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HIGHLIGHTS

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Theranos Has Invalidated Tens of Thousands of Tests

Theranos has invalidated tens of thousands of inaccurate tests run on its proprietary platform and equipment from other manufacturers, the company has confirmed.

Brooke Buchanan, a spokesperson for the Palo Alto, Calif.-based Theranos, said that less than 1 percent of all the tests run by the company have been invalidated or corrected. But out of a total of some 7 million tests performed by the company to date, even a number just below 1 percent would represent 70,000 assays. Buchanan did confirm that the number was in the tens of the thousands. They included some two years of tests performed on its Edison platform that the company claims can perform hundreds of lab tests using just a few drops of blood. She declined to give specific numbers regarding the tests performed on each of the platforms.

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Labs Ask OIG to Back Off on Co-Payment Collections

That laboratories could be left on the hook to collect co-payments and deductibles from patients enrolled in Medicare is a remote possibility these days, but the sector is concerned that it could happen nonetheless.

The most recent trigger is a report released in April by the U.S. Department of Health and Human Services' Office of the Inspector General known as the Compendium of Unimplemented Regulations. Within the report is a list of the 25 top unimplemented regulations.

Buried on page 50 of the 74-page report is a yet-to-be implemented recommendation for Medicare Parts A and B: "(The Centers for Medicare & Medicaid Services) should ... reinstate beneficiary deductibles and coinsurance (and notifications of amounts paid on their behalf) as a means of controlling utilization." Such a measure could reduce costs to the Medicare program by as much as $2.4 billion a year. Co-payments for lab tests were eliminated when the Clinical Laboratory Fee Schedule was implemented in the mid-1980s.

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Labs Ask OIG to Back Off on Co-Payment Collections, *from page 1*

However, given the often tiny co-payments associated with common laboratory tests that are performed on the Medicare population—essentially nuisance charges many enrollees would ignore—the sector sees it as a sort of slow death by millions of tiny cuts.

"The way it would usually be proposed, CMS would just cut the reimbursement by 20%, and we would be expected to collect it from the beneficiary," said Alan Mertz, president of the American Clinical Laboratory Association, which pushed back against the long unimplemented proposal. It has careened through the HHS corridors since about 1990 and Congress killed co-pay legislation about a dozen years ago—with a letter to HHS Inspector General Daniel Levinson expressing its concern that this would be a misstep.

"Collecting coinsurance is uniquely difficult for labs because, unlike all other health care providers, labs typically do not have face-to-face encounters with patients."

— Alan Mertz, president, American Clinical Laboratory Association

"Collecting coinsurance is uniquely difficult for labs because, unlike all other health care providers, labs typically do not have face-to-face encounters with patients. Most of the time, a Medicare beneficiary's specimen is obtained somewhere else, such as a physician's office, and sent to the lab, which then performs the prescribed testing," Mertz wrote. "As such, labs must rely on billing and collections to obtain the cost-sharing amount from beneficiaries. If those good faith efforts do not succeed, laboratories must absorb those losses along with the added costs of collecting the cost-sharing."

And Mertz noted that nearly a third of such co-payments would be completely uncollectible. About 18 percent of Medicare enrollees have incomes so low they are also eligible for Medicaid, and another 14 percent do not have Medigap or other supplementary insurance, suggesting again a financial obstacle toward making collections.

Moreover, the amounts to be collected by labs would in many instances be minute: Mertz compared it to "that annoying phone bill for 72 cents." Specifically, he mentioned the highly routine PT test for blood clotting times. According to Mertz, it is run about 24 million times a year for Medicare enrollees. Total reimbursement for that test is $5.36. A 20 percent co-payment would be $1.07. The cost of collecting such small sums would often be more than the payment itself, Mertz said.

And finally, Mertz noted, imposing co-payments would not actually control utilization, primarily because the decisions to run lab tests are made by clinicians, with relatively little input coming from patients. The ACLA also raised objections to another unimplemented regulation on the list: A periodic evaluation of the national fee schedule to ensure reimbursement is aligned with prices.

"It's a fairly outdated proposal," Mertz said, adding that it really didn't take the pending implementation of the Protecting Access to Medicare Act of 2014 (PAMA) into consideration. "They just threw everything in there that's ever been suggested."

In the meantime, it remains clear that the ACLA will be providing significant input anytime such proposals resurface.

Takeaway: The ACLA is zealously guarding the turf of the laboratory sector regarding even the discussion of implementing co-payments and deductibles for Medicare patients for services.

