least with eyes wide open. But for many, these databases are a valuable tool in the contracting process.

"They are a guide, a snapshot of what's being done in the marketplace," says Graham. "They give you a high-level view." But Graham knows that a multitude of factors come into play when it comes to pricing. Is the facility for-profit or not-for-profit? What is its size? Is this a multisource or sole-source agreement? "So you can't bank on getting to that low number."

"We know there are flaws, but they're minor," says Volpe, referring to comparative pricing databases. Volpe is aware that manufacturers use rebates to mask lower pricing, and he considers that possibility when examining the databases. "But at the same time, they give us a sense of where we are relative to the market. We have a better idea of how we can negotiate."

Bob Boswell, vice president, supply chain operations for OhioHealth, Columbus, Ohio, says that most vendors are OK with providers submitting pricing data to benchmarking organizations, because the data is blinded. "I know the effort that goes into making credible data," says Boswell, whose IDN was instrumental in the formation of VHA PriceLYNX. But Boswell, like other supply chain executives, looks carefully for outliers.

He feels he has to, not only so he can enter negotiations on firm footing, but so that he can maintain credibility with the surgical team. "Once our physicians feel that the information is credible, they're willing to work with us to get a better price. But if they see something that looks extraordinarily low, it would only take one or two of those to make them question the data."

To compile the database for VHA PriceLYNX, the organization collects information from 1,600 members on a regular basis, says Fincher. "We have $64 billion of data and more than 6.4 million items in our data file." To be included in the database, each item must include multiple price points.

The database allows members to see base prices, as well as typical rebates and discounts, says Fincher. "Our subscribers want to dispel the myth when [vendors] tell them, 'You can't get to this tier because you're not committed to this level.' Our tool will allow you to see, 'Is that the way this supplier really prices?' When you have a database as large as ours, you will see data trends that will either prove or disprove things."

And the issue of confidentiality and price-sharing? Not much of an issue at all, says Fincher. "Our members are sending us their a/p files; they're not sending us their contracts or agreements. It's just, 'Here's an item and here's what we paid for it.' That is clearly their data."

> **"We know there are flaws, but they're minor. But at the same time, they give us a sense of where we are relative to the market."**
>
> **– Joseph Volpe, vice president, supply chain, Wheaton Franciscan Healthcare**

Pricing discipline

Novation President and CEO Jody Hatcher makes the case that pricing databases are good for providers and vendors. "The marketplace is becoming more sophisticated," he says. "There's a recognition that pricing transparency is occurring in this industry, much as it has in the consumer market. It will also be a pervasive force in this marketplace."

And how can that work to the vendors' advantage?

Sellers complain all the time that they give the provider their best price, only to see the provider shop it around, says Hatcher. "My contention is, the reason they do that is because [providers] don't necessarily believe it is the best price. But if you can provide evidence about the distribution of pricing in the marketplace in a more transparent way, a lot of inefficiency in terms of re-negotiation will be driven out of the market."

Perhaps a more fundamental issue, and one that is being forced to the surface because of the ubiquity of information available today, is that of pricing discipline.

"Healthcare reform is forcing suppliers to exhibit discipline," says Hatcher. "They used to allow all their reps pricing authority. They would have national pricing guidelines, and then deploy decentralized pricing authority to the sales organization." But in today's environment, providers are looking to buy less, and vendors are looking to reduce SG&A costs, he says. Disciplined pricing can help both sides.

And some vendors agree. "Historically, as a company, we have allowed reps to price items," says one med/surg distribution executive. "We've given them flexibility, so that for any given item, we may have 500 different price points." Like those of many suppliers, this company's sales executives are frustrated when buyers, after consulting one of the pricing databases, demand the lowest price, even though their volume may not warrant it, he says. Or a customer may demand lowest price by SKU, not understanding that suppliers use the "loss leader" concept in their approach to pricing.

"It leads to an interesting dynamic in the market," he says. "I refer to it as a race to the bottom in the profitability chain."

There's only one way out of these frustrating and counterproductive situations, he says. "[Suppliers] are going to have to become very disciplined, and treat every customer the same, with the same rules and boundaries," he says. Suppliers in every market segment are facing the same choice, given the ubiquity of pricing data in the market, to the point that consumers can scan an appliance with their smartphone, then find out prices for the same product in competing stores in the immediate geographic area.

"If we believe we have this unique problem in healthcare, we're mistaken," he says. "Everybody knowing your price to certain customers is going to remove any ability to have one-off and special deals….I think the days of [vendors] getting a crazy price on an item and not ultimately embarrassing themselves with the customer and losing the business are gone. Buyers are way too smart; access to data is way too available; and those [suppliers] that don't want to become disciplined will be crushed."

John Marotta, CEO, Emerge Medical, agrees. "We want everyone to know our pricing, and confidentiality agreements between doctors and hospitals need to go away," he says. Denver, Colo.-based Emerge manufactures orthopedic surgical devices.

"If we believe we have this unique problem in healthcare, we're mistaken. Everybody knowing your price to certain customers is going to remove any ability to have one-off and special deals…"

In healthcare, sometimes the best customers get the worst pricing, he says, primarily because of tight-knit relationships between surgeons and vendors. "The issue is, the decision-maker [who uses] the product isn't the hospital, it's the physician, and the hospital is stuck with the purchase. So there needs to be pricing transparency in order for the physician and hospital to work together to make buying decisions." Pricing transparency can help manufacturers reduce their SG&A costs, and devote more of their profits to developing innovative technologies, which is what they should be doing, he says.

Surgeons' involvement

Most providers would agree that surgeons need access to pricing information. And that's why many either refuse or sidestep vendors' demands for total secrecy, according to those with whom *JHC* spoke.

Fincher agrees with those who believe that as scientists, physicians are driven by data. "The best way to influence physicians' behavior is to provide data they can look at and analyze. Comparatively and statistically, it makes sense." Pricing databases "open the door to a new level of communication with physicians," he says.

Says Wieder, "We have to be competitive in the marketplace. If we're paying a premium for a product, we can't be competitive. The doctor can't be competitive either, because [he or she] might lose business to a neighboring hospital or group. They need to know what the prices [of medical devices and implants] are in order to be competitive."

Meanwhile, Boswell's team shares cost information on the products and implants each physician uses in his or her procedures, so they can compare their performance against others. "Then we collect that information at the end of the meeting," he says. The system works out well, because "they're there to help us make good decisions." Having reliable information, for all to see, helps make that happen.

What now?

Attempts to legislate pricing transparency have failed before. But will they succeed this time around? "I don't think [legislation] really had legs before," says Wright. "But this time, it feels like it's been teed up a little higher. It's gaining some momentum right now."

