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LABORATORY INDUSTRY REPORT®

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HIGHLIGHTS

Aetna Cutting Lab Rates Well Below Medicare

Aetna is putting pressure on its laboratory network, demanding payment reductions for commercial work substantially below Medicare rates.

According to a letter Aetna sent to providers obtained by *Laboratory Industry Report*, Aetna invoked the new market fee schedule back in January, although it had to renotify providers in March because of unspecified communication issues. It began applying the new schedule June 1.

The letter was accompanied by a sample fee schedule that included professional component pathology rates for the Dallas area. The rates range from 30 percent to 50 percent below what Medicare is paying, even taking into consideration recent cuts the Centers for Medicare and Medicaid Services made to pathology services.

"Aetna's new baseline is substantially lower," said Eric Bettinger, chief financial officer of ClearPath Diagnostics in Syracuse, N.Y. He and other industry observers are concerned that this will embolden other carriers to cut their reimbursement as well.

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Cancer Genetics, Mayo Clinic Form Joint Venture

Cancer Genetics, a New Jersey-based company focused on molecular testing for cancer, has scored a big partner to help further its business interests: the storied Mayo Clinic.

Cancer Genetics and the Rochester, Minn.-based Mayo announced last month that the two will enter into a joint venture to develop new sequencing diagnostic tests to battle two types of the disease: hematological and urogenital cancers. There are about 150,000 hematological cancers diagnosed in the United States every year, with a mortality rate of 37 percent. There are more than 380,000 urogenital cancers diagnosed annually, with a mortality rate of 25 percent.

The company, known as OncoSpire, will be funded by Cancer Genetics with at least $2 million in cash provided by the company over the next three years, with the commitment rising to as much as $6 million if needed, officials said. The Mayo Clinic will donate in-kind contributions that include sequencing infrastructure, clinical expertise, and other operational resources, according to Samuel Smith, a Mayo spokesperson.

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■ **Aetna Cutting Lab Rates Well Below Medicare,** *from page 1*

Aetna officials declined to discuss its specific rates, citing the need for confidentiality. But it did confirm in a statement that "CMS reduced rates on the Medicare fee schedule for surgical pathology fees so we made a corresponding adjustment to the base national fee schedule."

Aetna's Test Pricing

CPT Code	Procedure	Aetna Price	2013 Medicare Rate
88300	Surgical pathology, gross	$2.65	$4.41
88302	Tissue exam	$3.89	$6.82
88304	Tissue exam	$6.58	$11.30
88305	Tissue exam	$21.86	$37.10

Source: Aetna and CMS

Aetna also noted that its national fee schedule has been below Medicare rates for years. "Aetna continuously monitors coding changes with Medicare/Medicaid fee schedule changes and we will adjust our national fee schedule as appropriate."

For a closer look at the contracting environment for laboratories and health plans see *Inside the Laboratory Industry* beginning on page 4.

Quest's Latest Acquisition Expected to Help Boost Bottom Line

Quest Diagnostics has continued on its acquisition spree, buying the toxicology laboratory business of Humana subsidiary Concentra.

The deal is the third major transaction by Quest since the fall and the second in as many months. It acquired the outreach business of the University of Massachusetts Memorial Medical Center in October and the outreach of hospital operator Dignity Health in California.

Concentra's Advanced Toxicology Network includes a laboratory in Memphis, Tenn., and serves clients nationally. Quest spokesperson Wendy Bost said that the national business is what made it interested in the acquisition.

"With this transaction, Concentra's patients, physicians and employer clients will gain access to Quest's industry-leading menu of innovative workplace drug and clinical lab diagnostic information services," Quest Chief Executive Officer Steve Rusckowski said in a statement. "The transaction is also consistent with Quest's disciplined capital deployment strategy, which includes generating one to two percent in growth per year through strategically aligned fold-in acquisitions."

Terms of the deal were not disclosed, and Bost would not provide any specifics about lab volumes. She said that it is likely some Concentra employees at its Memphis lab would be laid off by the end of the year but could not provide any numbers.

Concentra focuses on services such as occupational medicine, urgent care, and employee wellness programs. Its laboratory business was mostly a peripheral concern and was likely pulling focus from Concentra's other product lines, according to Michael Snyder, a principal with Clinical Lab Business Solutions in Cherry Hill, N.J.

"They don't want to be in the lab business," Snyder said. He added that the toxicology testing business has gotten extremely competitive and volumes have risen so quickly that it is creating a backlash among payers.

