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HIGHLIGHTS

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Theranos Strikes Deal With Pennsylvania Insurer; Begins Obtaining FDA Clearances

Upstart laboratory Theranos keeps chugging along, inking its first deal with a major payer and obtaining federal regulatory approval for its unique testing system.

The California-based Theranos announced earlier this month it has entered into a deal with Harrisburg, Pa.-based Capital BlueCross, which insures more than 725,000 lives and is the dominant payer in the central portion of the Keystone State.

Under the terms of the agreement, Theranos will provide test services to Capital BlueCross enrollees at two draw centers operated by Capital BlueCross. Theranos will also build additional centers in the state. It will begin providing full reference lab services in Harrisburg starting this month, officials for both firms said in response to questions

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Quest To Acquire Outreach Operations of MemorialCare Health

The slow shedding of ancillary hospital laboratory operations continues with Quest Diagnostics coming to terms to acquire the outreach services of the MemorialCare Health System in Southern California.

MemorialCare, a non-profit health care system based in Fountain Valley, Calif., is the predominant hospital operator in Long Beach and northern Orange County south of Los Angeles. It operates six hospitals in the region.

Industry observers say that hospitals have been shifting their focus away from outreach operations, which provide testing services to physicians and other providers in the institution's service area, as lab payments have been ratcheted down by both government and private payers and the logistics of such operations make it difficult to eke out any profit.

This deal was a long time in the making, with a source close to MemorialCare indicating to *Laboratory Industry Report* that Quest had approached the system as early as the first part of 2013 to sell its outreach operations.

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Quest To Acquire Outreach Operations of MemorialCare Health, *from page 1*

Quest had reached a bigger outreach deal in California in the first part of that year, acquiring the operations of Catholic hospital chain Dignity Health, which operates 32 hospitals statewide. That deal also included Dignity's outreach operations in Nevada, where it owns three other hospitals. That transaction came on the heels of Quest's late 2012 deal to acquire the outreach operations and other lab business connected to the University of Massachusetts Memorial Medical Center.

"This transaction underscores the attractiveness of Quest Diagnostics as a provider of high-quality, high-value diagnostic information services for hospital systems considering strategic alternatives for their outreach businesses."

— Steve Rusckowski, CEO, Quest

Later in 2013, the two-hospital John Muir Health in Northern California sold its outreach operations to Quest rival LabCorp. But there have not been any significant deals announced in the past couple of years.

MemorialCare's outreach operations will be consolidated at Quest's large test facility in West Hills, a Los Angeles suburb located about 50 miles north of MemorialCare's closest hospital. Quest has a significant presence in Southern California, operating more than 200 draw centers in the region, and can offer some esoteric molecular tests that are not on the MemorialCare menu.

Both entities have been closed-mouthed about the deal. A MemorialCare spokesperson declined to disclose test volumes for its outreach operations, and a Quest spokesperson did not respond to multiple requests seeking comment.

"We are excited about the opportunity to enable a larger number of physicians and patients in southern California to benefit from our diagnostic insights," said Quest Chief Executive Officer Steve Rusckowski in a statement. "This transaction underscores the attractiveness of Quest Diagnostics as a provider of high-quality, high-value diagnostic information services for hospital systems considering strategic alternatives for their outreach businesses."

The financial terms of the deal were not disclosed. Quest said the transactions should not have any impact on earnings during calendar 2015.

Takeaway: After a lull in the acquisition of hospital outreach laboratories, Quest's deal for MemorialCare's outreach services has perked up the transaction pipeline once again. G2

23andMe Raises $79 Million From Undisclosed Investors

23andMe, the California-based lab that has clashed with the Food and Drug Administration over the molecular testing it has offered to the public, has recently raised $79 million from outside investors, according to a recent filing with the U.S. Securities and Exchange Commission.

According to the July 2 filing, 23andMe said it is planning to raise $150 million in outside investments, and has raised $79.07 million to date. It has not disclosed the investors, and has not commented on the infusion of capital. Industry observers suggest that the company will use the money to focus on developing therapeutic treatments. In March, 23andMe formed a therapeutics group. It is headed by Richard Scheller, formerly an executive vice president of research and early development.

> *"Every single year for the last couple of decades it has become more inefficient and harder and harder to develop new therapies."*
>
> — Anne Wojcicki, CEO, 23andMe

The company initially made its mark by selling to the general public a $99 test that included interpretations of what kinds of genetic risks each individual faced. But the FDA essentially ordered the company to stop selling such interpretations without the agency approving its technology. 23andMe instead began only telling customers about their overall genetic makeup and heritage. It has to date received FDA approval for a single test for Bloom's Syndrome, an inherited disorder that affects a small portion of the general population.