Some believe even if legislative efforts fail, market forces will bring about transparency.

"Ultimately the payer will drive the change," says Marotta. Take bundled payment systems, for example, which call for providers to receive one payment for a procedure, and split the excess profit or share the loss. "If you have a pedicle screw system or some other medical device, and one costs $6,000 and another – that produces the same clinical outcomes – costs $3,000, which will the surgeon use?" he asks. They will migrate to the lower-priced device.

"So surgeons will be competing against the medical device company for their pay at the end of the day," he says. "And who's going to drive it? The payer, because hospitals are not having success in doing this. Incentives drive behaviors."

"The key point is that some purchasing agents are fighting confidentiality clauses and others are not," says ECRI's Lerner. "It is important that more join in this common effort aimed at a public good, rather than seek to benefit from the courage of others, if they know – or should know – that signing confidentiality clauses keeps overall prices artificially high.

"The free market needs reliable comparative information to operate efficiently. 'Free riders' fool themselves if they negotiate discounts from an anchor price that is too high and which results in them still overpaying after they achieve their 'discount.' The chances of the government intervening will increase if the private sector thwarts the free market, and if too few individuals defend the public's interests." **JHC**

"We have to be competitive in the marketplace. If we're paying a premium for a product, we can't be competitive. The doctor can't be competitive either, because [he or she] might lose business to a neighboring hospital or group."

– Greg Wieder

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References: 1. Data on file. Pfizer Inc, New York, NY. **2.** Heparin Sodium Injection, USP [prescribing information]. New York, NY: Pfizer Inc; 2011.

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The Light of Day

Reporting rule seeks to shine a light on financial relationships between buyers and sellers

The Centers for Medicare & Medicaid Services at press time was reviewing comments to its proposed rule regarding disclosure of payments made by medical products manufacturers to physicians and teaching hospitals. The rule was created as part of the Physician Payment Sunshine Act, which is intended to increase public awareness of financial relationships between drug and device manufacturers and certain healthcare providers. The Sunshine Act is part of the 2010 Patient Protection and Affordable Care Act.

"When people are faced with the difficult task of choosing the right doctor, they need all the information they can gather," said Peter Budetti, M.D., CMS deputy administrator for program integrity, when the proposed rule was published Dec. 19, 2011. "If your doctor is taking money from manufacturers of prescription drugs, suppliers of wheelchairs or other devices, you deserve to know about it. Disclosure of these relationships will discourage the inappropriate influence on clinical decision-making that sometimes occurs while still allowing legitimate partnerships."

What it is

The proposed rule would require manufacturers of drugs, devices, biologicals, and medical supplies covered by Medicare, Medicaid, or the Children's Health Insurance Program to report to CMS payments or other transfers of value they make to physicians and teaching hospitals. It would also require manufacturers and group purchasing organizations to disclose to CMS physician ownership or investment interests.

Left unmentioned in the latter provision were physician-owned distributors, that is, companies – primarily in the orthopedics market – that pay physician-investor/owners a percentage of the sale price of the products they use. It was the PODs that generated much bad press over the past several years, and which some observers blame for promulgation of the Sunshine rule. There is a chance that the omission of physician-owned distributors was an oversight or clerical error, and that it will be corrected when the final rule is published later this year, according to those with whom the *Journal of Healthcare Contracting* spoke.

CMS is proposing that manufacturers and GPOs submit a partial-year report on payments on Mar. 31, 2013. Once the data has been submitted, CMS will aggregate manufacturers' submissions at the individual physician and teaching hospital level, provide them with a 45-day period to confidentially review and, if necessary, correct the data, and make the data publicly available by Sep. 30, 2013. Manufacturers would be required to report to CMS the amount and nature of payments and other transfers of value in an electronic format on the 90th day of each calendar year thereafter.

Collaboration is OK…to a point

The proposed rule acknowledges that collaboration among physicians, teaching hospitals and manufacturers "may

contribute to the design and delivery of life-saving drugs and devices." What's more, the feds acknowledge that "financial ties alone do not signify an inappropriate relationship.

"However, while some collaboration is beneficial to the continued innovation and improvement of our health care system, payments from manufacturers to physicians and teaching hospitals can also introduce conflicts of interests that may influence research, education, and clinical decision-making in ways that compromise clinical integrity and patient care, and may lead to increased health care costs," the proposed rule states.

"[T]ransparency can shed light on the nature and extent of relationships, and may dissuade inappropriate conflicts of interest from developing."

Manufacturers of devices (including medical supplies) that require premarket approval by or notification to the Food and Drug Administration would be subject to the reporting requirements. That is to say, payments by manufacturers of Class I and some Class II devices would be excluded. "We believe this limitation may be appropriate for applicable manufacturers, because manufacturers that solely produce these exempt products have not been shown to have extensive relationships with covered recipients," said CMS. "Additionally, we believe this limitation might be appropriate because these financial relationships (to the extent they exist) are less likely to influence patient care."

The types of payment covered in the proposed rule are broad. They include consulting fees, gifts, entertainment, food, and ownership or investment interest. (See related piece.)

Distributors too?

While squarely pointed at manufacturers, the Sunshine law may affect distributors as well, according to observers.

It's possible, for example, that manufacturers will require their distributors to file reports with the manufacturer of any payments those distributors may make to providers, says Mitchell Kramer, senior partner of the law firm Kramer & Kramer LLP, with offices in suburban Philadelphia and Ann Arbor, Mich. He is also legal counsel for IMDA, the association for specialty medical distributors. "I've already seen such requests being made," he says.

There are a couple of reasons why manufacturers might do this, says Kramer. First, distributors may be seen as an arm of the manufacturer. If that's the case, manufacturers want to make sure they are in compliance with the law. Second, manufacturers may want to make sure they are in compliance with the law's demand that payments requested by or designated on behalf of a physician or teaching hospital be reported. The rule was constructed in such a way as to prohibit doctors and teaching hospitals from instructing manufacturers to direct payments intended for them to other entities, including, theoretically, distributors.

The types of payment covered in the proposed rule are broad. They include consulting fees, gifts, entertainment, food, and ownership or investment interest.

Though the proposed rule doesn't specifically address the issue of private labeling, it's likely that distributors of private-label products would be considered manufacturers under the rule, adds Kramer. In fact, the proposed rule does say that "certain companies which are under 'common ownership' with an entity that produces, prepares, propagates, compounds, or converts a covered drug, device, biological, or medical supply are also subject to the reporting requirements under this provision, even though they themselves may not be involved in the 'manufacturing' process."

The issue may be academic, at least for most distributors, because many private label products are either Class 1 or Class II devices, which would be exempt from the reporting requirement.

