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LabCorp Continues Shopping Spree by Acquiring ClearPath Diagnostics

Less than a month after its acquisition of neonatal specialty lab Sequenom, LabCorp acquired obstetric and gynecology testing firm ClearPath Diagnostics from private equity firm Shore Capital Partners for an undisclosed amount. Here is a quick review of the deal and the larger strategy it serves.

The LabCorp Strategy

"The Sequenom and ClearPath acquisitions represent a continuation of LabCorp's strategy of focusing on high-margin esoteric testing to drive revenue." Their previously announced long-term goal is $150 million in incremental revenues, including $100 million for companion diagnostics, by the end of 2018. Although it has also partnered with hospitals, LabCorp has relied on strategic acquisitions to build its technological base and expand its portfolio of sophisticated, specialty diagnostic testing services.

One of LabCorp's primary targets has been the women's health market. In December 2015, the company agreed to acquire independent women's health lab Pathology, Inc., including its patient testing and services businesses. In September, LabCorp acquired San Diego-based Sequenom, a company best known for its MaterniT prenatal genomic test.

How the ClearPath Deal Advances the Strategy

ClearPath's attractiveness as a target is the array of OB/GYN tests and services it provides, including the Hologic Aptima HPV assay, Combo

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PAMA Update: Status Report on Implementation of New Medicare Fee Schedule for Part B Lab Tests

Changes to Medicare Part B payment for lab tests under the Protecting Access to Medicare Act of 2014 (PAMA) take effect on Jan. 1, 2018. Less than 15 months from the deadline, the Office of Inspector General (OIG) just issued a report documenting the progress the Centers for Medicare and Medicaid Services (CMS) is making in implementing the new payment system. Here is what lab managers need to know about the report to keep on top of the PAMA implementation process.

Continued on page 2

PAMA Update: Status Report on Implementation of New Medicare Fee, *from page 1*

The Implementation Timeline

Implementation of the new system for establishing Medicare price rates on lab tests is in full swing and the pace is about to pick up. Here is a review of key dates along the way to final implementation:

A good way to get a grasp of what is going on is by considering the six discrete things CMS must do to implement the new PAMA lab fee schedule.

- **October 2016:** CMS to complete independent validation of data collection system and make it available for labs to begin registering;
- **By Dec. 31, 2016:** CMS must:
  - Finish educating labs on the new reporting requirements; and
  - Publish guidance describing the new ADLT application procedure;
- **Jan. 1, 2017:** Labs begin reporting of private payer data;
- **April to August 2017 (roughly):** CMS must:
  - Conduct testing to verify the accuracy and completeness of reported data; and
  - Use the data to calculate preliminary pricing rates;
- **September 2017:** CMS to publish preliminary pricing rates and seek public input on their accuracy;
- **November 2017:** CMS to finalize pricing rates;
- **Jan. 1, 2018:** New pricing rates take effect.

The Six Implementation Tasks and the Progress Being Made on Each

A good way to get a grasp of what is going on is by considering the six discrete things CMS must do to implement the new PAMA lab fee schedule. The OIG report explains what each of these "tasks" involves and describes the progress CMS has made with regard to each one so far, as summarized by the chart below.

PAMA Briefing: Current Status of Part B Payment Changes Implementation Final Implementation Deadline: Jan. 1, 2018

Task	Status	What CMS Has Done	What CMS Still Must Do
1. Issue final rule and lab industry guidance	**Almost complete**	▪ June 17, 2016: Final rule issued ▪ Issued guidance on data reporting procedures and requirements	▪ By January 2017: issue guidance on process for labs to apply to have a test designated as an ADLT ▪ Determine if additional regulations or guidance is needed
2. Establish and consult with advisory panel	**Complete**	▪ April 2015: Panel created ▪ 2015-2016: Panel met four times ▪ Panel has formed 2 subcommittees: i. One advises CMS on payments for automated "profile" tests ii. Other advises on ADLT application process	▪ Through April 2017: Continue to receive and consider recommendations of panel and subcommittees