As part of the transaction, Quest will provide toxicology testing services primarily to Concentra and its employer groups and clinical testing to its urgent and primary care facilities. "Quest will be exclusive provider of these services except in situations where Concentra has other contractual obligations," Bost said.

Quest's toxicology business is substantial enough that it provides annual reports on drug testing trends. Quest said in its statement that it expects the transaction to add positively to its bottom line by 2014.

Gene by Gene Slashes Test Prices, Could Put Pressure on Clinical Testing

Personalized genetics lab Gene by Gene has been slashing the prices of its tests—a move that could have an eventual impact on testing for clinical purposes, observers say.

The Houston-based company's recent price cutting move involves its maternal DNA, or mtDNA, test. Gene by Gene cut the price last month by more than 70 percent—from $159 to $49.

The results were instantaneous, according to Gene by Gene President Bennett Greenspan—daily test volumes doubled. The company was receiving about 70 orders a day prior to the price drop, Greenspan said.

"This will dramatically expand the number of people doing a soft DNA test," he observed.

In addition to cutting the cost of its mtDNA test, Gene by Gene reduced prices for its mitochondrial and Y DNA assays earlier this year. According to Greenspan, the company is performing about 12,000 assays a month, up about 20 percent from a year ago.

Despite the growth and price-cutting, Greenspan does not believe the genetic fact-finding his clients are embarking on will lead to clinically oriented molecular testing, such as searching for genetic predisposition to breast cancer and other medical conditions.

"I don't think it will put pressure on clinical testing, because it is a consumer product—but I would like it to," Greenspan said.

Others aren't quite so sure. Michael Snyder, principal of Clinical Lab Business Solutions LLC in Cherry Hill, N.J., believes it could pressure clinical labs to cut prices.

"It sets an expectation" that clinical labs could undertake gene sequencing testing for less than they currently charge, he noted.

Gene by Gene does perform clinical testing, primarily BRCA1 and BRCA2 assays for one of Israel's health services. That's because there is no patent on the gene in that country, according to Greenspan. Myriad Genetics owns the gene patents in the United States.

Greenspan noted that the company could make an announcement that would impact clinical testing sometime in June. That appears to coincide with an expected ruling from the U.S. Supreme Court as to whether genes can be patented.

Contracting Update: In Tough Environment, Labs Need to Get More Creative, Aggressive

Contract killers aren't just confined to reruns of *The Sopranos*. That was the message sent to attendees at G2 Intelligence's Lab Contracting Workshop last month. Although the presenters strived to remain upbeat, the messages they delivered at both the conference and in subsequent interviews contained a blunt and clear-eyed message: Renumerative contracts with payers are becoming extraordinarily difficult to obtain these days.

"With respect to lab contracting, this is the most difficult period we've seen," said Michael Snyder, a principal with Clinical Lab Business Solutions in Cherry Hill, N.J. And it's only the beginning, he added.

Getting a provider contract used to be a "clerical process where you filled out paperwork and provided CVs, and you either got approved or disapproved," said Eric Bettinger, chief financial officer of ClearPath Diagnostics in Syracuse, N.Y. That is no longer the case. "It's become a much more personalized process" where labs and pathology practices are very closely vetted, Bettinger observed.

"I don't know how many community hospital labs will survive even the next three years."
—Patty A. Sipes, senior vice president of sales and marketing, PAML

The pressure from regional insurers is not as acute, according to Bettinger. However the national players such as Aetna—which recently cut its rates to labs and pathologists well below Medicare (*see article on page 1*)—are where most of the difficulties are being found.

Doubtful Future

Those labs and practices that don't adjust to the brutal operating environment are in for a fate suffered by a variety of misguided or unfortunate characters on *The Sopranos*.

"I don't know how many community hospital labs will survive even the next three years," said Patty A. Sipes, senior vice president of sales and marketing for PAML, the Spokane, Wash.-based laboratory.

"It is truly becoming an environment where take-it-or-leave-it pricing can be presented," Snyder said. And according to Bettinger, labs are in a guessing game as to what each health plan is willing to pay.

What is driving this hostile operating environment? There are a number of factors. Many can be traced to the Affordable Care Act, the most dramatic aspects of which will be introduced next year. The initial premiums announced by health plans competing in the California and Oregon exchanges were on the low side and excluded large numbers of providers—strong indications that the payers plan to be vigilant about cost control. Cuts to Medicare through the sequester and a variety of outcome improvement initiatives

connected to the ACA are also piling on. And an increasing number of Medicare patients are moving into Medicare Advantage plans, which are also ratcheting down costs.