Providers react

Neither the American Hospital Association nor the Association for Healthcare Resource & Materials Management commented on the proposed rule. But Premier did submit comments to CMS Acting Administrator Marilyn Tavenner.

In his letter to Tavenner, Premier Senior Vice President of Public Affairs Blair Childs acknowledged that physician/industry relationships "are an important part of patient care and can aid in the development of better drugs and devices." Still, Childs maintained that greater transparency in these relationships is needed. "Patients and healthcare consumers require sufficient and meaningful information to determine the existence and possible impact of potential conflicts of interest that may influence the decision making of the very healthcare providers on which these patients and consumers rely."

"Our concern is, as so often [is the case] with written regulations, the law of unintended consequences."

– Glen Stream, M.D., president of the American Academy of Family Physicians

Physician groups, meanwhile, expressed conditional support to the proposed rule. "We absolutely believe in transparency to patients of the healthcare system in which they are treated," says Glen Stream, M.D., MBI, Rockwood Clinic, Spokane, Wash., and president of the American Academy of Family Physicians. "Patients deserve to know that the treatment recommendations being made by their personal physician are not unduly influenced by commercial interests or individual financial or proprietary interests.

"Our concern is, as so often [is the case] with written regulations, the law of unintended consequences. An interaction that is innocent, understandable and potentially positive gets painted with the same negative brush as those in press reports of rare but egregious forms of conflict of interest. The vast majority of practicing physicians hold their professional ethics in high regard.

"There is synergy between industry and those practicing medicine, which has produced a lot of the advances we enjoy," continues Stream. "We don't want to stifle that innovation. Device manufacturers need the input of physicians in evaluating their products; we have to be careful it doesn't cross that ethical line.

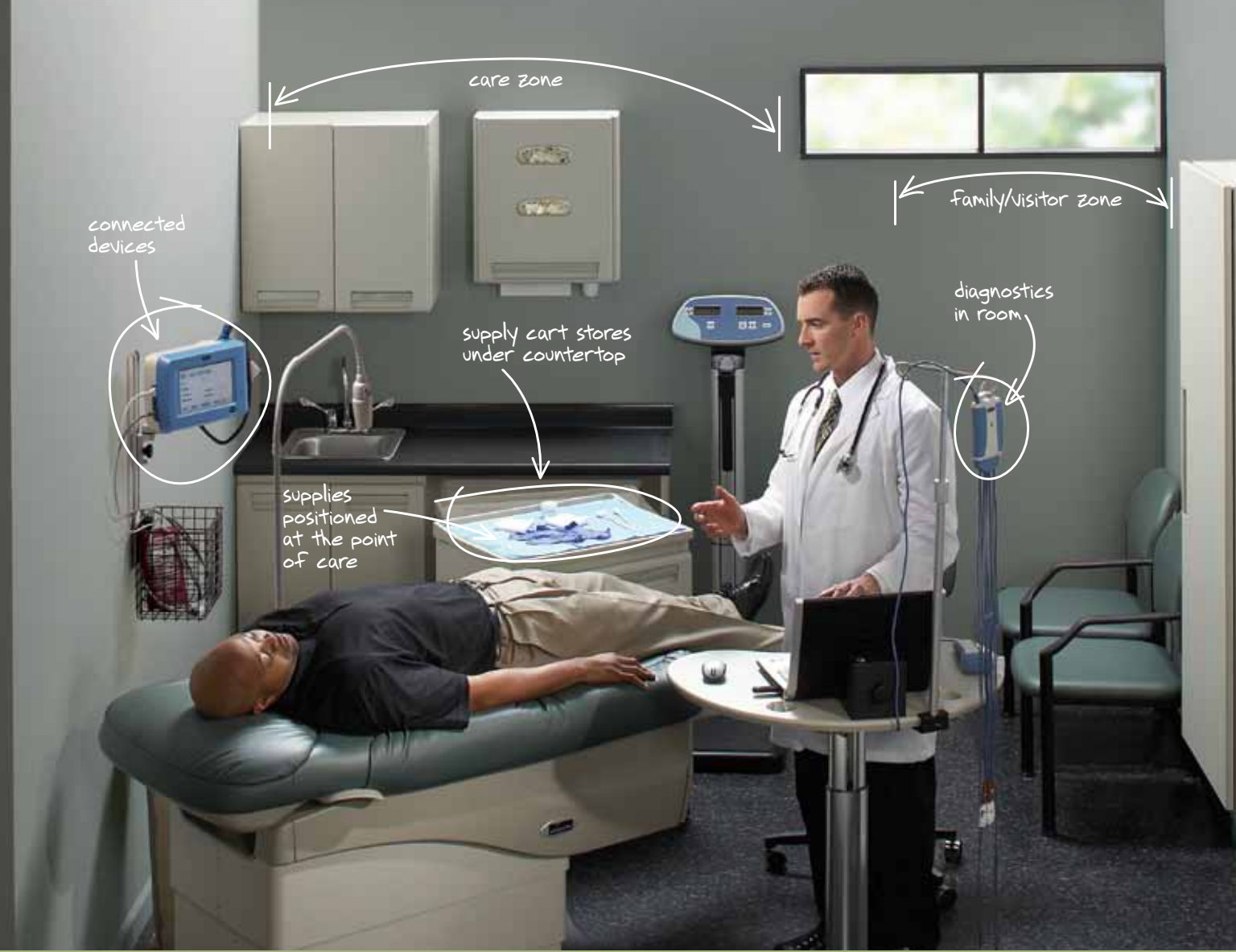
"And having a conflict of interest isn't always a completely avoidable issue. It's an issue about sunshine, about transparency. If there's a potential conflict, it should be disclosed and addressed, especially if it affects the patient's choice of options or what is being recommended to them.

What about context?

AdvaMed, the Washington, D.C.-based association representing approximately 400 medical device and diagnostics manufacturers, has long supported legislation calling for manufacturers to report transfers of value to physicians, says Christopher White, executive vice president, general counsel and secretary. "We believe that appropriate disclosure makes sense when the context is explained and the basis of the relationships [between manufacturers and physicians] are made clear and known to the public."

That said, AdvaMed believes CMS left unaddressed some important topics in its proposed rule, the most important of which is context. "There should be some context associated with payments, so patients understand why a particular physician was engaged to provide a particular service," says White. "Just providing the physician's name and dollar amount is of very limited value, and it could be detrimental to innovation. Perhaps the manufacturer retains a physician for consulting services; it's important to note that those consulting services led to a new invention or enhancement of a technology."

AdvaMed will also seek clarification on that portion of the rule that calls for manufacturers to track and report



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payments made on behalf of physicians and teaching hospitals, says White. The parameters of industry tracking and reporting obligations in this area are unclear, he says.

