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HIGHLIGHTS

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AMP Examines Costs for Genomic Sequencing

At a time when payments for molecular testing are under increasing debate, the Association for Molecular Pathology (AMP) has commissioned a unique study breaking down the costs for genomic sequencing.

The study focuses on the labor and consumable costs for four specific tests: A tumor panel of up to 50 genes (CPT code 81445); a panel of more than 50 genes (CPT code 81455); an XLID panel (CPT code 81470); and a hearing loss panel (CPT code 81430).

The AMP broke down the costs in five separate categories, including the cost of preanalytic consumables (to conduct DNA extraction and sequencing); preanalytic equipment use; labor costs; reporting costs; and costs of maintenance and overhead. Data from the Centers for Medicare & Medicaid Services (CMS) was used in most instances to calculate the costs.

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Walgreens Terminates Contract With Theranos

For months, Theranos has had to just battle skepticism that its proprietary testing platform was unworkable. Now the fallout from that skepticism has landed in a huge way.

The company's highly visible business relationship with Walgreens was terminated last month. The Chicago-based pharmacy retail giant said that Theranos' need to invalidate the results of approximately 70,000 tests conducted on its Edison platform and other lab equipment and the rejection of a correction plan by the Centers for Medicare & Medicaid Services (CMS) for its lab operations moving forward drove the decision.

"We have carefully considered our relationship with Theranos and believe it is in our customers' best interests to terminate our partnership," Brad Fluegel, a Walgreens senior vice president, said in a statement.

Walgreens said it was immediately shutting down Theranos testing sites at 40 of its stores in Arizona.

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Walgreens Terminates Contract With Theranos, *from page 1*

The cancellation of the deal came just 16 months after it had been announced with significant fanfare. Walgreens said at the time it had entered into the pact that "this is the next step in Walgreens' efforts to transform community pharmacy."

Walgreens had originally intended to place Theranos testing centers in its stores nationwide. But it had put expansion on hold last year after the *Wall Street Journal* began a series of reports questioning the viability of its Edison platform. Theranos officials said Edison could perform many bread-and-butter lab tests with just a few drops of blood, which itself could be drawn without using needles.

Company spokesperson Brooke Buchanan said that Theranos would continue to operate five independent testing centers in California and Arizona.

Theranos' ability to continue as an ongoing enterprise had previously been questioned. The loss of revenue and visibility from the Walgreens deal brings increasing focus to that question.

Theranos itself said it planned to continue to operate sites independently. "We are disappointed that Walgreens has chosen to terminate our relationship and remain fully committed to our mission to provide patients access to affordable health information and look forward to continuing to serve customers in Arizona and California through our independent retail locations," the company said in a statement.

Company spokesperson Brooke Buchanan said that Theranos would continue to operate five independent testing centers in California and Arizona. The company did not plan any layoffs as a result of the loss of the Walgreens contract.

Meanwhile, company Chief Executive Officer Elizabeth Holmes, who had dropped out of Stanford University at the age of 19 to start Theranos, was assigned a net worth by Forbes last year of $4.5 billion, making her one of the richest self-made women in the world. Recently, the magazine assessed her net value at zero. Although it still valued Theranos at around $800 million, Holmes' 50 percent share in the company is in common stock, meaning capital investors in the company would be first in line should Theranos be sold or liquidated.

Holmes, whom had long been known for a culture of secrecy at her company, plans to discuss Theranos' technology and how it works at the American Association of Clinical Chemistry's (AACC) annual conference in Washington, D.C. in August. An AACC spokesperson said recently that Holmes' presentation would go on as scheduled.

Takeaway: The termination of Theranos deal with Walgreens represents a huge obstacle for the company as it tries to correct its testing issues and engage in new business development. G2

Quest Expands Testing Site Deal With Safeway

Quest Diagnostics, which has taken small steps into the retail clinic business, will expand its existing relationship with the Safeway supermarket chain into five more states. Sonora Quest, a joint operation between Quest and hospital system Banner Health, had entered into an agreement with Safeway late last year to open two draw centers on supermarket sites in Phoenix and Scottsdale. The deal

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>
> — Steve Rusckowski, CEO, Quest

materialized as Safeway, which operates stores in 35 states under a variety of names, was trying to extricate itself from a similar retail site deal with troubled California-based laboratory Theranos.

Quest and Safeway announced plans last month to open 12 additional centers in California, Colorado, Texas, Virginia and Maryland.

