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HIGHLIGHTS

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Health Diagnostic Laboratory Tries to Remake Draw Centers

Health Diagnostic Laboratory (HDL) wants to make draw stations a bit more of a draw.

The Virginia-based HDL, which focuses on cardiometabolic testing in order to help patients improve their long-term health, has opened several stylish new draw stations aimed directly at making visits more palatable for patients.

The lab has opened five sites, known as My HDL Hub Centers, with four in Virginia and one in Knoxville, Tenn. Others will be opened as demand dictates, according to company officials.

Described by Chief Executive Officer Tonya Mallory as "Nordstroms-meets-phlebotomy," the draw centers have streamlined furniture and a green color scheme that plays into HDL's primary branding hue. Some of the artwork on the walls comes from Mallory's own hand. And the receptionist—known as a "concierge"—sits at an open-air desk without a glass partition.

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Quest Releases Smartphone App For Patients to Receive Direct Results

It was a case of *carpe diem* for Quest Diagnostics. On April 7, the day that federal regulations began to go into force allowing patients to receive tests results directly from a laboratory without a physician review, the New Jersey-based Quest released a sophisticated patient portal and affiliated smartphone application to take advantage of the change.

The app, known as MyQuest, was developed in-house and is compatible on both the iPhone and Android platforms. It allows patients to obtain their test results and interpretations directly from a Quest laboratory. In addition to receiving such data, the app allows patients to make appointments at the 2,200 Quest draw stations, send data to physicians, and create personal health profiles that include an individual's medical conditions, the medications they take, and other relevant information. The app can also be used to monitor information from the Withings mobile blood pressure cuff and body scale,

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"My HDL Hub gives people an experience they've never before had when getting blood drawn, and the moment they walk in the door to the second they leave is designed to place them in a position of control over their health," Mallory said.

The My HDL Hub Centers will also offer clinical health consultants to help patients focus on making diet and other lifestyle improvements. Ongoing classes will also be offered that include yoga, stretching or cardio exercises, and cooking lessons or demonstrations. Some of the new draw centers are located on the sites of fitness centers, which further communicates the message of improving and maintaining a patient's health.

"The hub is more a part of the wellness experience at the gym, where those type of activities are already taking place," Mallory said.

Two of the centers are also offering blood draws, analysis, and consultation to patients without a physician referral for a $295 out-of-pocket charge.

The proactive and consumer-oriented styling of the draw centers is an anomaly in the lab sector, where most sites are plain and straightforward. However, times may be changing, particularly as reimbursements are down and the battle for dollars has become tougher.

"It's called customer service, and it's a natural progression," said John Rhoades, a principal with Camino Consulting in Marquette, Mich. "It's getting more and more difficult to make money, and there has to be a rolling together of lab and outpatient services. It is thinking outside of the box."

Takeaway: HDL's decision to remake draw centers could spark the start of an industry-wide trend. G2

Aurora Diagnostics Is Feeling the Reimbursement Heat

Despite narrowing its losses significantly in 2013, Aurora Diagnostics, the Florida-based molecular laboratory, is the latest company in the sector to report ongoing struggles with maintaining revenue streams in the face of declining reimbursements.

Aurora reported a net loss of $73 million on revenue of $248.2 million for calendar 2013. That's less than half the $160.9 million loss it reported in 2012, but revenue declined 11 percent, from $277.9 million.

Aurora's March 25 10-K filing with the Securities and Exchange Commission blamed the revenue decline on "Medicare reductions, including changes to the 2013 fee schedule, the grandfather provision rule change and sequestration, as well as lower reimbursement from private insurance and the BlueCard Program."

However, total accessions were also on the wane, dropping 33,000 to 2.138 million. The average revenue per accession also declined 9.3 percent, to $116, compared to $128 in 2012.

Based on Medicare's ongoing changes to the Physician Fee Schedule, Aurora estimates that revenue from that stream will decline by $6 million in 2014, "before any change in conversion factor."

The company suggested that the Medicare cuts would not be the only headwinds it will face in the coming months. Aurora took noncash impairment charges of $53.9 million in late 2013. It included a write-down of $52.9 million in the carrying value of good will and another write-down of $1 million in the carrying value of intangible assets.

"If we cannot offset the reductions in our reimbursement from governmental payers and potential reductions from our non-governmental payers by reducing our costs, increasing our accession volume, and/or improving our service mix, we believe it could have a material adverse impact on our revenue, profitability and cash flow," Aurora said in its filing.