Task	Status	What CMS Has Done	What CMS Still Must Do
3. Collect private payer data reported by labs	**Significant progress**	▪ December 2015: Completed building of data collection system used by labs to report private payer data ▪ Testing of data collection system user experience, security and capacity partially completed—stress testing of user capacity hindered due to limitations of CMS's Presentation Zone	▪ Finish testing of data collection system user experience ▪ October 2016: Independent validation of system ▪ October 2016: Data collection system to be made available for labs to begin registering ▪ By January 2017: Finish educating labs about reporting requirements ▪ January 2017: Reporting begins ▪ January to March 2017: Collect first set of labs' private payer data
4. Ensure accuracy and completeness of reported data	**In progress**	▪ Creation of preliminary plans to conduct checks in mid- to late 2017 after labs submit first round of data ▪ Automated data verification and certification features incorporated into CLFS module	▪ April to August 2017: Conduct checks on first round of data labs submit ▪ September 2017: Publish pricing and volume data ▪ Starting September 2017: Seek public input on accuracy of preliminary Medicare payment rates ▪ CMS does **not** plan to independently verify whether all applicable labs submit their private payer data as required or the accuracy and completeness of the data of the labs that do report their data—*Result:* Risk of inaccurate payment rates
5. Determine and publish new Medicare payment rates	**In progress**	▪ Capacity to calculate new rates from data labs report incorporated into data collection system	▪ Early 2017: Collect data reported by labs ▪ Calculate Medicare payment rates from data ▪ November 2017: Publish the new payment rates ▪ January 2018: New payment rates take effect
6. Identify ADLTs	**In progress**	▪ June 2016: Publication of criteria for test to qualify as ADLT (as part of final rule) ▪ July 2016: Advisory panel subcommittee recommends ADLT application procedure	▪ By January 2017: Decide and issue guidance describing ADLT application procedure ▪ Thereafter: Review applications and decide whether tests qualify as ADLTs

Takeaway: 5 Things You Should Be Doing to Get Ready for PAMA. At this point, there are five things labs should be doing to get ready for the new Medicare Part B lab test payment system:

1. *Familiarizing themselves with the Final PAMA Rule (See "CMS Responds Positively to Requested Changes in Final PAMA Rule," LIR, July 7, 2016, p. 4);*
2. *Getting ready to register on the CMS's new data collection system when registration begins later this month;*
3. *Looking out for the two sets of materials CMS intends to release by year's end before reporting begins on Jan. 1, 2017:*
   a. *Educational materials explaining the payer data reporting process; and*
   b. *Guidance explaining the process to follow when applying to have CMS designate a test as an ADLT;*
4. *Preparing for the release of the preliminary lab test fee schedule in September 2017 and, if warranted, providing feedback on its accuracy; and*
5. *Being on the lookout for the final PAMA fee schedule which CMS intends to issue in November 2017.*

Inside The Lab Industry

OIG Report: Total Medicare Lab Test Payments in 2015 Same as in 2014

Medicare Part B paid $7 billion for lab tests in 2015, the same amount it shelled out in 2014. But 2015 Medicare payments for the top 25 lab tests dipped slightly to $4.1 billion, as compared to $4.2 billion in 2014. These are among the key conclusions of a new report issued by the Office of Inspector General (OIG) as part of its Protecting Access to Medicare Act of 2014 (PAMA) mandate to monitor Medicare payments for lab tests in advance of the new payment system taking effect on Jan. 1, 2018.

Medicare Lab Payments by the Numbers

The $7.0 billion paid for lab tests under the Clinical Laboratory Fee Schedule (CLFS) accounted for roughly 3% of all Part B payments made in 2015, according to the report. Where did that money go?

What Medicare's $7 Billion in 2015 Lab Spending Went Toward

Tests	Beneficiaries	Labs	Providers
474 million: number of tests billed	**27 million:** Medicare beneficiaries that received at least one test	**61,040:** labs that received Medicare payments	**612,812:** providers that ordered lab tests
3.7: average number of tests received by beneficiaries in a day	**17:** average number of tests per beneficiary	**$113,981:** average payments per lab	**570:** average number of tests ordered per provider
24: average number of tests per day for top 1% of beneficiaries	**109:** average number of tests per beneficiary among top 1% of beneficiaries	**$1.0 billion:** payments made to the top three labs	**7,250:** average number of tests ordered by top 1% of providers

Source: OIG "Medicare Payments for Clinical Diagnostic Laboratory Tests in 2015"

Fees Paid for Top 25 Lab Tests

As required by PAMA, the OIG report includes detailed analysis of the 25 most frequently ordered tests. Key findings:

- 23 of the top 25 tests of 2015 were also in the top 25 in 2014 (the two newcomers were drug confirmation (G6058), and amphetamine or methamphetamine (G6042));
- The $4.1 billion paid on the top 25 constituted 59% of Medicare payments made under the CLFS;
- Four of the top 25 tests posted increases in year-to-year payments of at least $10 million, including:
  - Opiates (drug) measurement (G6056)—up $35 million;
  - Drug screen, qualitative; multiple drug classes by high-complexity test method (e.g., immunoassay, enzyme assay), per patient encounter (G0431)—up $15 million;
  - Vitamin D-3 level (82306)—up $13 million; and
  - Benzodiazepines level (G6031)—up $10 million;
- Three of the top 25 tests posted decreases in year-to-year payments of at least $10 million, including:

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- Gene analysis (cytochrome P450, family 2, subfamily D, polypeptide 6) common variants (81226)—down $105 million;
- Chemical analysis using chromatography technique (82542)—down $24 million; and
- Blood test, clotting time (85610)—down $11 million;

- 54% of all Part B payments for the top 25 tests went to 1% of labs, i.e., 292 of 29,101;
- The next 4% of labs accounted for 25% of the payments for top 25 tests;
- The top eight tests *each* accounted for over $200 million in payments and, combined, $2.7 billion or roughly 66% of payments for the entire top 25 (see the table below for a breakdown of the individual tests).