Invitae Wants Higher Pricing From MolDX for Cancer Panel

Invitae is now getting paid by the Medicare program for its multi-gene cancer panel under interim pricing, but it is seeking a higher price in the near future.

The Centers for Medicare & Medicaid Services' (CMS) contractor Palmetto GBA determined under its MolDx pricing plan that Invitae should be paid through CPT code 81432, one of a group of codes formulated and released early this year to set permanent reimbursements for next-generation sequencing molecular tests.

"We're pleased to announce that we are now getting paid by CMS, and we believe this decision sends an important message regarding the clinical utility and cost-effectiveness of multi-gene panels when applied in a medically responsible way based on peer-reviewed science and clinical guidelines."

— Randy Scott, CEO, Invitae

Under the interim pricing guideline, Invitae would be paid $622.53 for its multi-gene panel that assays for 14 different genes related to hereditary breast, ovarian, and endometrial cancer. That compares to a reimbursement of $2,180.22 for BRCA1 and BRCA2 mutation analysis.

"We're pleased to announce that we are now getting paid by CMS, and we believe this decision sends an important message regarding the clinical utility and cost-effectiveness of multi-gene panels when applied in a medically responsible way based on peer-reviewed science and clinical guidelines," said Invitae Chief Executive Officer Randy Scott.

However, Invitae is not satisfied with the current interim pricing point. It recommended that its test be reimbursed at $950 when CMS issues final pricing guidelines later this year. That's the rock bottom reimbursement Invitae currently receives in contracts with commercial insurers for the test. It currently receives $1,500 for the test when it is conducted for commercial payers through a non-network provider. It charges uninsured individual patients $475.

The move by Invitae to ask for more money is not surprising; the laboratory sector has been in conflict with Palmetto over its MolDX pricing system for years, with many suggesting that it would have to take often significant payment cuts if the Medicare population is to have access to their assays, and that many prices are set below the actual costs of performing the tests.

In its most recent earnings release, Invitae said its cost of goods sold for each accession was about $600. The company generated just under $4 million in revenue for the first quarter ending March 31.

One sector observer who asked not to be identified suggested that Invitae has priced its tests so low compared to other labs that the prices set by MolDX will have little or no impact on its business operations—but its pricing model could harm other laboratories that perform next generation sequencing molecular tests.

Takeaway: Invitae is pushing for a higher price for its hereditary cancer panel from the Medicare program.

Inside The Lab Industry

Publicly-Traded Esoteric Labs Post Healthy Growth Numbers for Quarter

These are booming times for the publicly-traded esoteric laboratories, with their most recent quarterly reports radiant with relentlessly upbeat revenue numbers.

NeoGenomics

At the top of this greenhouse of growth would be the Florida-based molecular cancer laboratory NeoGenomics. For the first quarter ending March 31, it reported a 159 percent increase in revenue, to $59.7 million from $23 million from the year-ago quarter. Not only that, the company also broke into the black, reporting net income of $155,000, compared to a loss of $761,000 for the first quarter of 2015.

As a result of the numbers, NeoGenomics increased its 2016 guidance by $2 million apiece for both revenue and pretax earnings.

Company officials attributed that in part to the acquisition late last year of Clarient, Inc. for $190 million in cash and stock. That company, with annual revenue of $127 million in 2014, was among the biggest reasons for the enormous revenue boost.

"The acquisition of Clarient is providing scale advantages and we're beginning to realize synergies as planned," said NeoGenomics Chief Executive Officer Douglas Van Oort in a statement. "Customer retention has been excellent as a result of continued strong service levels. In addition, we achieved very strong core volume growth even as we engaged deeply in integration activities. Current and potential clients have responded exceptionally well to the acquisition, and our sales pipeline is very strong." NeoGenomic's own organic test volume grew by 36 percent compared to the first quarter of 2015.

As a result of the numbers, NeoGenomics increased its 2016 guidance by $2 million apiece for both revenue and pretax earnings. It expects the former to reach a range of $242 - $252 million, the latter in the range of $35 to $40 million.

Foundation Medicine

Although Massachusetts-based Foundation Medicine, which also offers complex molecular cancer tests, continued to operate in the red, it grew its first quarter revenue by 57 percent to $30.4 million. But it reported a net loss of $17.5 million, up from the $17 million loss reported in the first quarter of 2015.

Testing volume grew 14 percent during the quarter, compared to the first quarter of 2015. However, Chief Financial Officer Jason Ryan told analysts during a recent conference call the average reimbursement per test dropped from $3,200 in the fourth quarter last year to $3,100, a decline of nearly 4 percent. Diagnostic revenue dropped to $10.2 million from $11.1 million in the first quarter of 2015 and $12 million in the fourth quarter of last year. Ryan said that was linked to its

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non-small cell lung cancer testing going in-network with UnitedHealth, "which means we're not currently getting paid for other indications."

