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LABORATORY

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Price Transparency Initiative for Lab Tests Moderately Successful

The notion of price transparency in health care delivery has been gaining purchase in recent years. It's been driven by relentless cost-shifting to patients over the past decade, as well as providers that have come under scrutiny for inflating even the price of aspirin far beyond its actual cost.

Although transparency efforts have mostly been on the consumer end, they have been limited in scope. Providers don't want to disclose such information and have often lobbied state and federal lawmakers to keep such data under wraps.

And when a transparency initiative is placed on the provider side—as it was for lab test ordering involving a large Massachusetts medical group—it didn't nudge the needle all that much either, according to a study recently published in the *Journal of General Internal Medicine*.

The effort involved Atrius Health, a group practice of more than 1,000 physicians serving much of the Bay State. Atrius is gaining nation-

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G2 Releases New Market Analysis Report

The year 2014 may be one of the most momentous in health care delivery since the creation of the Medicare and Medicaid programs nearly a half-century ago. And G2 Intelligence, which publishes *Laboratory Industry Report*, has just released a forecast of what the lab sector is facing in the turbulent year ahead and in 2015.

G2's new report, "U.S. Clinical Laboratory and Pathology Testing 2013-2015: Market Analysis, Trends, and Forecasts," is now available in both print and electronic formats.

Authored by L. Eleanor J. Herriman, M.D., G2's managing director of advisory services; Jennifer Musumeci, associate director of advisory services; and Jenny Xu, Ph.D., director of research, the 200-page report provides a comprehensive outlook of the current state of the laboratory sector, outlines the challenges ahead, and provides a pathway for the sector's players to move forward.

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■ PRICE TRANSPARENCY INITIATIVE FOR LAB TESTS, *from page 1*

wide attention for its transparency efforts in other realms—it's one of the handful of providers in the nation where its doctors will meet with and apologize to patients after serious medical errors occur. And Massachusetts itself is on the leading edge of price transparency: Its hospitals, doctors, and insurers will all have to immediately disclose the cost of specific procedures to patients on request by the fall of 2014.

Atrius was a little ahead of the curve for transparency involving its own doctors: It placed the prices of 27 common laboratory tests in front of a group of doctors when they summoned the patient's electronic medical record (EMR). Twenty-one of the tests were considered lower cost (\$3 to \$40). They included a basic metabolic panel, strep throat screening, Pap smear, lipid profile, glucose, and urinalysis. Six others were considered higher cost (\$40 to \$100) and included chlamydia urine and genital screenings, B-type natriuretic peptide, parathyroid hormone, 25-OH vitamin D, and alpha-fetoprotein. The prices were based on 2010 Medicare rates.

Tests Routinely Reordered

These tests are administered in such high volumes that they're often reordered when a patient is referred to a specialist—as opposed to that doctor merely perusing the original test results, according to M. Susan Stegall, a laboratory industry consultant in Salem, Ohio.

"This happens even at places like the Cleveland Clinic," Stegall said, noting that she has experienced it personally as well.

Between May and November 2011, 153 Atrius primary care physicians were told the price range of the tests on an ongoing basis whenever they accessed their patient's EMR. They were compared to a control group of 62 primary care doctors who were not given any price information.

"Our study demonstrates that electronic health records can serve as a tool to promote cost transparency, educate physicians and reduce the use of potentially unnecessary laboratory tests by integrating the relative cost of care into providers' decision-making processes," Thomas D. Sequist, M.D., an Atrius Health physician and senior author on the study, wrote in an introduction to the study.

However, test ordering was only modestly impacted. Ordering patterns for only four assays demonstrated what the study's authors called a statistically significant reduction in their monthly ordering rate. Most were low-cost tests. They included glucose, which dropped 2.6 percent; alanine aminotransferase, better known as ALT, which dropped 2.3 percent; lipid profiles, which dropped 2.1 percent; and creatinine, which dropped 1.2 percent.

Only one high-cost test, the chlamydia urine screening, dropped 2.5 percent.

By contrast, testing volumes for that assay increased 12.7 percent among the control group. Orders for creatinine tests also increased among the control group 3.8 percent during the period when the initiative was in place. The control group's patients were about 2.2 years older on average than the study group and were

about 10 percent more likely to be enrolled in Medicare, although the study did not mention whether these differences may have had an impact on ordering volume.

Altogether, the reduction in test orders represented a cut of 0.4 to 5.6 fewer lab orders per 1,000 patient visits per month, a decrease the study's authors termed as modest.