However, the company has striven to remake itself in other areas. In January, it announced a collaboration with pharmaceutical giant Pfizer, Inc. that would use the data 23andMe has gathered on 800,000 individuals (that number has recently hit the 1 million mark). In a recent interview with the Market Place radio show, 23andMe Chief Executive Officer Anne Wojcicki outlined the company's future path.

"Every single year for the last couple of decades it has become more inefficient and harder and harder to develop new therapies. What I see as success is if we can actually change that by having a genetic approach to drug discovery," she said, adding that the company would take a "Moneyball" approach to developing new products. "If we can actually decrease the failure rate from nine out of 10 drugs in clinical trials to seven out of 10, it would be a major victory for drug discovery and drug therapies. That's my goal."

Takeaway: 23andMe has raised a significant amount of cash as it likely is pursuing a new path as a therapeutics development company. G2

Personal Genome Diagnostics Finds Potential New Ways to Fight Pancreatic Cancer

Personal Genome Diagnostics (PGD) has published an academic study concluding that there are far more "actionable" genes in tumors of pancreatic cancer patients than previously thought.

Working with researchers at the Johns Hopkins University School of Medicine, the Baltimore-based PGD determined that there are mutations in genes MLL, MLL2, MLL3 and ARID1A that suggest therapeutic utility in about 35 percent of all patients. More than 40 percent of patients also have circulating tumor DNA at diagnosis. In case of relapse after a tumor has been removed, such DNA can be detected by a blood test more than six months earlier than with the use of CT scans. Pancreatic cancer is particularly deadly, with five-year survival rates even at detection at the earliest stages of the disease below 15 percent.

"This collaborative study highlights how combining large-scale genomic analyses with clinical data can yield valuable new knowledge for pancreatic cancer," said PGD Vice President of Research & Development Mark Sausen in a statement. "Despite some limitations, the data uncovered in this study has immediate implications for the treatment of pancreatic cancer."

The study was published in the journal *Nature Communications*.

Takeaway: Personal Genome Diagnostics' research may create some clinical pathways for better treating pancreatic cancer. G2

Inside The Lab Industry

It's That Time of the Year for CMS Proposed Laboratory Regulations

Many Americans take vacations this time of year. If the laboratory sector is resting, it is doing so uneasily at best.

That's because the Centers for Medicare & Medicaid Services is not resting at all, distributing proposed rules and regulations that will pretty much determine how most labs will be paid in the coming year.

CMS recently issued its proposed 2016 Clinical Laboratory Fee Schedule (CLFS), 2016 Physician Fee Schedule (PFS) and updates to the Hospital Outpatient Prospective Payment System. The first contains some potentially bad news for drug testing labs; the second, cheery news for independent labs under the PFS; and the third, a yet-to-be determined impact due to potential fund shuffling.

Meanwhile, the entire sector is still waiting for the release of the proposed rules governing the Protecting Access to Medicare Act of 2014 (PAMA), which had been expected out around the Independence Day holiday but had yet to arrive as of press time. PAMA is expected to make the most radical changes to the CLFS since the mid-1980s. Starting in 2017, rates on the CLFS would be based on the weighted median of reimbursements paid by private payers, which have been ratcheted down significantly in recent years, with some large health plans cutting rates by as much as 50 percent.

"We are seeing exponential growth in this area, it will be important to have the issues both for coverage and pricing resolved."

— Rina Wolf, Xifin

2016 CLFS Could Hit Drug Testing Labs Hard

The biggest proposed change to the CLFS is really no change at all. The CMS said it did not want to issue new codes for testing for drugs of abuse, a niche in the lab sector that has grown dramatically in recent years with the growth of the prescription painkiller overdose epidemic.

"We stated our concern about the potential for overpayment when billing for each individual drug test rather than a single code that pays the same amount regardless of the number of drugs that are being tested," CMS said in its explanation that accompanied the codes. Instead, it has recommended deleting the 30 g-codes currently in use and replace them with two other g-codes, one for drug screening and one for follow-up confirmation screenings. Those codes would be priced later this month on the heels of a public meeting to discuss the CLFS recommendations.

"We are seeing exponential growth in this area, it will be important to have the issues both for coverage and pricing resolved," said Rina Wolf, vice president of commercialization strategies, consulting and industry affairs for Xifin, a San Diego-based laboratory consulting firm.

Inside The Lab Industry

However, Wolf noted that there has been some concern that only two codes have been recommended. The American Clinical Laboratory Association has suggested six codes in all, including two codes for presumptive testing and four codes for definitive testing.

