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LABORATORY INDUSTRY REPORT®

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HIGHLIGHTS

Medicare Cuts to CPT 88305 Threaten Bottom Line of Pathology Practices

The Centers for Medicare and Medicaid Services' (CMS) recent publication of a final rule that would cut the payment for the technical component (TC) of surgical pathology code 88305 by more than 50 percent has sent a shock wave through the laboratory and pathology communities and is likely to result in closure of some small pathology labs.

CMS's decision to reduce Medicare payment for the TC by 52 percent was moderated slightly by a 2 percent increase in the professional component of 88305. However, it was not enough to prevent pathology labs from taking a hard look at their operations as they move toward the new year.

"We thought [the reduction] might be in the range of 30 percent. We were completely surprised by the 52 percent cut," said Ben Davis, M.D., chairman, chief executive officer, and president of PathGroup, a large pathology practice in Brentwood, Tenn., near Nashville.

Davis's surprise was echoed by Cory Roberts, M.D., president of ProPath, a pathology lab in Dallas. "We were shocked. We had no inkling this was going to happen," he said. *Continued on page 2*

Molecular Testing Continues to Grow for Smaller, Publicly Traded Labs

Recent earnings reports for four publicly traded esoteric laboratories show that during a time of tight margins in the sector for bread-and-butter products, molecular and personalized medicine is continuing its steady growth curve.

The overall earnings picture for the labs—Response Genetics, Myriad Genetics, Combimatrix Corp., and Transgenomic Inc.—were mixed. Only one of the firms reported a net profit for the quarter ending Sept. 30. However, all showed growth among their molecular testing product lines.

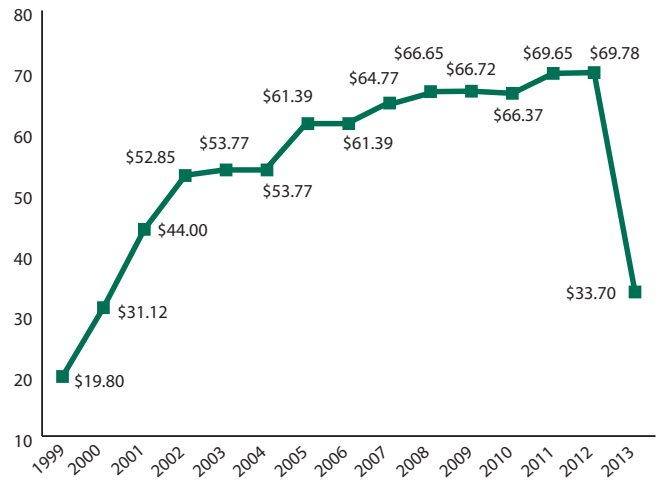
By far the biggest and most established of the firms is Salt Lake City-based Myriad Genetics, and the only one that was in the black. It reported net income of $30.1 million on revenues of $133.4 million for its fiscal 2013 first quarter. That compares to net income of $25.1 million on revenues of $104 million for the year-ago quarter. *Continued on page 6*

■ Medicare Cuts to CPT 88305, *from page 1*

Medicare payment for the TC of 88305 has increased steadily since 1999, when it stood at $19.80, reaching a high of $69.78 in 2012. The cut announced in November will reduce the TC to $33.70 in 2013, which is likely to force many small pathology labs to shut down and will cut the bottom line of all path labs.

PathGroup has been rapidly growing in recent years through both organic growth and acquisitions, with its staff of pathologists increasing 40 percent over the past three years, to 70 in total, according to Davis. But the cuts to 88305 could severely impact growth going forward, he believes.

Medicare Reimbursement for CPT 88305 (TC)



Source: Medicare Physician Fee Schedule

"Our view of the value of [acquisition] opportunities will be impacted by the apparent lack of profitability moving forward," Davis said. "I think we have to reevaluate our positioning in those kinds of transactions."

