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HIGHLIGHTS

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HDL Expects to Enter Settlement With Feds About Doctor Payments

Health Diagnostic Laboratory has confirmed it is nearing an agreement with the U.S. Justice Department regarding its past practices for reimbursing providers.

The Virginia-based purveyor of assays that test for chronic conditions such as diabetes and heart disease released a statement late last month that said in part, "we look forward to concluding a settlement with the Department in the very near future that will enable our company to avoid potentially expensive and protracted litigation and allow us to move ahead with our important work of helping improve the health of millions of Americans."

The *Wall Street Journal* reported on March 23 that HDL was nearing a settlement. Although HDL would not comment on the specific

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CMS Pulls Back on Blood Glucose Monitor Regs

The Centers for Medicare & Medicaid Services (CMS) has backed off on some of its CLIA mandates regarding blood glucose monitors in the hospital setting, although inpatient providers say the new proposal remains too strict.

CMS had issued draft guidelines last year regarding the point-of-care use for such monitors, which are relatively low-cost devices that are nearly ubiquitous in hospitals.

The original regulations pertained to the use of such monitors for off-label uses, which implicate virtually every hospital use of such monitors (the monitors are mostly designed and marketed for personal use). Under the proposed guidelines, hospitals that deployed monitors in situations considered off-label would have to operate laboratories that qualified under CLIA as high-complexity laboratories. The Food and Drug Administration has proposed similar guidelines for use for any device that does not have pre-clearance for use in a hospital.

Concerns have been raised by the hospital community that the regulations are too onerous, and would prompt many hospitals instead

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CMS Pulls Back on Blood Glucose Monitor Regs, *from page 1*

to turn to blood gas monitors, which are much more costly instruments. CMS met with representatives from both the American Hospital Association and state hospital lobbies on Jan. 28, and reissued guidance last month.

In that new memorandum, CMS officials observed that "there may be significant confusion as to what hospitals, or other providers, must do to meet the CLIA requirements for off-label use of a (sic) waived test systems."

Perhaps the most significant change to the proposed regulations is an acknowledgement that "using a device within the limitations or precautions and intended use indicated by the manufacturer would not constitute off-label use, and not cause such use to constitute high complexity under CLIA," with a change later in the proposed regulations that under such conditions the device would maintain its CLIA waiver status.

Nevertheless, some officials remain concerned about how the regulations dictate the day-to-day use of blood glucose monitors. For example, the revised regulations concede that neither CMS nor the FDA shall define a critically ill patient, and that some monitors have not been evaluated or cleared for use with such patients.

"What that does from our perspective is that it is asking a lab to use a waived test and ask hospitals to come up with definition of critically ill patients," said Alyssa Keefe, vice president of federal regulatory affairs for the California Hospital Association (CHA), which represents about 350 hospitals and has been pushing for changes in the proposed regulations. Keefe said each hospital making such a determination would be extraordinarily difficult, and such a lack of clarity could prompt some to back away from using the monitors on their most acute patients, "limiting the use of a valuable tool."

The American Association of Clinical Chemistry (AACC) has struck a more cautious note on the matter, issuing a statement from President David Koch, M.D., that reads in part "no device is fool-proof, and every laboratory test has limitations. As clinical laboratory directors, point-of-care coordinators, and operators of point-of-care testing devices, AACC members work to always be aware of a device's limitations and ensure that the test results contribute favorably to patient care."

There had also been concerns about some states jumping the gun on enforcing the regulations. For example, the New York Department of Health (NYDH) last year started to promulgate its own regulations that would limit off-label uses of the monitors, prompting the AACC to ask that agency to slow its efforts. The NYDH did not respond to a request asking if it had imposed that regulation.

However, both the CHA and AACC say they expect to continue to work with CMS to obtain further clarification in the regulations before they're finalized.

"We've been really pleased that they have taken an opportunity to be very receptive to listening to many points of view," Keefe said.

Takeaway: Although federal regulators are yielding on how blood glucose monitors should be used in the hospital setting, constituents affected by the change are pushing for more changes. G2

Smaller Esoteric Labs Heading in Different Financial Directions

Earnings data from some of the smaller esoteric laboratories paint a stark picture of the directions those enterprises are heading.

Florida-based NeoGenomics is the most successful of these labs. It reported net income of just over $1 million for the fourth quarter ending Dec. 31, up from $857,000 in the year-ago quarter. Revenue rose 36 percent to $25 million.