"If only one price is established for both types of testing, then CMS will overpay for the less expensive waived test or underpay for the more expensive immunoassay test," ACLA Senior Vice President JoAnne Glisson wrote to Marc Hartstein, Director of CMS' hospital and ambulatory policy group.

The schedule proposed by ACLA included four different codes that would cover the number of drugs being tested for at once, ranging from one to seven in the first level; eight to 15 in the second level; 16 to 34 in the third level; and 35 or more in the fourth. It suggested starting pricing at $154 and raising it $32 per level, topping out at $250.

Some of the Proposed New CLFS Codes

Proposed New Code	Test
800XA	Obstetric Panel
G0472	Hepatitis c antibody screening
812XX	BRCA1, BRCA2 gene analysis; full sequence analysis and full duplication/deletion analysis
812XH	"ABL1 gene analysis, variants in the kinase domain"
812XI	NRAS gene analysis
814XB	"Ashkenazi Jewish associated disorders (Bloom syndrome, Canavan disease, cystic fibrosis, familial dysautonomia, Fanconi anemia group C, Gaucher disease, Tay-Sachs disease), genomic sequence analysis panel, must include sequencing of at least 9 genes"
814XP	"Hereditary retinal disorders (retinitis pigmentosa, Leber congenital amaurosis, cone-rod dystrophy), genomic sequence analysis panel, must include sequencing of at least 15 genes"
814XD	"Noonan spectrum disorders (Noonan syndrome, cardio-facio-cutaneous syndrome, Costello syndrome, LEOPARD syndrome, Noonan-like syndrome), genomic sequence analysis panel, must include sequencing of at least 12 genes"
815XO	"Coronary artery disease, mRNA, gene expression profiling by real-time RT-PCR of 23 genes"
815XY	"Oncology (colon), mRNA, gene expression profiling by real-time RT-PCR of 12 genes (7 content and 5 housekeeping)"
815XQ	"Cardiology (heart transplant), mRNA, gene expression profiling by real-time quantitative PCR of 20 genes (11 content and 9 housekeeping)"
00XXM	"Oncology (high-grade prostate cancer), biochemical assay of four proteins (total PSA, free PSA, intact PSA and human kallikrein 2 [hK2]) "

Inside The Lab Industry

Industry observers say some labs are currently getting paid close to $1,000 to perform some of the more complex drug testing panels, which means even the ACLA proposal could lead to steep cuts. But one drug testing lab CEO indicated that a middle ground could be found relatively easily.

The CMS proposal for the Physician Fee Schedule for calendar 2016 includes up to a 9 percent reimbursement increase for independent labs...

"If we did 40 tests, and they could reimburse about $150 to $300, we could make it work," said Phil Radford, chief executive officer of Radeas, a laboratory based in Wake Forest, N.C. He added that a lot of the current costs of drug testing are connected with the need to perform 24-hour turnarounds and express air shipping.

In another development, CMS has proposed a new code for BRCA testing. According to a statement issued by the ACLA after a query from *Laboratory Industry Report*, "the additional BRCA code was created to accommodate the way new market entrants provide BRCA testing while remaining aligned with National Comprehensive Cancer Network guidelines and societal guidelines for those determined to be high risk."

The CMS is expected to issue preliminary CLFS pricing in September, and following another round of comments from labs, issue final prices in November.

Potential Reimbursement Raises on the PFS

The CMS proposal for the Physician Fee Schedule for calendar 2016 includes up to a 9 percent reimbursement increase for independent labs, while pathology practices could see an increase of as much as 8 percent.

"That's some good news," Wolf said, adding that the CMS had responded to prior comments about the need to raise the rates.

Michael Cherny, an analyst with Evercore ISI, noted that the proposed increases would have a minimal impact on Quest Diagnostics and LabCorp, representing less than 2 percent of each company's overall revenue.

The proposed OPPS rates contain an adjustment after last year's major change, which included a shift of about $2.4 billion in payments previously accounted for on the CLFS. However, the agency overestimated the shift, and about $1 billion was still paid on the CLFS. As a result, CMS is proposing reducing the 2016 conversion factor by 2 percentage points to account for the expected shift of another $1 billion in payments for laboratory services on the OPPS. Wolf indicated that it was too soon to tell if this proposed adjustment would have an impact on the overall payment flow to hospital laboratories.

Takeaway: The laboratory sector will experience relatively mild changes to the Clinical Laboratory Fee Schedule and Physician Fee Schedule. But it is uneasily waiting for the release of the PAMA rules.

Theranos Strikes Deal With Pennsylvania Insurer, *from page 1*

submitted by *Laboratory Industry Report*. Theranos also expected to hire additional employees in Pennsylvania, but the traditionally closed-mouth company declined to provide specifics.