PathGroup relies significantly on 88305 charges: Davis said 88305 accounts for 25 percent of the lab's net revenues.

"It will clearly impact the growth of jobs at our company," he said, adding PathGroup has about 800 employees. "That will be adversely impacted."

Instead of continuing on its aggressive growth path, Davis noted that PathGroup will be considering a hiring freeze as it has been prompted by the CMS announcement to revisit its 2013 budget forecasts.

Pathology Market to Tighten

Roberts's ProPath is in similar straits. The lab does a large volume of gastrointestinal and skin biopsies and Pap smears—all of which rely on 88305 payments. However, there are no plans for layoffs, as the company has already been cutting expenses and seeking greater efficiencies due in part to ongoing pressures from commercial payers, according to Roberts. "We're doing fine," he said.

But Roberts does see the cut in payments tightening the market for pathologists, despite the health care profession's voracious overall demand for physicians.

"Pathologists are going to have a tougher time finding jobs, and we may also have a tougher time finding partner-level physicians," he said. Roberts added that the market for histotechnicians has already tightened up, with ProPath receiving many out-of-state applicants for a position it is currently trying to fill.

In the meantime, both labs will likely continue to enhance their focus on molecular medicine, which has been a rapidly growing segment in comparison to other components in the lab sector.

Kathleen Murphy, a Ph.D. who was recruited by ProPath from her position as scientific director for Johns Hopkins Medical Institutions, has been instrumen-

CORRECTION: *In the Nov. 7, 2012, issue of* LIR, *we incorrectly stated that CPT 88305 is the first and only pathology code to top the $1* million *mark in Medicare-allowed charges in a single year. CPT 88305 is the first and only pathology code to top the $1* billion *mark in Medicare-allowed charges in a single year.*

tal in growing the lab's molecular business, according to Roberts.

"We do a significant amount of flow in molecular testing, and that is the direction in which we have been growing," he said.

And both Davis and Roberts say their labs would lodge public comments regarding the final rule on 88305. "It is a means of appealing to the CMS," Davis said—with the intent of creating enough momentum to get the agency to reconsider its position.

Quest Says Hospital Deals Big Key to Future Growth

Quest Diagnostics' deal to acquire the clinical outreach laboratory business of the UMass Memorial Medical Center and a plan to joint venture with UMass Memorial Health Care in a new lab in the Worcester, Mass., region is part of the firm's emerging strategy to partner more closely with hospitals.

During an investors' meeting in New York on Nov. 16, Quest Chief Medical Officer Jon R. Cohen, M.D., called the deal an extremely important component of the national laboratory's future strategy. "We believe hospital lab outsourcing is the future," he said.

Cohen, a longtime executive with the North Shore-Long Island Jewish Health System before joining Quest, noted that hospital C-suite executives throughout the country are looking for ways to cut costs while increasing revenue. As a result, Quest sees a large opportunity focusing on the approximately 2,700 hospitals nationwide with between 100 and 500 beds that would want to outsource their lab services.

"What is it they don't need to do anymore?" he said. "There is the opportunity to outsource their laboratory. . . . [W]e go in, reduce their fix costs, reduce their variable costs, and increase their cash flow."

Cohen estimated that depending on the specific relationship with a hospital, Quest could cut its annual lab costs by between 8 percent and 20 percent annually by negotiating better supply contracts and taking lab employees off their payrolls.

Timothy Johnson, a managing director with investment bank England & Co. in Washington, D.C., said national labs such as Quest are indeed attractive partners for hospitals. "They can achieve economies of scale through consolidation of facilities," he said in an e-mail.

That is essentially what is happening in the UMass transaction. Quest will consolidate the volume at its lab in Cambridge, Mass., that of its Athena Diagnostics unit, and the UMass volume into a single new facility it will build in the region over the next 24 months.

Johnson noted that such an investment is attractive for Quest in Massachusetts, since virtually every resident of the state has health insurance. "Universal health care in the state has had a positive impact on order volumes," he said.