"And it's also unclear who represents the teaching hospital," he continues. Is it the corporate entity, an officer, materials management? "So we seek further clarity."

At press time, AdvaMed was also planning to study CMS's cost estimates for implementing the rule. In its proposed rule, the agency wrote, "The burden associated with these requirements is the time and effort spent by applicable manufacturers and applicable GPOs collecting the data, compiling reports to send to CMS, as well as the processes for registering and submitting the data, and any corrections, if necessary, to CMS." The agency estimated that on average, smaller manufacturers would have to dedicate 50 percent of a full-time equivalent employee, whereas larger companies would have to dedicate between 5 and 15 FTEs to the process.

"We need to develop a better understanding of the implementation cost beyond the estimates set out in the proposed CMS regulations," says White. "The topic deserves further analysis.

Trouble over a prescription pad

"It strikes me that drawing some bright line between harmless promotion and unethical influence peddling is one of those exercises that always sets off the government-haters," notes Ted Almon, president and CEO of Claflin Co. "Inevitably the law will over-reach, and some poor slob will end up in trouble over a prescription pad or a logo pen.

"Obviously there has been some out-of-bounds behavior by the drug and device companies that crossed the ethical line, and that should be proscribed. But business lunches, promotional items, sports tickets, and other related stuff creates business and jobs for others in the economy with minimal interference of legitimate commerce.

"I am not an anti-government type, but this is where they always get themselves into trouble." **JHC**

Key provisions of Sunshine rule

Answers to key questions…IF the proposed Sunshine rule were to be accepted as written.

Who would have to report?

Manufacturers of devices (including medical supplies) that require premarket approval by or notification to the Food and Drug Administration. (This would exclude many Class I devices and certain Class II devices, which are exempt from premarket notification requirements.)

Any manufacturer that sells or distributes at least one covered drug, device, biological, or medical supply would be considered an applicable manufacturer, and hence, be subject to reporting requirements, even though it may also manufacture products that do not fall within the category (that is, Class I or certain Class II devices). Under the proposed rule, such a manufacturer would have to report all payments or transfers of value to a physician or teaching hospital, regardless of whether the particular payment or other transfer of value is associated with a covered drug, device, biological, or medical supply.

What would have to be reported?

- Consulting fees.
- Compensation for services other than consulting.
- Honoraria.
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- Grant.
- Any other nature of the payment or other transfer of value (as defined by the Secretary of Health and Human Services).

as an alternative, allowing applicable manufacturers to report multiple covered drugs, devices, biologicals, or medical supplies as related to a single payment or other transfer of value."

What would be excluded?

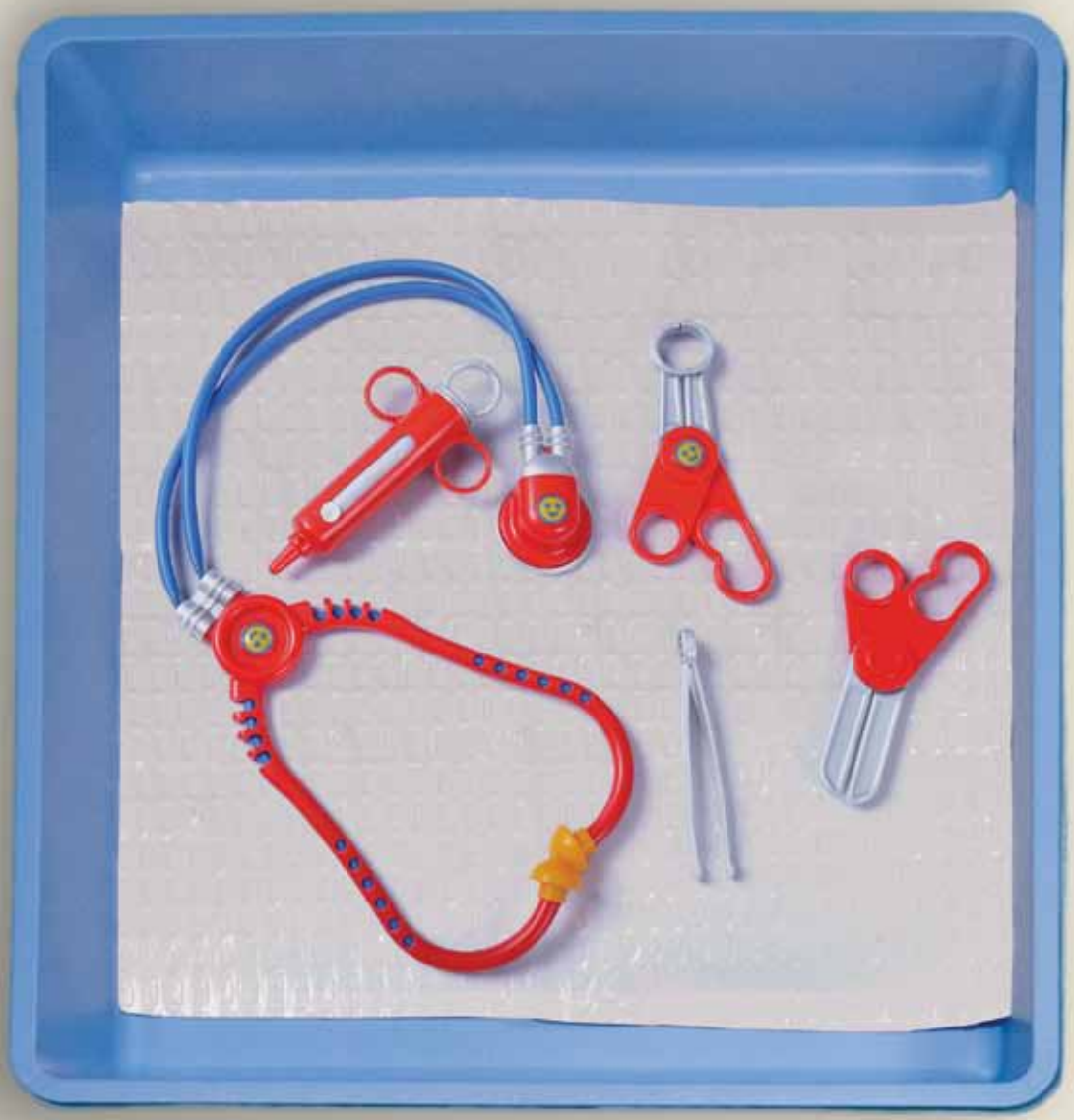
- Transfers of value less than $10, unless the aggregate amount transferred to, requested by, or designated on behalf of the covered recipient exceeds $100 in a calendar year.