The draw sites, known as patient service centers, will be about 400 to 500 square feet. They will include a dedicated restroom that will include a pass-through for specimens. Customers will be provided with notification devices so they can shop in the supermarket while waiting for their laboratory service. Safeway and Quest also plan to offer co-branded financial incentives and coupons to entice more customers to both businesses.

"We're building on what we learned in Arizona, which is that by providing laboratory testing services where patients also shop, we will make it easier for them to get the quality diagnostic insights they need in convenient locations," said Quest Chief Executive Officer Steve Rusckowski in a statement. Financial terms of the expansion were not disclosed.

Takeaway: Quest Diagnostics, after taking a tentative step into draw centers at supermarket sites, is expanding it significantly.

Grifols Takes 20 percent Stake in Singulex

Grifols, the Spanish biotech firm, has taken a 20 percent stake in a California-based laboratory for $50 million. The deal is among the latest involving overseas businesses taking stakes in laboratories in the United States, or vice versa.

In exchange for the cash infusion, Grifols will have an exclusive license to use Singulex, Inc.'s platform for screening of blood donors and blood plasma. The platform, known as SMC for single molecular counting, claims to be able to find biomarkers for diseases that were not previously identifiable. Singulex is planning to roll out a platform focused on laboratory diagnostics that will be marketed to reference and hospital labs.

Singulex, which is based in the Bay Area city of Alameda, holds six patents for using troponin biomarkers to evaluate a patient's cardiac health. The presence of troponin in the blood is an indication of heart muscle damage. The company's investors include Fisk Ventures, OrbiMed Healthcare Fund Management, Prolog Ventures and JAFCO.

"As one of the world's leaders in the manufacturing of plasma products to treat a variety of rare, chronic and life-threatening conditions, safety and screening of donated human blood and plasma is critical for Grifols," said Carsten Schroeder, President of Grifols' diagnostic division, in a statement. "Singulex's ... technology and leadership in next generation immunodiagnostics presents Grifols with the diagnostic sensitivity, accuracy and reliability to develop more advanced blood screening platforms." Singulex did not release any specific plans for the capital infusion from Grifols.

Takeaway: The continued globalization of the U.S. diagnostics market is demonstrated by Grifols taking a stake in lab startup Singulex.

Inside The Lab Industry

CMS Responds Positively to Requested Changes in Final PAMA Rule

The Centers for Medicare & Medicaid Services (CMS) has issued the final rules governing laboratories under the Protecting Access to Medicare Act of 2014 (PAMA). Labs appear to have won some significant changes—and victories—compared to the proposed rules, although experts are still poring over the nearly 300 pages of regulations.

Under PAMA, labs receiving more than $50,000 in revenue from the Medicare program are to gather up reimbursement data from private payers and submit them to Medicare for review. The intent is for CMS to use the data in order to realign its reimbursement for lab tests on the Clinical Laboratory Fee Schedule (CLFS) and make it more in line with the commercial market. That was prompted in part by a 2013 report by the Office of the Inspector General that had calculated that Medicare was paying between 18 and 30 percent more for lab tests than the commercial sector, costing the U.S. Department of Health and Human Services $1 billion per year.

CLFS Cuts Remain Significant

According to an analysis by the Chicago-based investment banking firm William Blair & Co., the final PAMA rules are expected to reduce CLFS payments by 5.6 percent in 2018, or $390 million; 4.9 percent over the first five years of implementation, or $1.7 billion; and 5.6 percent over a decade, or $3.9 billion. Those cuts are shallower than the projected savings in the proposed regulations, which totaled $5.1 billion over 10 years. However, the laboratory sector accepted a systematic stabilization of the entire CLFS rather than ongoing and unpredictable reimbursement cuts.

"The establishment of a market-based system for determining Medicare reimbursement for laboratory services was clearly preferable to the alternative—unlimited cuts to payment rates by CMS through its technological changes authority, as well as across the board reductions to the CLFS by Congress," said Alan Mertz, President of American Clinical Laboratory Association (ACLA), which led the lobbying efforts to modify the final PAMA regulations.

One of the biggest changes came in the criteria for laboratory participation in submitting commercial reimbursement data. Under the proposed regulations, it was going to be based on taxpayer identification numbers. That raised objections from the lab sector, concerned that it would exclude many hospital-based labs from reporting, as few such labs had TINs separate from the hospitals they served. Hospital reimbursement rates also tend to be higher than reference lab reimbursements, creating concerns that CLFS readjustments would skew downward.

As a result, the CMS apparently struck a compromise, relying on National Provider Identifiers attached to labs instead.