Less Dramatic Than Johns Hopkins Study

The findings were actually less dramatic than what was experienced by Johns Hopkins physicians, who also had a six-month window when they were presented with the Medicare cost of 61 different tests at the time of order. According to a study published in the *Journal of the American Medical Association* last April, lab ordering among physicians in the group exposed to the prices dropped about 9 percent. By contrast, volumes in the control group rose about 5.6 percent during the six-month period.

Nevertheless, Johns Hopkins saved about \$400,000 during the time when the test volumes dropped. And while that study's authors also called the results modest, the monetary gain is hard to ignore, even in a multibillion-dollar health care system. The Atrius study did not cite any specific cost savings. And while it is one of the largest multispecialty practices on the eastern seaboard, it is still a much smaller organization than Johns Hopkins.

Dilemma for Labs

Cutting the number of tests performed by a significant amount could prove troubling to some laboratories, which are already struggling with flat volumes. But Stegall noted that labs are slowly being prodded to prove their value, meaning ignoring or fighting efforts to move toward price transparency will hurt their bottom lines in the long term.

At the same time, Stegall also believes that showing prices to doctors isn't a cure-all for cutting down on unnecessary testing. "A hard stop works," she said, referring to a feature of an EMR system that blocks physicians from ordering duplicate tests within a narrow period of time. Physicians can often override such a feature but may be prompted to put their clinical reasons why into the patient's medical record.

And in terms of price transparency that may be truly transformative, Stegall noted that Theranos, a laboratory venture that is providing draw services through Walgreens pharmacies, may be a future indicator. Theranos charges consumers only 50 percent of Medicare charges for its entire test menu. However, the California-based lab has only recently commenced operations and is operating in only a handful of locations, making it unclear what kind of success the company might eventually enjoy.

An Atrius spokesperson was unable to make any of the physicians who authored the study available for comment.

Takeaway: Price transparency on the provider end may not make a significant dent in testing volumes. 

Inside The Lab Industry



Health Diagnostic Laboratory: A Rare Recent Success for Lab Sector

Health Diagnostic Laboratory Inc. (HDL) is a monster success story in a sector staving off contraction. And it's one that came perilously close to ending not far from the launchpad.

Less than five years ago, founder and Chief Executive Officer Tonya Mallory had made proposals to hundreds of potential investors. She and her husband had mortgaged their house and were bouncing checks for nominal sums when \$4 million came in from Tipton Golias, the founder of Helena Laboratories.

In 2009, when Mallory and her one full-time employee were seeking certifications in the process of ramping up, revenue didn't quite reach \$5,000. But by happenstance, Mallory's skeletal sales staff made a connection that wound up matching HDL with Bluewave Healthcare Consultants. It very quickly made marketing inroads for the company in Alabama and then other parts of the Southeast.

That's a sweet home for HDL, which sells cardiovascular, diabetes, stroke risk, and related biomarker and lab assays. They're melded with specialized in-person education for patients in an effort to improve their long-term health.

"The obesity rates are very high there, and therefore very viable for us," said Mallory, who decided to depart from her original plan of gradually building business in and around HDL's corporate headquarters in Richmond, Va.

As a result, HDL began racking up new physician clients with a swiftness seen by few other fledgling labs. Sales reached a remarkable \$81 million in 2010. If you don't have a calculator at hand, that's about a 1.6 million percent annual increase. They tripled to \$210 million in 2011 and then doubled to \$420 million last year. At the start of 2010, the company was performing about 300 assays a day. Now, it's performing 125,000, according to Mallory.

The company operates in 48 states and has nearly 800 employees. It is spending more than \$68 million on an expansion of its corporate headquarters, including an additional 60,000 square feet of laboratory space. The current lab is operating at 60 percent of capacity; the expansion will bring it down to 25 percent of capacity. That's in addition to another smaller lab in Kansas HDL now owns as part of its recent acquisition of the U.S. division of Oncimmune, a British company that focuses on lung cancer detection.

Mallory, 48, has been showered with accolades. She was recently named 2013 Virginia Business Person of the Year. In 2012, she was named Ernst & Young National Entrepreneur of the Year in the emerging business category.

Mallory enjoyed a similar huge success story with the U.S. division of Wako Chemicals, the manufacturer of reagents and other lab products. She built its chemical diagnostic division from less than \$5,000 a year in annual sales to more than \$20 million.

But because Mallory was a woman in a Japanese firm, she was told despite her success she wasn't going to advance.