A transfer of anything of value to a covered recipient when the covered recipient is a patient and not acting in the professional capacity of a covered recipient.

The name of the covered drug, device, biological, or medical supply associated with any payment, if the payment is related to the "marketing, education or research" of a particular covered drug, device, biological, or medical supply, would have to be reported. For example, if a sales representative takes a physician to dinner to explain the benefits of the applicable manufacturer's new product, the name of the product would be included. The CMS rule adds, "We are considering,

- Product samples that are not intended to be sold and are intended for patient use.
- Educational materials that directly benefit patients or are intended for patient use.
- The loan of a covered device for a short-term trial period, not to exceed 90 days, to permit evaluation of the covered device by the covered recipient.
- Items or services provided under a contractual warranty, including the replacement of a covered device, where the terms of the warranty are set forth in the purchase or lease agreement for the covered device.
- A transfer of anything of value to a covered recipient when the covered recipient is a patient and not acting in the professional capacity of a covered recipient.
- Discounts, including rebates.
- In-kind items used for the provision of charity care.
- A dividend or other profit distribution from, or ownership or investment interest in, a publicly traded security or mutual fund.
- In the case of an applicable manufacturer who offers a self-insured plan, payments for the provision of health care to employees under the plan.
- In the case of a covered recipient who is a licensed non-medical professional, a transfer of anything of value to the covered recipient if the transfer is payment solely for the non-medical professional services of the licensed non-medical professional.
- In the case of a covered recipient who is a physician, a transfer of anything of value to the covered recipient if the transfer is payment solely for the services of the covered recipient with respect to a civil or criminal action or an administrative proceeding.
- Transfers of value made indirectly to a covered recipient through a third party in cases when the applicable manufacturer is unaware of the identity of the covered recipient.

To view the CMS proposed rule, go to https://s3.amazonaws.com/public-inspection.federalregister.gov/2011-32244.pdf.



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By Curtis Rooney

Left to Their Own Devices

Pricing secrecy drives up costs, says government report

The U.S. Government Accountability Office (GAO) recently issued a report that confirmed what healthcare group purchasing organizations – their hospital members and customers – and anyone on the front lines of patient care knows: Medical device pricing secrecy decreases competition. "Gag clauses" limit the ability of hospitals and their GPO partners to effectively negotiate for medical products and services. They artificially drive up healthcare costs, leaving hospitals, patients, Medicare and American taxpayers to foot the bill. Left to their own devices, and without appropriate Congressional review and action, medical device manufacturers will continue to drive the cost of healthcare in this era of critical cost containment.

The GAO report, entitled, "Lack of Price Transparency May Hamper Hospitals' Ability to Be Prudent Purchasers of Implantable Medical Devices," examines pricing information for expensive implantable medical devices (IMD) and determines that there was substantial variation in the prices hospitals paid for the same devices. The GAO concluded that pricing secrecy clauses limit the ability of hospitals to negotiate for the best price.

Without GPO benchmarking, hospitals do not know what the appropriate price is and are forced to negotiate with device manufacturers with asymmetric information.

Medical device contractual confidentiality agreements ("gag clauses") prevent hospitals from sharing their own data and validating that they are receiving a fair price on the products they buy. Contracts between manufacturers and hospitals often forbid disclosure of prices, even to doctors, which makes it difficult to get physicians the information they need to consider cost when making decisions about devices. As a result, some hospitals unnecessarily pay thousands of dollars more than others for high-cost medical devices such as defibrillators, stents and hip replacements. In summary, these are not just the typical confidentiality clauses.

The GAO report finds that the price variation in what hospitals paid for the same types of devices is stark. For example, one hospital surveyed paid $8,723 more than another facility for an identical model of a device that regulates heart rhythm. In general, the item would cost a hospital between $16,445 and $19,007. One hospital reported spending about $4,500 for a specific primary total hip construct, while another paid about $8,000 (78 percent more) for the same device. In another instance, one hospital paid about $5,200 for a primary total knee replacement, while another paid about $9,500 for the same thing (i.e., 83 percent more).

The problem is even more obvious in small and rural markets, where community hospitals often lack the bargaining power of the larger facilities. This is particularly problematic in negotiations with behemoth device corporations. Without GPO benchmarking, hospitals do not know what the appropriate price is and are forced to negotiate with device manufacturers with asymmetric information. In an environment of increasing healthcare costs, the lack of price

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transparency will lead to higher Medicare spending. As the Medicare population grows and beneficiaries live longer, the demand for IMDs will increase. The Medicare program will continue to pay for an increasing number of procedures involving IMDs in the future.

Hospitals frequently deal with strong physician-manufacturer relationships regardless of the fact that physicians are not involved in price negotiations for IMDs. Strong physician preferences on varying models of IMDs reduce the ability of hospitals to standardize on one product, hence depriving them the ability to create economies of scale and reduce costs. Physicians also rely on manufacturer representatives to provide technical support during procedures, such as help with setting up the operating room, consulting with the physician about the procedure, and programming devices. Physician loyalty to certain manufacturers with whom they have consulting or professional relationships has been thoroughly documented. If manufacturers determine that a physician is unwilling to switch device models, they can be more aggressive in negotiations, often resulting in higher prices for hospitals, according to the GAO.

The medical device industry leverages its army of salespeople to drive unnecessary utilization and further enforce contractual "gag clauses" through litigation to keep prices a secret. This chills opportunities for collaboration and gives device makers a virtually unchecked ability to drive up costs for hospitals and Medicare. Because hospitals are unable to discuss device prices with the physicians who choose which products to use, hospitals have effectively become third party payers. It is common sense that keeping prices secret creates an inefficient marketplace. Imagine if you tried to buy a television, and the salesman told you he had four models of TVs, but that he wouldn't tell you the price until you received your credit card statement in the mail. Would you shop there again? You certainly wouldn't expect to receive the best deal.

Hospitals rely on GPOs to deliver the best products at the best value. All independent analyses show that GPOs save hospitals billions every year.

The medical device community often protests that medical devices make up only 5 percent of all healthcare costs. Hospitals, however, make up a much larger percentage of healthcare costs, and it is generally acknowledged that medical supplies often make up approximately 40 percent or more of all hospital spending. It is well documented that for many procedures, payments to manufacturers now take up virtually all of the hospital's Medicare DRG. This is unfair and unsustainable.

Hospitals rely on GPOs to deliver the best products at the best value. All independent analyses show that GPOs save hospitals billions every year. GPOs have also received votes of confidence from the GAO, Department of Justice, Federal Trade Commission, U.S. Supreme Court, academia, and virtually all of America's 5,000+ hospitals. It is time to remove the barriers to true transparency and further unleash the hospital cost-savings potential of GPOs.