Although calendar 2014 net income dropped to $1.1 million from $2 million in 2013, revenue was up by nearly a third, to $87.1 million from $66.5 million.

"This growth highlights the traction our commercial team is gaining and demonstrates that we are making good progress enhancing awareness and increasing demand for our testing services."

— Kenneth Berlin
CEO, Rosetta

According to Chief Executive Officer Douglas Van Oort, the company launched 48 new molecular and FISH-based tests and converted another 23 assays to next-generation sequencing. The revenue growth was achieved despite reimbursement cuts for FISH assays.

NeoGenomics said organic test volume grew 29 percent during the year. And while the average revenue per test declined by 4.2 percent, costs were reduced by 4.7 percent, leading to a slight boost in the gross profit margin.

Rosetta Genomics, a New Jersey-based laboratory with development operations in Israel, reported revenue of $1.3 million for calendar 2014, more than triple the $405,000 it reported in 2013. The company did not break out quarterly data. The company posted a loss of $14.5 million, compared to $12.9 million in 2013.

Rosetta develops and distributes tests that sequence microRNA materials, primarily for analysis of kidney and lung cancer, particularly mesothelioma.

"This growth highlights the traction our commercial team is gaining and demonstrates that we are making good progress enhancing awareness and increasing demand for our testing services," said Rosetta Chief Executive Officer Kenneth Berlin in a press release.

By contrast, Massachusetts-based Interleukin Genetics is trying to fend off dramatic contraction. It reported a fourth quarter loss of $1.6 million on revenue of $322,000. That compares to a fourth quarter 2013 loss of $1.9 million on revenue of $671,000. The company markets an assay that focuses on dental health, but it is also developing a cardiac health test.

Revenue for 2014 was $1.8 million, down from $2.4 million in 2013.

A statement issued by Interleukin indicated that employees had left the company and sales commissions were reduced. However, it had secured $10 million in financing that it would use for product marketing and to enter into agreements with potential distribution partners.

Takeaway: The smaller esoteric labs are on dramatically different financial trajectories. G2

Inside The Lab Industry

The FDA Is Seen as an Unwelcome Guest in the Lab Sector, But Its Presence Is Likely to Grow

It's been a given that the U.S. Food and Drug Administration regulates drugs, medical devices and the lab sector's in vitro diagnostic tests.

Although the agency has come under criticism in recent years as a government bureaucracy that has stifled business innovation in health care, that situation has not deterred its intentions to regulate additional facets of laboratory medicine. The FDA has said that the advances that have been made in the sector require closer scrutiny in order to guarantee the safety of patients and integrity of the tests being performed.

In recent years, the FDA has begun to try to assert itself into two significant areas of the laboratory field. The first, laboratory developed tests (LDTs), is a work in progress, with labs resisting the incursion, although it is likely that the FDA will eventually prevail and have some level of scrutiny in that area.

The other area where the FDA is seeking regulatory oversight is next-generation sequencing (NGS). It is a portion of the laboratory business that has grown nearly exponentially in just the past several years, as the number of molecular tests that involve multi-gene panels has rapidly multiplied (and most NGS-based tests are also LDTs). The Obama administration's recent push for personalized medicine is also expected to fuel future growth.

"Most IVDs detect only a single or a defined number of substances to diagnose one or several specified conditions. In contrast, NGS tests are capable of detecting the over 3 billion bases in the human genome, and in doing so identify the approximately 3 million genetic variants an individual may have. A single use of an NGS test could enable the diagnosis of any one, or more, diseases or conditions a patient presents with," the FDA said in a recent white paper on the issue.

As a result, the agency believes closer regulation of those tests is necessary. It has been seeking input from the lab sector as to how to do this from a series of workshops that began in 2011 and are continuing into this year. The agency is expected to eventually issue draft regulations of NGS, although FDA officials have not given a timeline for that event.

The Friction Point

The FDA's intent to regulate NGS-based tests not only raises the issue of government intervention, but comes at a time when the use of NGS-based assays is booming. Labs often charge four figures to perform such tests, and they have become a steady source of revenue at a time when reimbursements from government and commercial payers for more traditional assays have been ratcheted down.