The company also has $324.3 million in long-term debt—that's more than a year of revenue at its current level—and just $1.4 million in cash on hand, down from $10.8 million at the end of 2012.

Aurora appointed Daniel Crowley as chief executive officer in the spring of 2013, replacing Jon L. Hart, who was recently appointed as CEO of Medfusion. Crowley's annual base compensation is $1.2 million, nearly triple Hart's $450,000.

Takeaway: Aurora Diagnostics, like many other medium-sized laboratories, is feeling the squeeze from ever-constricting reimbursements from government and commercial payers.

Opko Introduces Prostate Cancer Test

Opko Health has introduced a new noninvasive predictive molecular test for prostate cancer.

The test, known as the 4Kscore, is intended to reduce the approximately 1 million prostate biopsies that occur in the United States every year. Such biopsies tend to be uncomfortable for the patient, can lead to internal bleeding or infection, and lead to negative test results 80 percent of the time.

Although some 238,000 Americans are diagnosed with prostate cancer annually, the aggressiveness of the disease varies widely. Long-term survival rates are nearly 100 percent up to stage three of the disease, making the need to undergo a biopsy debatable in many cases.

The 4Kscore requires a blood draw and measures the serum levels of four different prostate-derived kallikrein proteins: total prostate-specific antigen (PSA), free PSA, intact PSA, and hK2. That, accompanied with a digital rectal exam, can provide an accurate "Gleason score" of equal to or greater than seven, which is the equivalent to a stage two form of prostate cancer.

"We believe the 4Kscore TestTM will be an important benefit for urologists and their patients and may lead to lower overall health care costs," said Phillip Frost, M.D., Opko's chief executive officer.

The test was developed in conjunction with Memorial Sloan-Kettering Cancer Center and more than two dozen urology centers in the United States.

Takeaway: Opko Health has developed a noninvasive test that can eliminate virtually all of the health risks associated with prostate cancer biopsies.

CMS Payment Data Release Includes Labs, Pathologists

Putting an end to legal wrangling that dates back 35 years, the Department of Health and Human Services (HHS) earlier this month released a vast trove of Medicare Part B provider payment data that included clinical laboratories and pathologists.

"We believe the public has the right to know this information," said Centers for Medicare and Medicaid Services (CMS) Principal Deputy Administrator Jonathan Blum at a news conference on April 9, the day the data were released. Blum and other CMS officials cited a variety of reasons for the release, including the fact the Medicare program was funded by taxpayer dollars, the agency believed the public's interest in knowing the payment data outweighed that of the privacy of the providers, and the potential for the public to use the numbers to sniff out potential fraud.

The *Wall Street Journal* spearheaded the release of provider-specific payment data, which had been prohibited under a civil injunction since 1979 as the result of litigation by the American Medical Association (AMA).

In December 2010, the *Journal* published a story that was simultaneously illuminating but circumscribed about a group of spinal fusion surgeons who practiced at a medium-sized Kentucky hospital and were apparently leveraging patents they held on medical devices that could be used in the procedures to help them reap millions of dollars a year in royalties. And while the hospital, despite its modest size, was the third-biggest biller of Medicare for spinal procedures in the entire United States, the *Journal* was barred from reporting how much the doctors received in payments from the Medicare program.

The newspaper's attorneys went to court to overturn the injunction, finally prevailing last year.

"Currently, consumers have limited information about how physicians and other health care professionals practice medicine," said HHS Secretary Kathleen Sebelius, who ordered the data released the day before she announced her resignation. "This data will help fill that gap by offering insight into the Medicare portion of a physician's practice. The data released . . . afford researchers, policymakers, and the public a new window into health care spending and physician practice patterns."

The data also include payments made to clinical laboratories and pathologists. CMS released all fee-for-service data for any provider that performed a specific medical function a minimum of 11 times. The data do not include revenue derived from the Medicare Advantage health plans.

And while CMS touted its release as a boon to consumers, it was presented in a format that made it difficult for individuals to access. The raw data, which detailed $77 billion in payments that were made in fiscal 2012, contained more than 9 million lines of information and could not be opened in an Excel spreadsheet. A dozen separate files contained the data by provider

name, but individuals such as Salomon Melgen, M.D., a Florida physician who billed Medicare for more than $20 million and had his medical offices searched multiple times by the Federal Bureau of Investigation as a potential suspect of health care fraud, was absent from those files, as were other high-paid physicians. The data in a spreadsheet that listed aggregate payments to providers also appeared to contain inaccuracies.