Top 8 Lab Tests Based on Medicare Part B Payments in 2015

Rank	Test Description and Procedure Code	National Limitation Amount	Number of Tests (millions)	2015 Medicare Payments (millions)	Changes from 2014 Payments (millions)
1	Blood test, thyroid-stimulating hormone (TSH) (84443)	$22.87	21.2	$475	-$3
2	Blood test, comprehensive group of blood chemicals (80053)	$14.37	40.6	$458	+$5
3	Complete blood cell count (red blood cells, white blood cells, platelets) and automated differential white blood cell count (85025)	$10.58	41.5	$428	-$3
4	Blood test, lipids (cholesterol and triglycerides) (80061)	$18.22	27.2	$379	-$8
5	Vitamin D-3 level (82306)	$40.29	8.7	$337	+$13
6	Hemoglobin A1C level (83036)	$13.21	18.6	$241	+$5
7	Opiates (drug) measurement (G6056)	$26.48	8.1	$208	+$35
8	Drug screen, qualitative; multiple drug classes by high-complexity test method (e.g., immunoassay, enzyme assay), per patient encounter (G0431)	$98.96	2.3	$208	+$15

Source: OIG "Medicare Payments for Clinical Diagnostic Laboratory Tests in 2015"

Payment Trends

Although the $7.1 billion Medicare paid for all lab tests in 2015 was roughly the same as 2014's total, the report cites a couple of significant variances.

Drug tests up 19%: Medicare payments for drug tests were up 19% in 2015, from $910 million to $1.1 billion with 18 different drug tests generating increases of at least $1 million. Six of the year's top 25 were drug tests, as compared to four in 2014. According to the report, the spike "coincides with efforts to monitor drug abuse," according to the report. But, the report adds ominously, it could also be an indication of medically unnecessary testing. In fact, billing of medically unnecessary drug tests has been a focus of recent enforcement activity:

- On August 31, a Florida pain clinic called Coastal Spine and Pain paid $7.4 million to settle claims of routinely billing Medicare for Quantitative drug tests performed on elderly patients regardless of medical necessity;

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- On Aug. 18, two former lab professionals convicted of false billing of medically unnecessary drug tests were sentenced to 36 months in prison and ordered to pay $1.437 million in restitution; and
- Similar charges were among the allegations of a pair of whistleblowers in a case settled by PremierTox 2.0, Inc. for $2.5 million in April.

Molecular pathology tests down 44%: On the flip side, Medicare payments for molecular pathology tests analyzing genetic material to determine how patients will respond to treatment decreased 44% from $466 million to $259 million year-over-year. The report says the decline was concentrated in payments for three different tests but does not specify the tests' names. The decline coincides with efforts to prevent medically unnecessary genetic testing, the report adds.

Looking Ahead

The report includes new insights into the new Medicare payment rates for lab tests. The private payer data that CMS will use to set new payment rates is expected to come from 5% of labs, including 1,398 independent labs and 11,149 physician office labs. These 12,547 labs accounted for 69% of Medicare payments for lab tests in 2015. The report also confirms that 0 of 6,994 hospital labs will report private payer data.

Although payment rates will be generally lower under the new payment system, the report states that rates for 22 of the 25 top tests will go up in some parts of the country, with 38 states seeing at least one of the top 25 tests receive increases ranging from $0.02 to $30.27 per test (see the graphic below).

Note: New York has three local fee schedules, and California, Kansas, and Missouri each have two local fee schedules. For States with more than one fee schedule, the number shown is an average for the State's fee schedules

Takeaway: The OIG's report on the top 25 lab tests doesn't show a major shift in the top tests and mirrors a national focus on drug testing.

Medicare Lab Test Pay Increases by State

Number of Top 25 Lab Tests that Will Have Higher Medicare Payment Rates	States
0	Alaska, Arkansas, California, Florida, Minnesota, Montana, Nevada, New Jersey, Pennsylvania, Virginia, Wisconsin
1	Colorado, Delaware, Georgia, Hawaii, Louisiana, Maine, Maryland, Massachusetts, New Mexico, North Carolina, North Dakota, Oklahoma, South Dakota, Texas
2	Arizona, Connecticut, Idaho, Illinois, Iowa, Mississippi, Missouri, Oregon, South Carolina, Tennessee, Utah, Washington
3	Indiana, New Hampshire, Rhode Island, Vermont, West Virginia
4	Alabama, Kansas,
5	Ohio, Kentucky, Nebraska
6	New York
7	Michigan, Wyoming

Source: OIG analysis of Medicare's 2015 Clinical Laboratory Fee Schedule.