Inside The Lab Industry

"We are pleased that CMS will delay the program start date and include data from hospital-based labs in setting payment rates."

— Tom Nickels, EVP, American Hospital Association

Mertz said he believes this would include most of the labs that would have been excluded under the proposed rule. "It is certainly a move in the right direction," he said.

Bruce Quinn, M.D., a senior director with FaegreBD Consulting in Los Angeles and an expert on reimbursement said that built-in median rate reductions that are limited to 5 percent in any direction are intended to curb any dramatic cuts. However, he also noted that he has yet to delve deeply into the regulations. "I don't think anybody has enough data to know," he said in an email.

Another victory for the labs was a one-year delay in implementation of the PAMA-based rates. Data will be gathered in 2017, with changes to the CLFS implemented in 2018.

"We are pleased that CMS will delay the program start date and include data from hospital-based labs in setting payment rates," said American Hospital Association Executive Vice President Tom Nickels. "The one-year delay will give labs more time to develop the technology needed to participate in the program. Including hospital-based labs will better reflect market trends and lead to more appropriate reimbursement."

There were also changes regarding the definition of advanced laboratory-developed tests, or ADLTs. The definition had initially excluded tests based on proteins. That has been changed, but Mertz said the ACLA is still examining how that change might impact members.

One other change that has been introduced into the ADLT criteria is a requirement that labs present evidence and attest to the test's unique algorithm.

"We believe that next-generation sequencing/microarray-based complex testing will fall under the ... definition of ADLT. By mandating clinical evidence, CMS has raised the bar (won't be easy for me-too type of tests to get reimbursed without clinical data)," wrote Vijay Kumar of the investment banking firm Evercore ISI.

Impact on Publicly-Traded Labs

The consensus on how PAMA would impact publicly-traded laboratories is mixed.

Zacks Research said in a statement that it was "highly disappointed with the recent CMS proposal related to PAMA." But Amanda Murphy, an analyst with William Blair, was more sanguine.

"We expect the final rule to affect clinical lab stocks positively," said Amanda Murphy, an analyst with William Blair & Co. in Chicago, in a recent report. "We believe the labs with the lowest cost structure are ultimately the best positioned

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in the implementation of PAMA and may ultimately benefit from increased consolidation opportunities as smaller labs face ongoing Medicare pressure. We also generally view the rule to be favorable to the smaller labs with proprietary assays, which typically see meaningfully higher payments from private payers."

"We believe PAMA implementation will bring welcome transparency and certainty to Medicare pricing. This in turn should help fuel innovation in diagnostics, which is transforming patient care and helping to make precision medicine a reality."

— Bonnie Anderson, CEO, Veracyte

Murphy added that "we continue to like LabCorp given low exposure to the Medicare CLFS (at 7 percent of revenue) and potential earnings upside driven by the Covance transaction. We also increasingly like Myriad given the recent pullback; while investors continue to focus on the hereditary cancer testing market, we see increased value in the company's newer tests (Prolaris, Vectra, and the companion diagnostics franchise). We also like small-cap names NeoGenomics, given the company's strong fundamental performance, and Veracyte, given what we view to be compelling valuation (albeit recognizing the limited liquidity in the name)."

Kumar was concerned that larger labs will benefit specifically from the rules regarding ADLTs. "We expect this to favor larger companies that have deeper pockets to fund clinical trials. Second, by raising the hurdle, we expect pricing to firm up in the longer run, as we see potentially lesser competitive intensity," he wrote, adding that the final rules "will have a mixed impact to next-generation sequencing providers such as Illumina, Thermo Fisher Scientific, Qiagen and Roche Diagnostics."

Veracyte itself seemed to be pleased about the final rules. The California-based company, which has developed a variety of molecular tests centered around detecting thyroid cancer, issued a fairly neutral statement.

"We believe PAMA implementation will bring welcome transparency and certainty to Medicare pricing. This in turn should help fuel innovation in diagnostics, which is transforming patient care and helping to make precision medicine a reality," said Veracyte Chief Executive Officer Bonnie Anderson. "Of course, details matter and we look forward to reviewing the PAMA rule closely and continuing to engage with CMS on its implementation."

Veracyte is not the only entity that plans to dig deeper into the final PAMA regulations. "ACLA's next step is to evaluate completely this final rule, and consult with our membership," Mertz said.

Takeaway: The laboratory sector has won significant victories in the final PAMA rules.

EDITOR'S NOTE: G2 Intelligence, in partnership with the American Clinical Laboratory Association presented a special webinar analyzing the final PAMA rule on June 28, 2016 at 2pm EDT. To purchase a recording of the webinar visit www.g2intelligence.com or call customer service at 1-888-729-2315.