“There is a lot of frustrating things about Japanese management, a lot of good things as well,” said Mallory, whose experience with Mako has made her generous with her own employees on issues such as health benefits, family leave, and even seed money to start their own ventures. “Somewhere in the middle is probably the most efficient and best situation.”

She left Wako in 2004 after spending virtually her entire career with the firm, then spent three difficult years attempting to build a facility in Richmond for Berkeley Heart Lab—a project that was killed when Berkeley was acquired. That’s when she decided to strike out on her own.

Sexiness and Customer Service

Industry observers say HDL has been able to reach the heavens so quickly because they offer something few other labs do—a combination of test results uniquely designed and packaged to make them both appealing to doctors and patients, as well as strong customer service and personalized outreach.

Peter Francis, president of Maryland-based Clinical Laboratory Sales Training, described HDL’s approach to providing test results as “sexy”—a word rarely applied to anything in the lab sector. The company color codes results in green, yellow, or red to give both clinicians and their patients a very quick idea of where problem spots may lie.

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*—Tonya Mallory,
Chief Executive Officer,
Health Diagnostic Laboratory*

“It’s flashy, good, and colorful, and it sells,” he said.

According to Mallory, the color-coding system takes any arbitrariness out of the results and improves communications between the patient and physician.

But HDL also follows through on the lab results. They employ about 100 clinical health consultants who travel to the offices of the lab’s client physicians. They are medical professionals—cardiac nurses, dietitians, smoking cessation experts, and pharma-

cists. They will sit down with a patient whose testing has detected a current or impending health care issue and educate them on ways to change their lifestyles for the better. They will also discuss with the doctors ways to better utilize HDL’s testing panel in order to improve interactions with patients and focus on new ways of delivering care.

Mallory described HDL’s business model as disease management mixed with some laboratory services. “I am not selling them testing,” she said. “What we actually do is provide answers to the disease state in the doctor’s office.”

Years of working in the lab business and studying the traditional health care delivery models eventually convinced Mallory that doctors may not delve deeply enough into a patient’s conditions because of their training, professional inclination, or finances. Mallory’s mother-in-law had a fatal kidney disease go undiagnosed for a year because her doctor did not run the appropriate assay early in the diagnostic process. Her sister, a diabet-

ic, suffered two heart attacks in a week and was moments from being discharged from the hospital because her cardiac panel indicated she was fine. The cardiac stress test Mallory insisted on for her sister proved otherwise. Instead of being discharged, she underwent double bypass surgery.

That a health issue may be lurking undetected is HDL's unofficial motto (the official motto: "beyond disease diagnosis"). The home page on the company's Web site notes that half of heart attack victims have normal cholesterol levels, something Mallory repeats during a lengthy telephone interview. And the HDL Web site states that the U.S. market is ripe for such detective work: A third of Americans are diabetic or prediabetic, and a third have some form of cardiovascular disease.

Partly as a result, HDL has obtained a following so devoted that Francis has come across doctors willing to pack their own tests and FedEx them to Richmond even though they practice right next door to a draw station.

"There are those people who really latch on to wanting to delve into and get as much as a vial of blood as possible, and have some company like HDL help them out," he said.

Challenges and Questions Remain

Although HDL has had a truly fantastic first five years, it is also experiencing some of the pains associated with such swift growth. Mallory noted that revenue will be flat for 2013, as the company has been victim of the same cuts in reimbursement that the rest of the sector is struggling to address.

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***—Peter Francis,
President,
Clinical Laboratory Sales Training***

Sources have also indicated that HDL may be cutting corners to grow business, with the lab potentially paying doctors as much as \$30 for a blood draw. Such a practice would violate federal and many state anti-kickback laws. Mallory denies this is the case. She noted that the company pays \$3 for a blood draw per federal guidelines, as well as other phlebotomy services "like all other labs in the country."

And HDL may also be under investigation by state or federal agencies, sources say. It's an allegation that could not be confirmed. "As a policy matter, our company does not confirm or deny or comment upon any pending or threatened legal proceedings or investigations," Mallory said in a written response. HDL only hired a chief compliance officer in September, but Mallory said that it was a logical hire.

"We grew so fast, we're just trying to react to that growth. Our second year we tried to get things off the ground from an operational standpoint. In the third year and beyond, we're trying to fill in the gaps with the talent to operate at this level," she said. "It's just a natural progression of growing up—and trying to be a good corporate citizen."

Takeaway: Health Diagnostic Laboratory's unique perspective on the use of testing has led to phenomenal growth, but big challenges remain ahead. 