The GAO report shows that medical device pricing secrecy is impeding the ability of hospitals and GPOs to lower costs and achieve private sector cost containment. At a time when all parties to the healthcare system are trying to rein in spending, Congress should take steps now to eliminate contractual gag clauses and increase price transparency in the medical device marketplace. **JHC**

Curtis Rooney is president of the Healthcare Supply Chain Association, www.supplychainassociation.org.

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By Robert Betz, Ph.D.

The Tax Trail

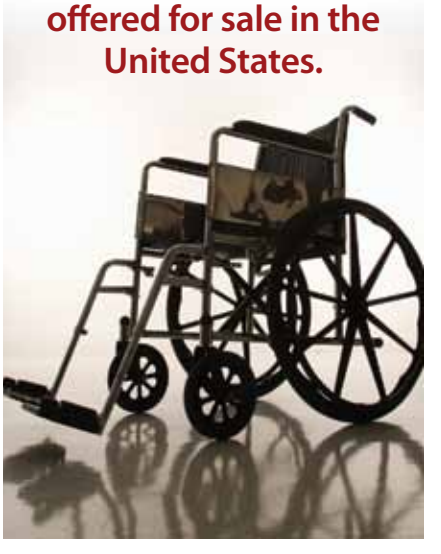
The history behind – and future of – the medical device excise tax

Samuel Johnson, that towering figure of 18th-century English literature, once said about excise taxes "A hateful tax levied on commodities, and adjudged not by the common judges of property, but wretches hired by those to whom excise is paid." No recent issue has roiled the non-labor side of health care more than the upcoming 2.3 percent excise tax on medical devices provided for in the Affordable Care Act (ACA). There are several key questions about this issue. How did the excise tax on medical devices come into being? What is the current implementation status? What is a prognosis for changes, if any, in implementation?

The history behind taxing health care

The interest in the federal government in taxing health care items/products goes all the way back to 1938 with the enactment of the Federal, Food, and Cosmetic Act (FDA Act). This act defined devices as "instruments, apparatus, and contrivances, including their components, parts, and accessories, intended (1) for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals and (2) to affect the structure or any function of the body of man or other animal." The act prohibited all interstate dealings in "adulterated" or "misbranded" devices and authorized the FDA to seize such devices by proceeding against their manufacturers in federal courts. The FDA could not prevent a device from coming onto the market; it could only ask a court to stop the continued sale or enjoin the production of a device already introduced into interstate commerce.

The Chairman's Mark called for the imposition of a fee on any person that manufactures or imports medical devices offered for sale in the United States.



For those of you interested in a little additional "lite" bed-time reading, the U.S. Federal Internal Revenue Code Chapter 32 (Manufacturers Excise Taxes) of Subtitle D deals with excise taxes imposed on the sales of certain products by a manufacturer, producer, or importer.

On Oct. 26, 2002, the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) was enacted into law. MDUFMA amends the FDA Act to provide FDA important new responsibilities, resources, and challenges. MDUFMA has three particularly significant provisions: user fees for premarket reviews; establishment inspections which may be conducted by accredited persons (third-parties); and new regulatory requirements for reprocessed single-use devices. Since MDUFMA, there has been some discussion of additional taxes on the health sector to fund FDA reviews.

After the 2008 election, the Obama Administration was looking

for friends – and identifying non-friends – for their health reform initiative. Many health-related organizations bellied-up and supported President Obama's health reform legislative juggernaut. The friends' price of poker was accepting spending cuts or revenue enhancements for their sector. For this support, and/or non-opposition, the friends got to sit at the negotiating table to keep a watch on their other friends around the table. The non-friends faced a different fate. For them, they got higher cuts and/or revenue enhancements than they would have if they had chosen to be at the table earlier in the process. Thus entered the decidedly unfriendly $20 billion medical device excise tax which evolved from eventual collaboration with AdvaMed, the Medical Device Manufacturers Association, and the National Venture Capital Association.

In September 2009, Congress was at full gallop as it worked with the Obama Administration on moving national health reform forward. Over in the U.S. Senate, the Finance Committee released the "Chairman's Mark" for the "America's Healthy Future Act," which incorporated a number of amendments submitted by Finance Committee Members on both sides of the aisle. The Chairman's Mark called for the imposition of a fee on any person that manufactures or imports medical devices offered for sale in the United States. The aggregate fee on the sector was conservatively estimated to be $4 billion payable annually beginning in 2010. The proposal's aggregate fee would be apportioned among the covered entities each year based on each entity's relative market share of covered domestic sales for the prior year. Additionally, the provision required that the fee be paid on an annual basis. A covered entity under the provision included any manufacturer or importer of medical devices offered for sale in the United States and would include both domestic and foreign manufacturers and importers of such products. Finally, the provision stipulated that the term "covered entity" would include a parent company, its affiliates, and other related parties.

On March 23, 2010, President Obama signed the ACA into effect. It became Public Law 111–148 and included Section 4191 which imposed an excise tax on the sale of any "taxable medical device" by the manufacturer, producer, or importer of the device in an amount equal to 2.3 percent of the sale price.

In October 2010, the IRS published a notice requesting public comments on issues related to implementation of the new excise tax on medical devices imposed by section 4191 of the Code, which was added by section 1405 of the ACA. The new excise tax applies to sales of taxable medical devices after Dec. 31, 2012.

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January 2011 saw Congressman Jason Altmire, a Democrat from Pennsylvania, joined with Representative Erik Paulsen, a Republican from Minnesota, to introduce H.R. 436, the Protect Medical Innovation Act. This bipartisan piece of legislation would immediately repeal the medical device tax as part of the new health care law.

In late January, 2012, Chairman David Camp of the House Ways and Means Committee held a hearing on the impact the ACA will have on the U.S. economy and employers' ability to hire new workers and retain existing employees. At the hearing, Congressmen Paulsen discussed H.R. 436 and noted that 62 percent of the medical

technology industry is small businesses that are innovators and take risks in order to create medical devices. He observed that the medical device tax will help to kill an industry, and that it will be very difficult to jumpstart it in the future. Another observation Representative Paulsen made was the medical device industry currently employs about half a million individuals. His contention was that the $20 billion medical device tax would be a real job-killer for this innovative industry.

This is a tax on innovation and job creation that will ultimately stifle the development of life-saving medical devices with costs that will be passed on to consumers. It's time for this White House to get behind real pro-growth policies to get our economy moving again."