Much of the business growth actually occurred in the testing for biopharmaceutical customers. Revenue in that realm grew to $20.2 million from $8.2 million during the first quarter of 2015.

Despite the report in revenue growth, Foundation has not made any changes in its 2016 forecast, which includes revenue in the range of $110 and $120 million and expenses in the range of $175 to $185 million, meaning the company will not report a net profit in 2016.

"We achieved a strategic reimbursement milestone of signing a group-purchasing agreement that we believe will accelerate our ability to secure payer contracts for Afirma with key health plans this year."

— Bonnie Anderson, CEO, Veracyte

Veracyte

South San Francisco, Calif.-based Veracyte has also been experiencing significant growth with its Afirma test centered around thyroid cancer, one of the most over-diagnosed diseases in health care, even though its losses grew.

The company reported revenue of $13.6 million, compared to $11.2 million for the first quarter of 2015, an increase of 21 percent. However, it reported a loss of $10.1 million, compared to $7.6 million a year ago, an increase of 33 percent.

"We achieved a strategic reimbursement milestone of signing a group-purchasing agreement that we believe will accelerate our ability to secure payer contracts for Afirma with key health plans this year," said Veracyte Chief Executive Officer Bonnie Anderson. She added that the company was pushing for Medicare coverage for its bronchial genomic classification test. A similar test for idiopathic pulmonary fibrosis is expected to be launched by the end of this year.

Veracyte stuck to its guidance of $59 to $63 million in revenue for the year. It reported revenue of $49.5 million for 2015 and $38.2 million in 2014.

2016 First Quarter Earnings

Company	1Q 2016 Net Income	1Q 2015 Net Income	1Q 2016 Revenue	1Q 2015 Revenue
Neogenomics	$155,000.00	-$761,000.00	$59.7 Million	$23 Million
Foundation Medicine	-$17.5 Million	-$17 Million	$30.4 Million	$19.3 Million
Veracyte	-$10.1 Million	-$7.6 Million	$13.6 Million	$11.2 Million
Genomic Health	-$6.4 Million	-$15 Million	$70.5 Million	$57.7 Million
Myriad Genetics*	$32.6 Million	$21.4 Million	$190.5 Million	$180 Million

*Third Fiscal Quarter Source: Company Reports

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Genomic Health

Redwood City, Calif.-based Genomic Health narrowed its losses significantly while increase its revenue. It reported a loss of $6.4 million on revenue of $70.5 million. For the first quarter of 2015, it lost $15 million on revenue of $57.7 million.

Test volumes grew 16 percent during the quarter. However, the company also noted its rapid expansion globally, with test volume overseas growing 33 percent, while now accounting for 22 percent of total test volume. It represented $10.4 million of total revenue.

Chief Executive Officer Kim Popovits told analysts during a conference call that revenue for the year was expected to grow 12 to 17 percent, and that pre-tax earnings would eventually move into the black.

Amanda Murphy, an analyst with William Blair & Co. in Chicago, upped her revenue guidance for the year from $328 million to $333 million. "The ability for the company to reaccelerate growth with new products and indications has been impressive, which has been further enhanced by a benefit from meaningful outcomes data," Murphy wrote.

"We made significant progress in securing new product reimbursement coverage this quarter, and coupled with positive developments in our other development programs, we remain confident in our ability to deliver on our ... strategic goals."

— Mark C. Capone, CEO, Myriad Genetics

Myriad Genetics

Salt Lake City-based Myriad Genetics continues its bounceback from the 2013 U.S. Supreme Court decision invalidating its patent on the BRCA gene.

The company reported net income of $32.6 million on revenue of $190.5 million for its fiscal third quarter. That compares to net income of $21.4 million on revenue of $180 million for the year-ago quarter.

"We made significant progress in securing new product reimbursement coverage this quarter, and coupled with positive developments in our other development programs, we remain confident in our ability to deliver on our ... strategic goals," said Myriad CEO Mark C. Capone.

Although Myriad's hereditary cancer testing revenue, its biggest book of business, dropped 2 percent compared to a year ago, all other segments rose. The biggest gain was made by the company's Prolaris prostate cancer test. Prolaris revenues a year ago were $500,000 for the quarter. For the most recent quarter, they were $5.2 million.

Takeaway: The publicly-traded esoteric laboratories are posting relentlessly upbeat numbers for the first part of 2016.