However, he also believes such deals will proliferate in other parts of the nation. He noted that Quest earlier this year acquired S.E.D. Medical Laboratories from Lovelace Health System in New Mexico. Part of the transaction included Quest's management of the inpatient labs at Lovelace's four hospitals.

"I would expect to see more deals like this," Johnson said.

Inside The Lab Industry

When It Comes to ACOs, Labs Can't Table Their Actions

Eleanor Herriman, M.D.
Director of Advisory Services,
G2 Intelligence

As the health care industry moves toward full-bore reforms in payments and deliveries, laboratories will either find themselves at the table—or on it.

That is the choice lab executives must make as their revenue streams shift profoundly, prodding them to provide more efficiencies and value to their customers, according to a G2 Intelligence executive.

Eleanor Herriman, M.D., G2's director of advisory services, told an audience at the Lab Institute in Washington, D.C., last month that employees, rather than their employers, are now paying for the bulk of their health care costs. That has occurred as the result of a shift to high-deductible and other cost-sharing health plans.

"Employees are now paying more than employers out of pocket, and that is a major tipping point," Herriman said.

Meanwhile, many health care providers are going to receive fixed payments from commercial and Medicare payers—as much as 10 percent or more of total payments in the coming years. That will occur primarily through bundling, with payments in part based on performance. Herriman expects that the Centers for Medicare and Medicaid Services will "roll out" bundling nationwide by 2016, including the lab-heavy specialty of oncology.

Those labs that are "at the table" will get there by providing downstream and measurable clinical value by "going way beyond test reports," Herriman observed. That includes teaming with clinicians to provide more data and aggressively negotiating compensation on value-based contracts.

Conversely, your lab will be "on the table" if you are perceived as a vendor merely providing a commodity test report.

"In a bundled world, to a provider, their profit [will be achieved by] lowering other provider's revenues. It becomes dog-eat-dog," Herriman said.

Oncology Opportunities

However, there are a myriad of opportunities for labs to become team-players and prove their value, particularly given the ever-increasing complexity of medicine and an ongoing shortage of primary care physicians.

"This is a perfect setup for pathologists," Herriman said, noting that they and their laboratories can participate to a greater extent in clinical decision support. "Providers have a whole new set of needs."

One particular need area is oncology, which has been an early target for bundled and value-based payments.

"Oncologists are having all sorts of financial struggles. They need to optimize their treatment decisions for efficacy, toxicity, and cost," Herriman said, while preventing complications and hospitalizations and leaving room for palliative care options.

That means more sophisticated analysis by laboratories, such as determining whether specific medications are losing their effectiveness against specific tumors.

Herriman believes the market for pathologists in this area is significant. Based on the gain-sharing of savings in a bundled payment environment, on-

cology alone could reap pathology $2.1 billion a year by 2016, along with the $8.5 billion in non-skin cancer testing expected to occur. That total figure could rise to $11.7 billion by 2020.

In the world of accountable care organizations, Herriman estimates that the share for pathology laboratories alone could be about $332 million a year in 2014 and $739 million by 2017. That is based on an estimate of 5 percent of an estimated 7.5 percent in potential shared savings for providers. Based on population numbers alone, Herriman estimated that the average pathology lab covering 15,000 Medicare lives would receive a total annual payment of $472,000.

An Opportunity From Errors

Labs can also provide valuable services to clinicians to avoid what is still a troubling trend toward medical errors. According to Herriman, clinicians err on diagnostic decisions about 15 percent of the time, and this contributes to 15 percent of adverse events. They are simply overloaded with too much information and often too many patients. Laboratories have an opportunity to provide clarity and intervene before disaster strikes, or even just to reduce average lengths of stay. Based on data compiled by Michael Laposata, M.D., who practices at Vanderbilt University Medical Center and previously at Massachusetts General Hospital, pathologists were able to reduce the average length of stay for patients being treated for pulmonary embolisms by three days to two—a reduction of 33 percent.