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2 assay, and Trichomonas vaginalis assay, as well as Becton Dickinson's Affirm VPIII to differentiate and identify vaginitis pathogens, Meridian Bioscience's Illumigene tests for Group B Streptococcus and HSV 1&2, and molecular diagnostic PCR testing.

The acquisition of ClearPath will combine "LabCorp's comprehensive women's health service offering" with ClearPath's local expertise to create "an unmatched blend of value and quality to our obstetric and gynecologic customers and patients," noted William Haas, LabCorp senior vice president and co-leader of LabCorp diagnostics.

Takeaway: Recent LabCorp deals focus on esoteric testing and women's health.

Theranos Closes Labs to Focus on Technology

Theranos announced that it will shut down its laboratory operations in the wake of the Centers for Medicare and Medicaid's (CMS) sanctions resulting from the 2015 inspection of its Newark, Calif., laboratory.

In July, CMS rejected the company's proposed corrective action as failing to "constitute a credible allegation of compliance and acceptable evidence of correction" of the deficiencies cited in the inspection. CMS's proposed sanctions include:

- Revocation of the lab's CLIA certificate;
- Cancellation of its approval to receive Medicare/Medicaid payment for lab services;
- Penalties of $10,000 per day until deficiencies are resolved; and
- Banning Theranos founder Elizabeth from Holmes owning, operating or directing a lab for two years.

CMS also asked the lab for a list of the names and addresses of all physicians and clients who used its services since January 2014. Theranos had taken steps to appeal those sanctions before this announcement.

On Oct. 5, the company released a statement saying "[a]fter many months spent assessing our strengths and addressing our weaknesses, we have moved to structure our company around the model best aligned with our core values and mission." That structure includes closing clinical labs and wellness centers affecting over 300 employees in Arizona, California and Pennsylvania.

The company will now focus on developing technology—namely the miniLab, which Holmes detailed at the AACC annual meeting in August. The miniLab is a compact device (2.5 cubic feet) containing a mini-robot that processes single-use cartridges with a Theranos Virtual Analyzer remotely dictating protocols for processing. "Our ultimate goal is to commercialize miniaturized, automated laboratories capable of small-volume sample testing, with an emphasis on vulnerable patient populations, including oncology, pediatrics, and intensive care," according to the company's Oct. 5 statement.

Takeaway: Theranos is an excellent example of how CMS sanctions and the negative publicity they bring can cause a lab to shift strategic direction.

INDUSTRY BUZZ

Randox Labs Introduces Alzheimer's Genetic Test

The Irish company Randox Laboratories says it has developed a test that can detect an elevated risk of Alzheimer's disease in patients before symptoms appear.

About 5 million Americans have been diagnosed with or are believed to have Alzheimer's, a disease which leads to deposits of protein on neurons and robs patients of memory and other brain functions and eventually kills them. Incidence of the disease has risen in recent decades as the U.S. population continues to age and live longer. Treatments for dementia-causing diseases are extremely expensive, costing roughly $236 billion a year. Most sufferers of Alzheimer's are not diagnosed until they are symptomatic.

Test Detects Gene Mutation Leading to Alzheimer's

The test uses a microchip in blood testing to detect mutation of the ApoE4 gene, a variant in protein processing. Patients that inherit the gene from one parent have a three times greater than average risk of developing Alzheimer's; the risk climbs to as high as 12 times above average if patients inherit the mutation from both parents.

Results of a trial of the test, which is not yet available in the U.S., were compared in 384 patients against a standard molecular test that confirms the presence of Alzheimer's. Patients that tested for an elevated risk were in complete concordance with the results from the molecular test.

"Pairing this test with medical and family history for risk of Alzheimer's disease has the real potential to advance personalized medicine," says Randox research scientist Emma Harte. "This fast, accurate testing will allow doctors and patients to make more informed choices earlier to slow the potential progress of Alzheimer's. This type of testing is important in our quest to understand and diagnose Alzheimer's and empower patients to understand risks, consider medication, and even make early lifestyle changes."

The findings of the study were presented at the American Association of Clinical Chemistry's annual conference in Philadelphia.

Takeaway: Early trials indicate that a lab test being developed in Europe may be effective in early detection of patients at an elevated risk of Alzheimer's disease, which would represent a significant treatment and economic breakthrough.

References

Food and Drug Administration 888-463-6332

Foundation Medicine 617-418-2200

HIMSS Analytics 312-638-9400

NeoGenomics 239-768-0600

OPKO Health 305-575- 4100

Palmetto GBA 803-735-1034

Quest Diagnostics 800-222-0446

Randox Laboratories 44-28-9442-2413

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