CMS spokesperson Rachel Maisler said the agency does not comment on the billing practices of individual providers and would not provide an answer when asked if the data in the Excel spreadsheet format were complete and accurate.

Using a database to search the information created by the *Wall Street Journal*, *Laboratory Industry Report* was able to determine that Quest Diagnostics, the nation's largest national lab, was also the biggest recipient of Medicare Part B fee-for-service payments, which totaled $669.8 million in 2012. LabCorp was a close second, at $633.4 million. A LabCorp spokesperson said the North Carolina-based company derives about 12 percent of its revenue from the Medicare program. Its revenues were $5.8 billion in 2013.

Amounts Laboratories Were Paid by Medicare In 2012

Provider Name	Amount Paid by Medicare, 2012
Quest Diagnostics	$669.8 million
LabCorp	$633.4 million
Millennium Laboratories	$190.0 million
Health Diagnostic Laboratory	$139.1 million
Unilab	$124.1 million
Ameritox	$99.6 million
Bio-Reference Laboraroties	$95.1 million
Solstas Lab Partners	$77.9 million
Natural Molecular Testing Corp.	$70.3 million
Clinical Pathology Laboratories	$62.4 million
Lab One	$60.2 million
Myriad Genetics	$54.1 million
Genoptix	$50.2 million
Genomic Health	$49.3 million
Sonora Quest Laboratories	$45.8 million
Aegis Sciences	$36.2 million
Miraca Life Sciences	$33.8 million
Clarient Diagnostic Services	$32.5 million
Shiel Medical Laboratory	$29.8 million
Physicians Choice Laboratory Services	$24.9 million

Source: Centers for Medicare and Medicaid Services via Wall Street Journal

Quest and LabCorp, which control about 20 percent of the entire laboratory market, dwarfed the other labs in terms of the payments they received. They were more than triple the size of the third-highest payment recipient on the list, San Diego-based Millennium Laboratories.

The data regarding individual physicians were more controversial. Ophthalmologists tended to be the highest billers, but many have indicated that they were often billing in their name on behalf of a group practice and that their payments included near-cost reimbursements for macular degeneration drugs that can cost as much as $2,000 for a single dose.

Highest-Paid Pathologists In Medicare program, 2012

Provider Name	Location	Amount Paid by Medicare, 2012
Michael C. McGinnis	Wrightstown, N.J.	$12.6 million
Franklin R. Cockerill	Rochester, Minn.	$11.1 million
Robert M. Aportela	Delray Beach, Fla.	$5.2 million
Jon Keller	Palo Alto, Calif.	$4.2 million
Ann Anderson	New Hyde Park, N.Y.	$4.2 million
Brian A. Babbin	Fort Myers, Fla.	$3.9 million
George C. Kalemeris	Fort Myers, Fla.	$3.6 million
Mary Kay Vaske	Springfield, Mo.	$3.5 million
Tanner L. Mattison	Dallas	$3.1 million
Albert Cohen	Delray Beach, Fla.	$3.0 million

Source: Centers for Medicare and Medicaid Services via Wall Street Journal

"These payments are practice revenues that must cover business expenses, including pay and benefits for practice staff, billing and other professional services, office rent, utilities, professional liability insurance, medical equipment and supplies," the AMA said in a statement meant to clarify the meaning of the payment data.

Although pathologists do not prescribe medications for the most part, their practices tend to have high overhead expenses compared to other medical practices because of the ongoing need to purchase reagents in bulk, as well as often pricey diagnostic equipment. And they often practice in groups as well.

"The raw Medicare payment data cannot be fully understood without proper context and will lead many to draw false conclusions," said Gene N. Herbek, M.D., president of the College of American Pathologists. "For instance, a single pathologist's billing number may be used by a laboratory to bill for several pathologists' work, as well as the laboratory's technologists, but the data attributes all of the laboratory's Medicare payments to that one pathologist. In these circumstances, identifying an individual pathologist as receiving millions of dollars in Medicare pay is inaccurate and misleading, but that is the impression the public receives with raw Medicare data."

The highest-paid pathologist in the Medicare program in 2012 was Michael C. McGinnis, M.D., who practices with Plus Diagnostics and Pathology Corp. of America. The two entities include 12 pathologists with offices in Rahway and Freehold, N.J. McGinnis did not immediately return a phone call seeking comment.

Takeaway: The provider-specific payment data released by the Centers for Medicare and Medicaid Services include a massive amount of raw information but little clarity in the way that laboratories and pathologists conduct their businesses and practices.