A look inside the tax

Scroll forward to Feb. 7, 2012, and our friends at the Internal Revenue Service (IRS) release their notice of proposed rulemaking providing the first glimpse of how the government will implement the 2.3 percent excise tax provided for in the ACA. The IRS proposed rule defines "taxable medical devices" as those that generally meet the definition under the FDA Act and are used in humans. Under the ACA, veterinary devices and those sold for export or further manufacture are automatically excluded.

The companion legislation to H.R. 436 in the U.S. Senate was introduced by Senator Orrin Hatch (R-Utah). In his introductory comments he said, "Job creators and consumers shouldn't have to foot the bill to pay for the President's partisan health spending law."

At the Ways and Means hearing, Congressman Paulsen went on to say that the IRS proposed regulation for the medical device excise tax "further highlights the fierce urgency of repealing this job-crushing tax on innovation before it is too late. [This] move by the Obama Administration is further proof that the medical innovation tax will increase healthcare costs while putting thousands of jobs on the line."

The companion legislation to H.R. 436 in the U.S. Senate was introduced by Senator Orrin Hatch (R-Utah). In his introductory comments he said, "Job creators and consumers shouldn't have to foot the bill to pay for the President's partisan health spending law." Hatch went on to add, "Hitting medical device manufacturers – an innovative engine of our economy – with a job-killing $28.5 billion tax hike is exactly the wrong thing under a weak economy.

The IRS said that all devices required to be listed by the FDA Act in section 201(h) of the code as amended at 21 U.S.C. 301 et seq. (2006) are considered "taxable medical devices" and are subject to the excise tax unless the device falls within an exemption. These exemptions are: eyeglasses, contact lenses, hearing aids, and any other medical device determined by the Secretary to be of a type that is generally purchased by the general public at retail for individual use. There are other specifications

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related to whether the device is regularly available to consumers who are not medical professionals, and whether consumers who are not medical professionals can safely and effectively use the device for its intended medical purpose with minimal or no training from a medical professional.

Finally, the proposed IRS rule contains a safe harbor provision for many over-the-counter products that would otherwise be considered "taxable medical devices." In short, the IRS is arguing that devices are subject to the tax if they fall within the Food and Drug Administration's domain and are human-use products.

The Congressman is missing 25 out of 66 members of the House Medical Technology Caucus.

Despite the significant number of co-sponsors in the House, the reality is there will not be a bright line effect of the excise tax on consumers' costs for health care and health insurance. So consumers (a.k.a. voters/constituents) will not be actively involved in seeking the repeal of the medical device excise tax. Fact is, spending on taxable medical devices represents less than 1 percent of total personal health expenditures, so a small increase in the price would likely have an almost imperceptible effect on health insurance premiums. What is more, consumers will

Despite the significant number of co-sponsors in the House, the reality is there will not be a bright line effect of the excise tax on consumers' costs for health care and health insurance. So consumers (a.k.a. voters/constituents) will not be actively involved in seeking the repeal of the medical device excise tax.

The next step

So what happens next? Well, on the one hand, the IRS will be moving forward aggressively to get the final rules published by this coming fall. The excise tax will apply to sales of taxable medical devices by the manufacturer or importer after Dec. 31, 2012. On the other hand, Representative Paulsen has 228 co-sponsors for his bill to repeal the medical device tax in the House – a significant political achievement. Interesting, though, is who is not a co-sponsor. probably be swamped by other factors and concerns about the ACA implementation. That being said, without major constituent opposition to the excise tax, come January 2013, manufacturers will be subject to the new tax. The IRS regulations implementing the tax will most likely be finalized in the months ahead. This tax may indeed stifle medical device innovation in the future and cost needed jobs. Nevertheless, the stars are seemingly not lined up against this excise tax moving forward. **JHC**

Note: The author wishes to specifically thank Kathleen Casey, Undergraduate, Columbian College of Arts and Sciences, a Political Science Major with a Focus in Public Policy, at the George Washington University, for her research contributions to this article.

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Robert T. Yokl, Chief Value Strategist, Strategic Value Analysis® in Healthcare

Performance-Based Purchase Service Contracts

Why price shouldn't be a factor

My firm occasionally receives requests from supply chain professionals to price benchmark their healthcare organization's purchase service contract portfolio, only to turn down these assignments since we believe that price shouldn't even be a factor in determining the intrinsic value of a hospital's service agreements. It should be all about results, not transactions!

Your contractor's pay should then be incentivized to lower your cost per adjusted patient day based on a predetermined mutually agreed upon target.

For years, purchase service contracts' pricing had been based on transactions (i.e., linen pounds processed, square footage cleaned, snow removal per inch, etc.), which didn't give your hospital's contractors any incentives to improve their cost and quality performance. That's why performance-based service contracting is gaining interest with hospitals, systems and IDNs who want to reframe and reset their relationships with their contractors to achieve new levels of success.

As an illustration, it's not the price per pound quoted in your laundry/linen service contract you should be fixated on, but instead you should be concerned about the cost per adjusted patient day of your total laundry/linen outsourced operations. This is the cost driver or metric that can and should be carefully managed and controlled by your contractor. Your contractor's pay should then be incentivized to lower your cost per adjusted patient day based on a predetermined mutually agreed upon target. This enables both parties of the agreement to form a true partnership, shared vision and joint business plans to reduce or maintain your hospital's laundry/linen cost per adjusted patient day.

This best practice is particularly attractive if you have been in a business relationship with contractors for many years, since a level of trust already exists and a baseline of performance has already been established. Moving from a transactional to a performance-based contract with these trustworthy, reliable and long-standing contractors will enable you to reboot your relationship with them to reach an even higher level of performance than you ever thought possible.

Simply stated, if you want to turn up the heat with your service contractors, you will need to move from a transactional (paid for a completed activity) payment model to a performance-based (paid only for results) model. This latter model uses a mix of performance-driven incentives to increase productivity, improve service quality and reduce the total costs of operating your outsourced function or activity – not your transaction cost. It's a new way of thinking about how to structure your purchase service contracts, that's the right methodology, at the right time, if you want to truly lower your purchase service contract cost, not just nibble around the edges as we have all done for years. **JHC**

Robert T. Yokl is president and chief value strategist of Strategic Value Analysis® In Healthcare, which is the acknowledged healthcare authority in value analysis and utilization management. Yokl has nearly 38 years of experience as a healthcare materials manager and supply chain consultant, and also is the co-creator of the new Utilizer® Dashboard that moves beyond price for even deeper and broader utilization savings. For more information, visit www.strategicva.com. For questions or comments, e-mail Yokl at bobpres@strategicva.com.