Theranos Has Invalidated Tens of Thousands of Tests, *from page 1*

Buchanan said the tests were either invalidated or corrected on a case-by-case basis, depending on whether a sample remained extant or other circumstances. Retests are being offered free of charge, she added.

The *Wall Street Journal* first reported on the invalidated and corrected test issue last month, although Theranos did not confirm that that was the case at the time the newspaper published its story.

> *"Their reputation has been sullied by exposé after exposé, and given the fact they were so secretive and highly suspect to begin with, I can't imagine how they can economically move on from this."*
>
> — Dennis Weissman, Washington, D.C.-based laboratory consultant

Buchanan said the test issue was confined to Theranos' primary laboratory in Newark, Calif., and did not involve a second facility in Arizona. The company is in the midst of opening a third facility in Pennsylvania, Buchanan confirmed.

The *Wall Street Journal* has reported that many of the invalidated tests were sent to medical practices in the Phoenix area, where Theranos operates most of its clinics on the sites of Walgreens pharmacies.

Laboratory Industry Report contacted about a dozen medical practices in and around Phoenix, and while clerical staff said they had not been affected, several said they were aware of providers that had been impacted. Those providers did not respond to requests seeking comment.

The issue with the tests and the other storm clouds gathered around the company has raised some doubts about its ability to continue as an ongoing venture. It went from a valuation of $9 billion just a few months ago to the subject of federal probes about the accuracy of its tests and potential criminal investigation regarding whether investors may have been misled about the viability of its technology. A deal with Walgreens to install testing centers at many of its stores has been stalled.

Although other laboratories in the past have had to correct or invalidate tests due to an operational or regulatory issue, the sheer volume in this matter is unprecedented, according to Dennis Weissman, a Washington, D.C.-based laboratory consultant.

"Their reputation has been sullied by exposé after exposé, and given the fact they were so secretive and highly suspect to begin with, I can't imagine how they can economically move on from this," Weissman said.

He added that most of the venture capital firms that had previously invested in Theranos had expertise in businesses other than health care and had been looking to diversify. That fact and the tightening of the venture capital market means the company is unlikely to get other funding in the foreseeable future.

Several other sector and compliance experts did not respond to requests seeking comment on the matter.

Buchanan said the company would soldier on.

"We have no concerns. It is business as usual (in the Arizona lab) and we continue to expand the company," she said.

Takeaway: Theranos' decision to invalidate or correct tens of thousands of tests casts some doubts on its ability to continue operations as an ongoing venture.

INDUSTRY BUZZ

Luminex Enters Into Deal to Acquire Nanosphere

Texas-based Luminex has agreed to acquire Illinois-based bacterial testing lab Nanosphere in a deal valued at $83 million.

The transaction value, at $1.35 per share, was about an 80 percent premium over Nanosphere's recent trading price. It includes an acquisition price of $58 million and the paydown of $25 million in Nanosphere's debt. Luminex said the deal was an ideal strategic fit and would complement its current infectious disease portfolio. It is being completed with cash on hand.

Nanosphere has developed and distributes molecular tests that focus on bloodstream, gastrointestinal and respiratory infections, many of them hospital-acquired and aggressive in nature. Its Verigene testing platform can perform such tests with a turnaround time of about two hours, giving clinicians enough time to formulate appropriate treatment plans. It has about 240 clients nationwide to date. The company has been on a rapid growth path, booking $21 million in revenue for 2015 and is forecast to reach between $28 million and $30 million for calendar 2016.

"The acquisition of Nanosphere will significantly enhance Luminex's growth trajectory by expanding our product portfolio, delivering access to new markets and strengthening our pipeline of future products to make us the partner of choice for all molecular labs," said Chief Executive Officer Homi Shamir. "The deal demonstrates prudent execution of our fourth strategic growth pillar—leveraging our financial strength to accelerate growth in our target markets."

Luminex officials said the deal would be accretive to its bottom line earnings by the end of 2017.

"Luminex will recognize significant strategic benefit moving forward as our customer base and leverage in our expanding menu contribute to accelerated revenue growth," said Nanosphere CEO Michael McGarrity.

Under the terms of the deal, Nanosphere would operate as a wholly-owned subsidiary of Luminex. The deal is expected to close by the second half of this year. The announcement of the deal boosted Nanosphere's stock by about 80 percent, to around $1.30 per share.

Takeaway: Luminex will boost its portfolio in hospital-acquired infection testing with the acquisition of Nanosphere. G2

References

American Association of Clinical Chemistry
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American Clinical Laboratory Association
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Foundation Medicine
617-418-2200

Genomic Health
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