■ **Quest Releases Smartphone App for Patients to Receive Direct Results**, *from page 1*

which are typically used to monitor ongoing conditions in patients with chronic conditions such as hypertension or congestive heart failure.

Quest officials say the easier exchange of information is expected to encourage greater dialogues between patients and their providers.

"Because most health care decisions are based on diagnostic insights, patients who access their lab results may be more likely to have a well-informed dialogue about medical options with their physician," said Jon R. Cohen, M.D., Quest's chief medical officer.

The use of mobile applications to facilitate the movement and sharing of information has been growing in health care—Kaiser Permanente, for example, provides a sophisticated mobile app for its patients—but their use on the consumer side in the laboratory sector has been sparse. Health Diagnostic Laboratory launched a patient-oriented mobile app last month, but that appears to be the entire mobile lab-patient interface for now.

LabCorp, the second-largest laboratory in the nation, has a mobile app for providers and a patient portal for desktop and laptop computers, but not yet one for smartphones, according to a company spokesperson.

Although the changes of the regulations regarding patient sharing are expected to stir some more of the larger labs to create applications, that appears to be in its preliminary phases. "I have heard some discussion occurring but have not seen any specific applications yet," said R. Scott Liff, president of business development at the Kellison Co., a laboratory consulting firm in Cleveland.

The lab sector has been split over what kind of patient demand there will be for direct testing. Some lab executives that operate in the nine states that allowed data transmission to patients say the demand has been relatively low. PAML, the largest laboratory in the Pacific Northwest, says demand to see tests in Oregon—which permits direct transmission—has been tiny. Others, such as the University of Pennsylvania Health System, which automatically transmits all test results to patients after a physician review, say such sharing has been very popular. And there is also debate as to whether demand will be greater among younger more tech-savvy patients compared to their older counterparts.

According to Quest officials, the demand by patients to receive their test results directly has been fairly strong. It was receiving about 50,000 requests per month from patients for their test results in the states that allowed direct transmission prior to the changing of the federal regulations, said company spokesperson Wendy Bost. Given that the number of states that will make them available has more than tripled overnight, Quest sees demand rising accordingly.

"We expect that number to increase as patients nationally choose to access their lab data directly," Bost said.

Takeaway: The change in federal regulations surrounding the transmission of lab results directly to patients may create a new market for consumer-oriented mobile apps. G2

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INDUSTRY BUZZ

CardioDx Releases More Studies Validating Economic Utility of Its Corus CAD Test

CardioDx, the California-based molecular laboratory that develops and distributes tests that assess a patient's risk for coronary artery disease, has issued a new study regarding how its Corus CAD assay impacts the clinical decisions of physicians.

The test assesses a patient's likelihood of having obstructive coronary artery disease when they are suffering suspect chest pains. CardioDx has touted the assay as a lower-cost and less-invasive replacement for diagnostic procedures such as a cardiac angiography, which requires a catheterization and can cost thousands of dollars. And the company has been particularly aggressive in providing research that promotes the cost benefit of undergoing the test.

According to research of nine primary care physicians preparing diagnostic workups of 251 patients who underwent a Corus CAD test, 58 percent modified their diagnostic strategy. Among those patients who scored lower on the test for developing coronary artery disease, 60 percent experienced a reduction in further cardiac testing. Fifty-seven percent of those patients who had further testing reduced were female, an eyebrow-raising statistic since women at risk for cardiac conditions tend to be less symptomatic than men. The study's results were recently published in the *Journal of the American Board of Family Medicine*.

The results of the test follow on the heels of another study undertaken by CardioDx that concludes the use of the Corus CAD test reduced diagnostic costs an average of 9.4 percent—a cut that could save larger health plans millions of dollars a year. That study was also recently published in an academic journal, *Population Management*.

"The . . . trial adds to previous studies of clinical utility in cardiology and highlights the ease with which the test can be integrated into everyday primary care practice for internists and family medicine physicians," said Mark Monane, M.D., CardioDx's chief medical officer. "As a personalized, advanced genomic test, Corus CAD is helping primary care clinicians accurately and efficiently determine whether or not their patients need further cardiac evaluation."

Takeaway: CardioDX continues to tout the economic benefits of its tests through its deployment in clinical studies. G2

References

Aurora Diagnostics
561-626-5512

Camino Consulting
906-361-4238

CardioDx
650-475-2788

College of American Pathologists
847-832-7000

Health Diagnostic Laboratory
804-343-2718

Kellison & Co.
216-464-5160

LabCorp
800-222-7566

Opko Health
305-575-4100

Quest Diagnostics
800-222-0446

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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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