"If you bring that evidence to a hospital administrator and say, 'This is what our lab wants to do,' that is how you become a value-generating lab."
—Eleanor Herriman, M.D.

"That's real money," Herriman said. "If you bring that evidence to a hospital administrator and say, 'This is what our lab wants to do,' that is how you become a value-generating lab. It completely changes the frame of thinking for the lab and the pathologist. And the money for that—as opposed to lowering the number of molecular tests—is very different."

Herriman suggested that labs focus on services they can provide in areas with high clinician diagnostic error rates such as coagulation, myocardial infarction, infectious disease, adverse drug reactions, transitions of care (e.g., hospital to skilled nursing facility or intensive care unit to a noncritical unit), and high-impact settings such as the emergency room.

However, Herriman cautioned that such goals are not easy. "You have to manage a patient population all the way up from the entire community . . . over time and across all conditions and procedures," she said, adding that accomplishing such a feat requires an enormous amount of information, markers, and risk assessments.

But Herriman noted that labs do indeed possess such information—in the form of informatics-based risk prediction, individualized medicine guidance, utilization management and quality, and coordination programs.

"We really are in a unique position to systematize personalized medicine," she said.

Molecular Testing Continues to Grow, *from page 1*

Revenue from molecular testing grew 22 percent, to $127.3 million. Myriad's products focus on testing for breast, ovarian, and colorectal cancer.

"We believe that our initiatives of growing existing tests and markets have fueled these strong financial results," said Myriad Chief Executive Officer Peter D. Meldrum.

The Omaha, Neb.-based Transgenomic, the second largest of the companies, is a far cry from Myriad in size: its revenues are less than a 10th of the more established lab. It reported a net loss of $2.8 million for the third quarter ending Sept. 30, compared to a net loss of $1.3 million for the third quarter of 2011. Revenues dropped 4 percent to $7.9 million, compared to $8.3 million for the year-ago quarter.

However, the company reported "double-digit growth" in its clinical laboratories segment, credited to sales of its C-GAAP test, which determines whether or not patients would benefit from a regimen of the Plavix anti-platelet drug. CEO Craig Tuttle noted the firm recently acquired ScoliScore, a genetic test that helps determine the progression of adolescent idiopathic scoliosis.

Los Angeles-based Response Genetics reported a net loss of $1.4 million on revenues of $5.4 million for the third quarter, compared to a similar loss on revenues of $5.1 million for the year-ago quarter. The company, which develops tests to determine a patient's response to various cancer therapies, said sales of its ReponseDX test had grown, while gross margins had nearly doubled compared to the fourth quarter of 2011.

"We believe we are well positioned, both strategically and financially, to continue building a strong organization to capitalize on the promise of personalized medicine," said CEO Thomas Bologna. Response reported $10.8 million in cash on hand, compared to $2.6 million for the second quarter of June 2012.

The smallest of the firms, Irvine, Calif.-based CombiMatrix Corp., reported that its third-quarter revenue reached $1.29 million, up 5 percent from the $1.24 million reported for the year-ago quarter. It also narrowed its net loss to $1.34 million, compared to $2 million for the third quarter of 2011.

CombiMatrix performs prenatal and oncology testing. It reported that it performed a total of 1,356 billable diagnostic tests for 110 customers during the quarter, compared to 1,157 tests for 101 customers in the third quarter of 2011.

CombiMatrix officials said the company would focus more on the prenatal market moving forward, and its oncology efforts would be in partnership with other labs.

"We expect the momentum that we have built in the past two quarters will continue into the . . . new year," said CEO Judd Jessup. "We are actively seeking and signing up large customers in the prenatal segment and . . . will begin to more than offset the revenues we are forgoing in the de-emphasized oncology market."