Theranos will offer Capital BlueCross enrollees a suite of 285 mostly basic tests, with pricing at 50 percent below current Medicare rates and posted on the Theranos website. Theranos uses a proprietary technology to draw a minute amount of blood for testing without the use of needles.

"FDA review is a uniquely rigorous process we undertook voluntarily because we remain deeply committed to ensuring that our systems and all of our laboratory developed tests are of the highest quality."

— Elizabeth Holmes, CEO, Theranos

Such rates are contrary to the relative lack of price transparency for consumers elsewhere; a 2014 study by the health care pricing firm Castlight Health found that prices for simple tests such as lipid panels varied by more than 400 percent depending on the city where it was being offered, ranging from $19 to $89. A Theranos lipid panel is $9.21.

"Our partnership with Capital BlueCross is centered on a common mission—to provide access to high-quality, affordable health care, so that people everywhere can own their health and take action to live their best lives," said Theranos Chief Executive Officer Elizabeth Holmes in a statement. Theranos and Capital BlueCross officials say the collaboration is expected to see savings that are "very significant," although it would take some time for that to materialize.

The move into Pennsylvania will diversify Theranos' business base. Most of its current testing operations are in Arizona, where it operates 41 centers on the sites of Walgreens retail pharmacies. It operates one other near its California headquarters in Palo Alto. Company officials say millions of tests have been performed at these centers to date, although some sources have indicated that activity at the Arizona centers has been relatively sluggish.

Meanwhile, Theranos also announced that it had received clearance from the U.S. Food and Drug Administration (FDA) for its testing platform and for its herpes simplex 1 virus IgG assay. The company has pledged to obtain FDA approval for its technology and all of its tests.

"FDA review is a uniquely rigorous process we undertook voluntarily because we remain deeply committed to ensuring that our systems and all of our laboratory developed tests are of the highest quality," Holmes said.

Forecasting future growth for Theranos has been difficult, given its tendency toward being closed-mouthed. "Our base understanding is that (its testing platform) is a nano-tech-based approach, but the company has been very secretive on this front and has been unwilling to share any details through peer-reviewed publications," Evercore ISI analyst Michael Cherny wrote in a recent report. "We also have zero idea as to how much money has been spent to develop the platform, what is the planned rollout for additional CLIA-labs, or what is the current capacity for the company to be able meet its customer targets related to the multi-hour turnaround time it promises."

Takeaway: Despite industry skepticism regarding Theranos' business model, the company is continuing to move forward with developing business deals. G2

INDUSTRY BUZZ

Aurora Diagnostics Enters Into Collaboration With University of Nevada

Aurora Diagnostics has entered into an operational and clinical collaboration with the University of Nevada School of Medicine.

Aurora Diagnostics' Western Pathology division has absorbed the university's laboratory operations at its new laboratory in Reno, where it will also perform the technical component of all pathology services, according to company spokesperson Bill Halldin. Western Pathology will also provide credentialing, contracting, and billing and collection services for all the work originating through the university.

Three Aurora pathologists practicing in the Reno region will also be added to the university faculty. Another Reno pathologist and 26 others practicing in Las Vegas will become adjunct faculty. Aurora will reimburse the university for expenses related to academic support and faculty salaries, according to Halldin. Aurora and the university will also explore clinical research partnerships, the company said.

Marcus Erling, M.D., managing director of Aurora Diagnostics' Western Pathology division, has also been appointed interim chair of the school's pathology and laboratory medicine departments.

"Aurora Diagnostics Western Pathology brings extraordinary depth in the field of anatomic pathology to our school," said Thomas L. Schwenk, M.D., dean of the School of Medicine, in a statement.

No money has exchanged hands as a result of the agreement, other than what is collected by Aurora for services rendered, according to Halldin.

Aurora, which is based in Palm Beach Gardens, Fla., operates laboratory and pathology practices at 23 locations in 15 states, primarily in the Northeast and Southwest. In April, it amended an existing line of credit with Cerberus Business Finance to add $40 delayed draw term loan to fund future acquisitions.

For the first quarter of 2015, Aurora reported a loss of $9.4 million on revenue of $59.5 million, according to a recent filing with the U.S. Securities and Exchange Commission. That compares to a loss of $6.6 million on revenue of $57 million during the first quarter of 2014.

Takeaway: Aurora Diagnostics has entered into an affiliation with a medical school in order to expand its reach in the western U.S. G2

References

23andMe
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Aurora Diagnostics
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Capital Blue Cross
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MemorialCare Health System
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Personal Genome Diagnostics
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