Inside The Lab Industry

One company that specializes in both NGS testing and platforms, San Diego-based Illumina, has seen revenue and profit explode. It reported $1.6 billion in revenue for fiscal 2014, nearly triple the total of five years before. The company did not immediately respond to a request seeking comment for this article.

Spokane, Wash.-based PAML, the largest regional laboratory in the western United States, has made over a significant amount of its business model in just the past few years due to NGS. According to its Chief Executive Officer, Francisco Velázquez, M.D., the company has made about 10 hires in just the past year—including physician and doctorate-level positions—as it brings most of its NGS testing in-house.

"It has certainly strengthened our competitiveness, and our focus on oncology, as well as our ability to attract talent," Velázquez said. He added that he expects NGS-based testing to play a significant role not just in cancer detection and treatment, but public health issues such as the control and prevention of infectious disease outbreak.

Redundancy?

Not surprisingly, the laboratory industry has greeted the latest incursion from the FDA about as warmly as it has on the LDT issue: It has questioned whether the agency's scrutiny is needed at all.

The American Association of Clinical Chemistry (AACC) observed in a recent statement that it "appreciates FDA's efforts to seek input from the healthcare community before developing new policy in this area, but is concerned that FDA regulation of next-generation sequencing could impede the advancement of precision medicine." One of the lobby's specific concerns is that the FDA will be intruding into an area where the CLIA regulations work just fine.

"We believe ... that the current oversight mechanisms in place for next-generation sequencing are sufficient for dealing with the particular challenges this technology presents and that further FDA involvement at this time might hinder the advancement of this field," said AACC President David Koch, M.D. in the statement. Of course, it's the same argument that has been put forward over the regulation of LDTs.

The AACC believes the Clinical Laboratory Improvement Amendments, or CLIA, are sufficient to regulate the sector. And given the Centers for Medicare & Medicaid Services, itself a huge regulatory body, already has purview of that domain, the FDA's presence seems redundant at best.

Velázquez shares that position. "The lab industry is already regulated through CMS and CLIA, and there is industry-specific knowledge that is very important,

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"The more complex this process becomes, the more difficult it will be to have resources to (comply)."

— Francisco Velázquez, M.D.

as well as various regulatory requirements, whether it is CLIA or deemed status," he said. "And the FDA has minimal if any experience (in this area), and the learning curve is going to be enormous."

Velázquez is particularly concerned that the years it may take for the FDA to thoroughly acclimate itself to this new regulatory environment could mean lengthy delays in obtaining product approvals for tests that would move fairly quickly through the CLIA process. There's also confusion as to whether the FDA would tier the regulatory process based on how complicated the test is, or on its potential for causing patient harm (which is how it proposes to regulate LDTs).

"The more complex this process becomes, the more difficult it will be to have resources to (comply)," Velázquez said. "It may be easier among labs with significant size that can allocate the excess capacity to the process," which would put smaller labs at a distinct competitive disadvantage in terms of developing groundbreaking new NGS-based tests.

The Association for Molecular Pathology has taken a slightly softer position, although it is still wary of the FDA's involvement in the laboratory business. "It is critical that FDA recognize the promise these new technologies hold for patients and health care providers, and refrain from taking actions that could impair this progress. As such, we believe that FDA can best contribute to patient care, medical advancement, and public health by ensuring that the performance characteristics of FDA-cleared or approved instruments, test kits, software, and reagents that are sold to customer laboratories are consistent with vendors' claims in their labeling, promotional materials, and sales activities," it said in a statement.

But in the comments it sent to the FDA in response to another workshop it held in February, the AMP believes that the agency should not have any say in test creation or adjustments. "Any modifications made within a laboratory to adjust an NGS test to better suit the needs and requirements of the laboratory and the patient are within the purview of appropriately trained molecular professionals, and thus, should be regulated by the Centers for Medicare & Medicaid Services under the CLIA program," it said.

The American Clinical Laboratory Association has retained top-flight legal counsel over the wrangling with the FDA concerning the regulation of LDTs. It hasn't reached that level yet with the issue of NGS-based tests—but then again, the agency has yet to draft any regulations.

Takeaway: The wrestling over the FDA's move toward regulating next-generation sequencing technology suggests that the lab sector will battle the agency's incursion into other portions of its business over the long-term. G2

HDL Expects to Enter Settlement With Feds, *from page 1*

financial components of the settlement beyond the statement it issued, the *Journal* said it would include a payment of $47 million. HDL also said it would enter into a five-year corporate integrity program that would include monitoring by the U.S. Department of Health and Human Services' Office of the Inspector General for the next five years.