ACMG Criticizes Making Clinical Gene Data Proprietary

The American College of Medical Genetics and Genomics (ACMG) has taken a tough stance on what it calls the "monopolistic" practice of developing proprietary databases on the clinical meaning of gene variants.

The ACMG board approved a position statement earlier this month that asserted "clinical data underlying genome annotation that informs the clinical interpretation of molecular variants are fundamental to the practice of genetic and genomic medicine." However, it believes that restricting information is harmful to the practice of medicine.

"The ACMG believes that gene testing and the clinical data on which genetic data are interpreted must remain widely accessible and affordable, and that the development and improvement of safe and effective genetic tests should not be hindered," it said in a statement it issued on Nov. 6. "Monopolistic practices that limit a given genetic test to a single laboratory are inconsistent with ACMG's goals of broadly accessible and affordable genetic tests."

Michael Watson, executive director of the Bethesda, Md.-based ACMG, noted that the next phase of human genome project—the international gene mapping effort that is now in its third decade—will focus on the clinical and biological meaning of gene sequences and variants.

The new phase of the project "will require capturing information from a very large number of people from diverse populations across the U.S. and internationally. Information that informs us about the meaning of genome sequences should be in the public domain where it can be used for the benefit of all," Watson said.

Withholding Data 'Impedes Integration'

The ACMG said any laboratory that possess proprietary genetic data puts it in "the position of practicing medicine, since only they have the ability to use data to inform medical decision-making." Moreover, the withholding of such data "impedes its integration into medicine" and inhibits "the training of the next generation of medical and laboratory geneticists, physicians, and scientists."

As a result, the organization concluded that "payers, regulators and providers should work to bring the clinical data into publicly available resources," although it did not provide any specifics as to how to accomplish that goal.

The ACMG did not mention any specific laboratories or industry segments in taking its new position, or in the statement that it issued.

INDUSTRY BUZZ

Health Reform Implementation Challenging for Labs

The re-election of President Barack Obama earlier this month all but guarantees that the Patient Protection and Affordable Care Act (ACA) will be enacted in its entirety.

The biggest components of ACA will be implemented in late 2013 and early 2014, when millions of Americans will be able to purchase commercial health insurance on electronic exchanges in their states. Millions more will qualify for federal coverage such as Medicaid or the Children's Health Insurance Program.

Meanwhile, the Centers for Medicare and Medicaid Services will continue to expand programs that pay providers based on the quality of care they deliver and financially penalize them for medical errors that lead to the readmission of inpatients within 30 days of discharge.

What do these reforms mean for the laboratory industry?

Brian Carr, chairman and chief executive officer of Regional Diagnostic Laboratories in Brentwood, Tenn., thinks it could bode tougher times for the industry as a whole.

"The further implementation of [the ACA] doesn't promise the same kind of upside for labs than hospitals," said Carr, who believes labs will come under tougher pricing pressures in the coming months and years. His company was founded earlier this year as part of a $250 million investment by the Warburg Pincus private equity firm to acquire labs, although it has yet to pull the trigger on a deal.

Observers say that labs will strive to work more closely with the burgeoning number of accountable care organizations (ACOs), which pay providers fixed payments and allow them to share in any resulting savings. Jon R. Cohen, M.D., the chief medical officer for Quest Diagnostics, said his organization would partner with hospitals in running ACOs.

Eleanor Herriman, M.D., director of advisory services for G2 Intelligence, notes that labs could improve their revenue position by helping hospitals in ACOs cut down on medical errors and reduce their expenses. While labs will be challenged by health reform implementation, she believes the law presents labs with new opportunities as well (for more on these opportunities, see *Inside the Lab Industry* on page 4).

References

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G2 Intelligence
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Myriad Genetics
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PathGroup
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ProPath
214-237-1660

Quest Diagnostics
800-222-0446

Regional Diagnostic Laboratories
615-577-5885

Response Genetics
800-700-7110

TransGenomic
402-452-5400

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