■ G2 RELEASES NEW MARKET ANALYSIS REPORT, *from page 1*

The report identifies seven specific trends G2 believes is affecting the laboratory sector. They include reimbursement, the physician-as-employee model, molecular medicine, consumer health care, and others.

Overarching all of these trends is the rolling out of the primary components of the Patient Protection and Affordable Care Act (ACA) in 2014 and the years beyond.

Although health care reform will create an influx of millions of new commercial and Medicaid health plan enrollees in the coming months and years, how that will impact the lab sector remains to be seen. G2 concluded that lab revenue experienced a decline in 2013 of about 2.8 percent after two prior years of relatively vigorous growth. The organization expects lab revenue to be challenged by a confluence of market forces over the next couple of years.

For example, molecular testing—which has been powering much of the sector’s growth in recent years—grew a scant 4 percent in 2013, impacted by the gap-fill payment system used by the Centers for Medicare and Medicaid Services to price new molecular CPT codes that replaced prior code-stacking methodology and reduced overall reimbursement by about 15 percent. G2 discusses its forecast for this market in 2014 and 2015 in the new report.

Reimbursement cuts also hit the anatomic pathology market hard as well—particularly the 52 percent reduction in the technical component of CPT code 88305, the most widely billed procedure in the entire segment. The report discusses the horizon ahead for the segment, with both a forecast for 2014 and 2015 and a discussion of how it will likely adapt and change.

Hospital laboratories, which are still one of the biggest forces in the sector, are also under pressure from the ACA. They face the need to update their health care IT structure while battling declining outreach revenues due to their parent institutions retaining more doctors as employees. The report delves at great length into what hospitals are doing to reshape this particular revenue stream.

The report also examines challenges facing independent laboratories. Many have reported drops in revenues and margins, prompting staff layoffs and other cut-backs. It examines how the changes in the overall marketplace are creating both new opportunities and challenges.

The report includes sizing for the various laboratory markets, as well as revenue for each segment, new payment and care delivery models, and a discussion of what various laboratories are doing to respond to the new and ongoing pressures.

“U.S. Clinical Laboratory and Pathology Testing 2013-2015: Market Analysis, Trends, and Forecasts,” may be purchased for \$1,495 at www.G2Intelligence.com/ClinPathTesting or by calling 800-531-1026.

Takeaway: G2 Intelligence offers the most comprehensive report available on the current laboratory sector and how it will evolve in the future. 

Foundation Medicine Releases Blood-Based Molecular Cancer Panel

Foundation Medicine, the Cambridge, Mass.-based molecular laboratory, has launched a new test panel that focuses specifically on hematologic cancers.

The panel, known as FoundationOne Heme, was developed in conjunction with Memorial Sloan-Kettering Cancer Center in New York City. Sloan-Kettering provided its sizable database on hematologic cancers, allowing Foundation Medicine to fine-tune its proprietary gene marker detection technology and algorithms.

There are about 150,000 new cases of blood-based cancers—leukemia, lymphoma, and myeloma—diagnosed in the United States every year, up significantly over the last decade. They represent about 10 percent of all cancer diagnoses each year and cause about 55,000 deaths, also about 10 percent of the nationwide total.

Although the five-year survival rates from the hematologic form of the disease have dramatically improved over the past 50 years, they remain below 50 percent for myeloma and less than 60 percent for leukemia. Higher survival rates are tied to earlier detection and determination of the most effective drug regimens—something the Foundation Medicine tests are expected to improve.

“This new test is designed to fit within routine clinical practice and provide a physician with all of the relevant genomic information needed to make an informed treatment decision, which may include a targeted therapy or clinical trial,” said Michael Pellini, M.D., Foundation Medicine’s chief executive officer. Company officials said the test can also be used on pediatric forms of the disease.

In a recent filing with the Securities and Exchange Commission, Foundation Medicine indicated its research on the new test indicated it is more accurate in analyzing the genetic state of hematologic cancers than established tests such as BRAF, JAK-STAT, and IDH1/2.

FoundationOne Heme is the second product introduced by Foundation Medicine. It introduced a molecular assay for solid cancer tumors last year. Although the company has yet to show a bottom-line profit, its revenues for the first nine months of 2013 are nearly quadruple the same period from a year ago. However, the company’s stock is about 35 percent lower than when it began trading in September.

Takeaway: Foundation Medicine is continuing with its oncology-based molecular assay development. **G2**

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Kimberly Scott, Managing Editor, kscott@G2Intelligence.com; Ron Shinkman, Editor; Heather Lancey, Designer; Beth Butler, Marketing Director; Dan Houder, President and Publisher
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