AMP Examines Costs for Genomic Sequencing, *from page 1*

The overall costs of the tests ranged from $578 for the 5-50 gene panel (five different protocols were examined for the study); to $1,949 for the hearing loss panel (three different protocols were used for that test, including it in a consolidated genetic panel, where the cost was just $1,048).

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>
> — Samuel K. Caughron, M.D.

The purpose of the study, officials say, is to ensure that CMS and other payers bear in mind what it actually costs for labs to perform such tests and that they are reimbursed accordingly.

"It is very important that molecular laboratories continue to publish data on the health economic value, as well as the effectiveness and utility of molecular procedures to demonstrate value to payers," said Samuel K. Caughron, M.D., Laboratory Medical Director for Shawnee Mission Medical Center in Mission, Kansas and chair of the AMP's economic affairs committee.

Caughron observed that last year's gapfill process "resulted in many of the MACs not recommending prices for genomic sequencing panel, and the ones that were priced were either at or lower than the microcost analysis developed by AMP." He noted that the final payment determined for CPT code 81445 was $597.31, even as AMP's study found costs ranging from $577.99 to $907.82 for this procedure (*Laboratory Industry Report* will delve into proposed 2017 gapfill pricing in the next issue).

According to Caughron, publishing such costs could encourage greater transparency among the Medicare Administrative Contractors (MACs), which set reimbursement for various parts of the country.

"AMP believes the gapfill process as originally intended to work could be an effective process to price new molecular tests," he said. "However, AMP strongly favors greater transparency and definition to the process, with accountability for all MACs to appropriately engage in the process."

Takeaway: The Association for Molecular Pathology is trying to preserve reimbursement for its members for often pricey and difficult to perform genomic tests.

Total Costs For Certain Molecular Tests

Test	1-50 Gene Tumor Panel	50+ Gene Tumor Panel	XLID Panel	Hearing Loss Panel
Preanalytics Consumable Costs	$299.00	$766.00	$596.00	$1,174.00
Preanalytics Equipment Costs	$9.00	$126.00	$26.00	$103.00
Preanalytics Labor Costs	$17.00	$59.00	$34.00	$5.00
Bioinformatics/Reporting Costs	$86.00	$699.00	$160.00	$256.00
Validation Maintenance Overhead Costs	$287.00	$298.00	$99.00	$354.00
Total Cost Per Sample	**$698.00**	**$1,948.00**	**$915.00**	**$1,892.00**

Source: Association of Molecular Pathology

INDUSTRY BUZZ

Thermo Fisher Scientific Signs Testing Development Deal With Chinese Hospital

In another sign of the continuing globalization of laboratory services and the allure of the world's most populous nation, Massachusetts-based Thermo Fisher Scientific has entered into a collaboration with the West China Hospital of Sichuan University to develop a precision medicine testing platform. Financial terms and other specifics of the deal were not disclosed, but the parties said the intent was to make West China Hospital "a leading global molecular diagnosis center." The deal was announced at the China-U.S. High-Level Consultation on People-to-People Exchange (CPE) in early June.

"The collaboration between Thermo Fisher and West China Hospital is a perfect example of America's efforts to strengthen ties with China in science, technology and health. The agreement reinforces the spirit and goals of the CPE," said Richard Stengel, U.S. undersecretary of state for public diplomacy and public affairs, in a statement.

West China Hospital is the largest acute care facility in China, with 4,300 beds—more than double the size of the largest hospitals in the U.S. It is also the nexus for specialty care for Southwestern China.

"We are exploring opportunities to collaborate with renowned, industry-leading international companies to harness and capitalize on our strength in pathology," said Li Weimin, president of West China Hospital. "With our partners at Thermo Fisher, we are working to enhance the quality of pathological research and clinical diagnosis. We are also exploring an opportunity to extend our partnership in Western China by accelerating the development of precise pathological diagnoses that will ultimately help improve people's lives."

China has become a big target for both laboratories in the U.S. and in other nations to pursue new business. Earlier this year, WuXi NextCODE, the Icelandic and Chinese laboratory concern, became one of the first companies to obtain a certification in China from CLIA, the College of American Pathologists and California for its laboratory in Shanghai, China's most populous city. That is permitting the company to perform molecular testing on specimens gathered in California.

Takeaway: Thermo-Fisher Scientific is among the latest laboratory companies to pursue testing and business development pacts in China.

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Association for Molecular Pathology
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