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Jim Fitzgerald to retire

Jim Fitzgerald, president of HealthTrust Purchasing Group and Parallon's Supply Chain Solutions business unit, will retire effective May 31, 2012. Fitzgerald oversaw the initial formation of HealthTrust in 1999, its financial and operational functions, and managed the contracting for clinical supplies, pharmaceuticals and capital equipment, totaling approximately $20 billion annually. He is a member of the Federation of American Hospitals and serves as a board member of the Tennessee Minority Supplier Development Council. A national search for Fitzgerald's successor was to be initiated immediately.


Jim Fitzgerald

Parallon Business Solutions, LLC, headquartered in Franklin, Tenn., provides providers with revenue cycle and business process consulting, workforce management solutions, supply chain services and group purchasing. HealthTrust Purchasing Group, headquartered in Brentwood, Tenn., supports nearly 1,400 not-for-profit and for-profit acute care facilities, as well as nearly 11,000 ambulatory surgery centers, physician practices and alternate care sites.

Novation recognizes suppliers for service excellence

Novation recognized 25 suppliers in recognition of the service they provided to the healthcare organizations of VHA and UHC. The awards were announced at Novation's annual Supplier Summit in February. The GPO honored the overall supplier of the year with the first annual Mark McKenna award. McKenna served as the president and CEO of Novation from 1999 through 2006, and he passed away in October 2011 after a lengthy battle with cancer. The recipient of this year's McKenna Award was Philips Healthcare.

Other award-winners were:

- Spectrum Surgical Instruments (Diversity Supplier of the Year).
- Owens & Minor (Diversity Advocate of the Year).
- Sage Products (Innovative Technology Award, for the company's 2% CHG pre-operative skin prep cloth).
- Kimberly-Clark (Standardization Participation Leadership Award).
- Arizant (Standardization Operational Excellence Award).
- Medline Industries (Environmental Excellence Award).
- Cook Medical (Academic Medical Centers Participation Award).
- Covidien (VHA Supply Networks Participation Award).
- BD (IDS Program Support Award).
- Henry Schein (Non-Acute Partner of the Year).
- Chuck Marcaccio of Hospira (National Account Manager of the Year).
- Philips Healthcare (Capital & Imaging Supplier of the Year).
- Siemens Healthcare (Group Buy Supplier of the Year).
- Astellas (Pharmacy Brand Supplier of the Year).
- Mylan Institutional (Pharmacy Generic Supplier of the Year).
- Seneca Medical (Medical-Surgical Distributor of the Year).
- AmerisourceBergen (Pharmacy Distributor of the Year).
- AmSan (Specialty Distributor of the Year).
- Teleflex (Medical-Surgical Supplier of the Year).
- Synthes (Physician's Preference Supplier of the Year).
- AMN Healthcare (Purchased Services Supplier of the Year).
- OfficeMax (Support Services Supplier of the Year).
- DeRoyal (NOVAPLUS Supplier of the Year).
- Sagent Pharmaceuticals (NOVAPLUS Pharmacy Supplier of the Year).

CONTINUED OBSERVATION DECK

and patients (the ultimate end user), with limited supply chain involvement," says SMI. "A significant 'disconnect' exists between the common value analysis model that focuses on costs, efficiency and value for developed products, and the research and development model with costly investments to develop new products. Supply chain is often the driving force behind a provider's value analysis process and culture, and thus is in the position to promote the necessary change that emphasizes quality patient outcomes with CER information."

In other words, the authors suggest, healthcare providers can have a favorable impact and offer guidance to medical device developers as they conduct their research on new technologies. Communication before and during the R&D process might help prevent millions of dollars wasted on technologies that the market doesn't want or can't use.

Comparative effectiveness research offers a new opportunity for JHC readers willing to stretch themselves.

To download the free SMI Executive Briefing, go to www.smisupplychain.com and click on "Industry Tools." **JHC**

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VHA

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By Mark Thill

Comparative effectiveness research: Big term, big opportunity

Comparative effectiveness research is a relatively new term in the healthcare lexicon, and one with which supply chain professionals should familiarize themselves. That's what makes Strategic Marketplace Initiative's Executive Briefing, "*Comparative Effectiveness Research (CER) and the Healthcare Supply Chain*" such good reading.

As SMI points out, comparative effectiveness research attempts to compare different diagnostic or treatment options for clinical conditions. These interventions may be procedures, devices, drugs, tests or behavioral interventions. The comparative information can be generated from reviews of published research, or from new studies that yield new evidence.

It truly is the part of the post-healthcare-reform landscape, and probably will be regardless of how the Supreme Court rules later this year. The question is, what role can supply chain executives play in it? That's the question that SMI tackles in its Executive Briefing.

To date, efforts to maximize the value of comparative effectiveness research have been primarily focused on clinical systems, data management, and associated processes. Little attention has been paid to connecting it to the supply chain. But that's changing.

SMI points out that "collaboration and understanding between clinical, operations and administration" is critical in today's environment, and suggests a "cross-disciplinary effort surrounding [comparative effectiveness research including] clinicians, supply chain management representatives, and representatives from finance, risk, quality and senior leadership."

Comparative effectiveness research will affect healthcare systems in a number of ways, SMI points out. For example, it may provide an opportunity to redesign existing committee structures, such as technology assessment committees and value analysis groups. But that's not all. Such research may also stimulate the development of information technology systems that will facilitate the collection and analysis of data that includes the cost of product, of procedure and of hospitalization, not to mention clinical outcomes.

But if supply chain executives are to play any role in comparative effectiveness research, they may need to stretch their skill sets. As SMI says, "This new era of healthcare reform is revealing the need for [supply chain management] to expand its skills and leadership in areas such as partnership development, data analytics, clinical utilization, group facilitation, project management and change management."

While supply chain executives have long tapped into clinical staff for help with utilization, product selection and value analysis, the new breed of executive will have an increased need to tap into clinical knowledge and experience if they hope to support physician interaction in product decision-making.

No one is suggesting that supply chain executives become clinical experts. "Physicians articulate the critical perspective on the factors impacting different treatment options, including medical practice standards, patient population variables, safety, cost and historical trends," points out SMI. But the supply chain executive is in a position to deliver comparative product information to clinicians through newsletters, presentations, webinars and dedicated websites.

"Participation of physicians in [comparative effectiveness research] efforts with [supply chain management] establishes an atmosphere of patient-centeredness," the authors point out. "Creating active communication between physicians and supply chain management allows available evidence to drive clinical and product decisions. For areas without solid evidence, this open collaboration allows discussion of the options available and ways that the hospital system could be involved in evidence generation."

Comparative effectiveness research presents an opportunity not just to establish new and deeper relationships with the clinical staff, but with vendors as well, says SMI.

"Currently, product development activities are frequently driven by feedback from physicians (product user)

(*Continued on page 56*)

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