"The agreement ... will contain an explicit denial of any wrongdoing. We have consistently sought to comply with all applicable legal and regulatory requirements, and are committed to continuing to do so," HDL said in its statement, also noting that "we wish to make it clear that HDL, Inc. has worked cooperatively with the Department of Justice since the inception of its investigation of various diagnostic laboratory industry practices, many of them common within the industry."

Citing confidential sources, *Laboratory Industry Report* reported in late 2013 that HDL was likely under the scrutiny of federal regulators for its practice of paying providers up to $30 or more to receive specimens from patients. While HDL co-founder and Chief Executive Officer Tonya Mallory denied at the time that her company was making such payments, she would neither confirm nor deny that an investigation was under way.

Last July, a federal investigation was confirmed by the *Richmond Times-Dispatch*, and the *Wall Street Journal* confirmed that HDL was paying doctors as much as $20 per draw—the $3 the Medicare program allows for a venipuncture, and another $17 for what HDL described as handling fees. Some medical practices were earning as much as $4,000 a week from the HDL payments, according to *Wall Street Journal*.

HDL discontinued the practice in June 2014 after the U.S. Department of Health and Human Services issued an advisory saying that such payments could violate the statutes governing kickbacks to doctors and create an incentive to commit fraud. Mallory left the company last September to work with her brother in a startup firm. She co-founded the company in 2008 and it had sales of more than $400 million a year by 2012, nearly 40 percent of which came from payments from the Medicare program. HDL said as part of any settlement it would continue to participate in all federal programs, including Medicare and Tricare, the benefits program for dependents of members of the military.

Mallory's replacement, company co-founder and chief laboratory office Joe McConnell, ended the company's relationship with its independent sales and marketing arm, BlueWave Healthcare Consultants, last January. BlueWave acted as HDL's primary conduit to doctors. That company, which was founded by former colleagues of Mallory's, earned $220 million in sales commissions from HDL between 2010 and 2014, according to the *Wall Street Journal*. BlueWave has since filed suit against HDL for breach of contract.

The pending settlement would not include either Mallory or BlueWave, according to the *Wall Street Journal*.

Takeaway: Health Diagnostic Laboratory is trying to put its rocky episode with physician payments behind it. G2

INDUSTRY BUZZ

Quest Diagnostics, Vermillion Enter Into New Marketing Agreement for Ovarian Cancer Test

Vermillion and Quest Diagnostics have had a sometimes tumultuous business relationship, but the two companies recently came to terms on a new distribution deal of the former's assay for ovarian cancer.

Under the terms of the agreement, the OVA1 test will be distributed to Quest's customers in 39 states. Quest will collect and transport specimens in those states and transport them to labs owned by the Vermillion subsidiary Aspira Labs. In the other 11 states, Quest will perform the testing in its own labs until Aspira receives the approvals to operate laboratories on its own.

Quest will receive a payment from the Texas-based Vermillion to perform the logistics and testing. The financial terms of the deal were not disclosed.

"We are pleased that we are taking steps to offer OVA1 testing through ASPiRA on behalf of Quest Diagnostics clients," said Vermillion Chief Executive Officer Valerie Palmieri in a statement.

The new agreement comes on the heels of a settlement between the two companies of a dispute that began in 2013. Vermillion had terminated an agreement that it had entered with the New Jersey-based Quest in 2005 to distribute OVA1 and another test, claiming Quest was in breach of that agreement. Quest continued to distribute the test while both sides negotiated a new pact.

According to documents filed with the Securities and Exchange Commission the day the companies entered into the new pact, Vermillion agreed to pay Quest $1.07 million to settle the dispute. It also received a $100,000 credit against any royalty payments owed under the new contract.

Vermillion is heavily dependent on the Quest pact for its revenue. In 2014, $1.2 million of its $2.5 million in total revenue came from royalty payments from Quest.

Vermillion also agreed not to market any test that competes against Quest unless it is proprietary in nature, or to market the OVA1 test to any company in the U.S. whose annual sales exceed $2 billion.

Takeaway: Vermillion and Quest have smoothed over some of the more contentious aspects of their relationship.

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