The scenery isn't any more attractive among the current commercial book of business. According to Snyder, at least a quarter of employer groups have shifted to high-performance or so-called "narrow" provider networks that focus on keeping costs down while heaping ever-higher deductibles and copayments into the arms of their workers. As a result, both constituencies want more data on price transparency.

There is also a push by plans to deliberately steer patients into the cheapest possible care option. "I've seen plans that will pay the members to go to a lower-cost provider and send them a check for 10 bucks," Snyder said.

"What the health plans are looking for is, 'who can give us a full package? Who can help lower our costs?'" Sipes observed.

Limited Leverage

Moreover, by representing little more than 3 percent of total health care expenditures, labs do not have a significant amount of leverage with health plans, if they have any leverage at all.

"I've seen plans that will pay the members to go to a lower-cost provider and send them a check for 10 bucks."
—Mike Snyder, Clinical Lab Business Solutions

"To the health plan industry, [labs] are beige," Snyder said.

But representing just a small portion of the health care buy is not the only problems labs have. According to Snyder, most have done little to prove their value to payers and have remained focused on volume rather than quality metrics.

"There is no recognized quality standard. I hear this a lot from health plans," Snyder said.

Some Possible Options

The labs are not without options. They can move to carve a role out for themselves in accountable care organizations, yet another face of the ACA.

However, Snyder in particular is pessimistic about this notion. "Labs have very little impact in putting together an ACO deal," he said, even though national labs such as LabCorp and Quest Diagnostics have repeatedly told analysts that the ACOs need their services.

The expansion of the Medicaid program in at least half of the states is expected to bring in millions of previously uninsured individuals in the coming years who will require laboratory and pathology testing and follow-up assays.

However, Medicaid pays a fraction of Medicare or commercial rates, making it challenging for many labs to eke out a profit serving those patients.

"It is certainly a growth area, and I think we will have to manage that growth with [Medicaid's] compressed margins," Bettinger said. "There may be some tests we can't do, but you have to be careful. It's tough to cherry-pick tests with your . . . clients."

Instead, the focus for labs in order to persevere is on the management of chronic conditions, such as kidney disease. Snyder noted for example that the proper identification and management of a chronic kidney disease patient—with lab results used to closely monitor their condition—can prevent them from progressing into a case of end-stage renal disease and the inevitable dialysis and hunt for a transplant donor.

"That's a savings of $60,000 per year per patient," Snyder said. If labs can pitch a way to accomplish those kinds of savings, the health plans are likely to listen.

IT Is a Must-Have

However, labs cannot achieve such savings and the other efficiencies desired by payers within a vacuum. Much as the HITECH Act has connected hundreds of thousands of physicians to electronic medical record systems over the past several years, labs are also going to have to invest in health care IT.

"Our physicians meet with the health plan's chief medical officer, and they can specifically talk about what differentiates them."
—Eric Bettinger, chief financial officer, ClearPath Diagnostics

"The data piece is huge. . . . [P]hysician connectivity is the biggest item when we talk with plans," Sipes said. She suggested partnering with other entities that can help provide the IT component more readily. However, labs should continue to emphasize the non-IT items that they handle well, such as turnaround times, customer service, physician loyalty, and the quality of the pathology work that they do, Sipes added.

ClearPath, for example, clearly communicates the quality levels of the services it provides on a daily basis, such as how often it pulls slides and performs second screens on Pap smears.

Closer Contact

Labs will never disappear entirely since they play a critical role in health care delivery. But labs and pathology practices will have to make a greater effort to gain contracts.

One of the things that Bettinger emphasizes is face-to-face meetings with top-level health plan executives in order to make ClearPath's business case more clearly. This is being pursued particularly after a contract proposal may initially be turned down.

"Our physicians meet with the health plan's chief medical officer, and they can specifically talk about what differentiates them," Bettinger said.

■ **Cancer Genetics, Mayo Clinic Form Joint Venture**, *from page 1*

"Individualized medicine and genomic testing give us a fundamental understanding of the inner workings of wellness and disease. We recognize the transformative power of these tools and are committed to using every resource at our disposal to bring individualized medicine to our patients," said Gianrico Farrugia, M.D., a Mayo Clinic gastroenterologist and director of Mayo Clinic's Center for Individualized Medicine.

Farrugia is one of the six-member board of governors that will oversee OncoSpire's operations. Three of the members are from Mayo, while three are from Cancer Genetics, including its chief executive officer, Panna Sharma.

The company has been moving away from the development stage in recent years. Although Cancer Genetics posted a $6.7 million loss on revenue of $4.3 million in 2012, its revenues were up 40 percent compared to 2011. Its 2012 losses were far lower than the $19.9 million loss it reported in 2011. For the first quarter of 2013, revenue was up nearly 50 percent from the first quarter of 2012, while clinical test volume was up nearly 20 percent.

At the moment, the distribution plans for any new diagnostic products have yet to be finalized.

"There is no one fixed distribution channel. OncoSpire will work with Mayo to commercialize diagnostic laboratory services through Mayo Medical Laboratories," Smith said. "OncoSpire will also work with Cancer Genetics to commercialize diagnostic products [such as FDA-approved kits]. OncoSpire may also directly commercialize laboratory services and products."

However, the ambitions of the joint venture are not limited. Smith said OncoSpire would eventually "expand biomarker development activities" beyond hematological and urogenital cancers.

Foundation Medicine Says Panel Is More Effective Than Hotspot Testing

Foundation Medicine's genomic profile is more effective than typical hotspot testing in determining genetic alterations that could be acted on medically, the company announced late last month.

According to the Cambridge, Mass.-based Foundation Medicine, its FoundationOne genomic panel uncovered medically actionable genetic alterations in 76.4 percent of the more than 2,200 cancer tumors it profiled in its laboratory. Moreover, 61.5 percent of the alterations spotted by Foundation's panel would not have been identified through hotspot panels used to identify specific forms of cancer, the company claimed.

The findings from the in-house study were presented at the recent annual meeting of the American Society of Clinical Oncology in Chicago.

FoundationOne's single test offering is the genomic panel, which retails for about $5,800 and became available in 2012. Test results are accompanied by suggested matches between the detected genetic alterations with Food and Drug Administration-approved drugs and pending clinical trials for other treatments.

INDUSTRY BUZZ

Pharmacogenomics Paving the Way at Maryland Hospitals

Cardiac stenting and catheterization patients at the University of Maryland Medical Center (UMMC) and Baltimore VA Medical Center are now undergoing genetic tests to better shape their post-treatment options and decisions.

The patients are being tested for variations in the CYP2C19 gene, which can lead to different rates of metabolization of clopidogrel, a widely used anti-clotting drug marketed as Plavix. It is suspected that as many as a quarter of the U.S. population has a gene variant that makes them react differently to standard dosages of Plavix.

"Knowing a patient's genotype is helping us to make more informed decisions for our patients," said Mark R.Vesely, M.D., a cardiologist who practices at both hospitals and also teaches at the University of Maryland's School of Medicine. "A combination of aspirin and clopidogrel is the routine choice of medications many physicians will prescribe for their stent patients. But patients who are likely to have a poor or moderate response may be better protected by other medications or possibly a higher dose of clopidogrel. It comes down to what is best for each patient."

The CYP2C19 test ranges in price from about $200 to $500. It is being offered free to the UMMC and VA patients as part of a National Institutes of Health initiative analyzing the efficacy of genetic testing programs.

"We plan to share lessons learned . . . to develop best practices for implementation of pharmacogenetics in everyday clinical practice. We are putting together a toolbox that will be useful to other institutions," said Alan R. Shuldiner, M.D., associate dean for personalized medicine and director of the personalized and genomic medicine project at the UM medical school.

There has been some controversy regarding the medical efficacy of the CYP2C19 test. Shuldiner was lead author of a 2009 study published in the *Journal of the American Medical Association* that linked variations in the gene to reduced effectiveness in the use of Plavix—research that led to the Food and Drug Administration issuing an advisory. However, the American Heart Association and American College of Cardiology have said there isn't enough evidence to support genotyping.

References

Cancer Genetics 201-528-9200	Foundation Medicine 617-418-2200	PAML 509-755-8600
ClearPath Diagnostics 315-234-3300	Gene by Gene 832-381-5410	Quest Diagnostics 800-222-0446
Clinical Lab Business Solutions 908-237-2807	Mayo Clinic 480-301-8000	University of Maryland Medical Center 410-328-8667

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