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LABORATORY INDUSTRY REPORT™

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HIGHLIGHTS

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Upcoming Conferences

Lab Institute
It's Make or Break Time: A Path Forward For Labs
Oct. 16-18, 2013
Hyatt Regency Crystal City
Arlington, Va.
www.labinstitute.com

Lab Leaders' Summit 2013
Dec. 9, 2013
Union League Club of New York
New York City
www.lableaderssummit.com

Laboratory and Diagnostic Investment Forum
Dec. 10, 2013
Union League Club of New York
New York City
www.labinvestmentforum.com

Molecular Pricing Improves on Average, But Many Tests Not Priced at All

Final 2013-2014 Medicare prices for many new molecular pathology (MoPath) codes published Sept. 30 average about 26 percent higher than the proposed (interim) rates released earlier this year, though the median improvement is just 6 percent.

The Centers for Medicare and Medicaid Services (CMS) published prices for just 65 of the 114 new MoPath codes. According to the agency, only codes that are currently being paid by Medicare administrative contractors (MACs) are listed. Some codes listed in the May 9, 2013, posting are not currently shown because the service is no longer being paid by the MAC.

CMS is allowing a 30-day reconsideration period on these final prices, so it is possible there could be additional changes when the agency announces final amounts for the 2014 Clinical Laboratory Fee Schedule later this year.

For more on final molecular pricing and questions that remain, see *Inside the Laboratory Industry* beginning on page 4.

Health Diagnostic Laboratory Publishes Cost-Effectiveness Data

The one thread that loops completely through the volume-to-value proposition has been data—many laboratory leaders want to transition their business model into this new realm, but actually offering cohesive support for it outside of specific assays and clinical situations has been challenging.

Last month, Health Diagnostic Laboratory (HDL) took an audacious step forward in the march toward value. It published a study in a peer-reviewed academic journal touting the cost-value proposition of its assays—all of them.

According to the study, which was published in *Population Health Management*, patients who received HDL's cardiovascular testing panel had significantly lower health care costs moving forward than other patients.

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Veracyte Plans Public Offering

Veracyte, the San Francisco-area laboratory that specializes in molecular testing for thyroid issues, has plans to go public.

The company released its Afirma thyroid molecular test in early 2011. The assay is used to reduce the number of unnecessary thyroid surgeries by moving beyond fine needle aspiration biopsies—and the inconclusive results they obtain in about a quarter of the 535,000 procedures performed in the United States every year. An Afirma panel retails for $4,275.

Veracyte filed an S-1 registration with the Securities and Exchange Commission (SEC) late last month, less than three months after it received $28 million in series C tranche funding from its major investors.

According to the SEC documents, Veracyte will raise up to $75 million through the initial public offering and trade on Nasdaq. Of the sums raised, $40 million would be split evenly between expanding sales and marketing, with the remainder put toward debt reduction and administrative expenses. Morgan Stanley & Co. would handle the underwriting.

Financial data accompany the S-1 suggests the release of the Afirma test has been a boon for Veracyte. Although the company reported a loss of $18.6 million in 2012, revenue was $11.6 million, more than quadruple the $2.6 million reported in 2011 (the company reported a loss that year of $14.4 million). Test volumes zoomed from 6,400 to nearly 26,000.

The company will likely rely only on sales of Afirma for the long term. "We are in various stages of research and development for other diagnostic solutions that we may offer, but there can be no assurance that we will be able to identify other diseases . . . or when we will be able to successfully commercialize these solutions," the prospectus said.

Veracyte also did not project when it might become profitable, noting that it was expected to report net losses for the foreseeable future. It relies on Medicare for slightly more than a third of its revenue, and two major commercial insurers—UnitedHealthcare and Aetna—account for about 20 percent.

Takeaway: Veracyte, like many other Bay Area high-tech companies, will try to cash in by going public, but what level of success it achieves remains to be seen.

Mayo Clinic to Open New Stem Cell Lab

Mayo Clinic's satellite provider in Arizona has plans to construct and open a new laboratory for prepping tissue for bone-marrow-based stem cell transplants.

The Phoenix-based Mayo Clinic is one of the busiest stem cell transplant providers in the Southwest. It performs more than 200 adult procedures annually, plus another 30 pediatric transplants in conjunction with Phoenix Children's Hospital.

Processing for stem cell transplantation includes a variety of laboratory procedures. Among them are removal or enrichment of specific cell populations,

cryopreservation, and thawing and preparation of progenitor cells for infusion into the patient.

The number of bone marrow transplants in the United States has been growing steadily. More than 30,000 are performed per year nationwide, triple the figure from the late 1990s. The five-year survival rates for lymphoma and leukemia patients who undergo the procedure are about 10 percentage points higher than compared to those patients only undergoing chemotherapy.

Physicians affiliated with the Mayo Clinic said in a statement that the new lab will operate at an increased processing capacity, improve turnaround times, and provide the potential for research-related activities, including those in the field of regenerative medicine.

The 6,200-square-foot laboratory is set to open in the summer of 2014. Jim McVeigh, a Mayo spokesman, was unable to provide cost of construction or current laboratory volumes and projections after the new facility opens.

Takeaway: The increase of exotic procedures such as bone marrow stem cell transplants is driving demand for new laboratory space.

MolecularHealth Aiming to Enter U.S. Market

MolecularHealth, the Swiss firm whose molecular tests focus on oncology care and drug testing, is gearing up for a major distribution and sales push in the United States.

The company has opened an office in the Houston suburbs and appointed an executive staff, all formerly of U.S. Oncology, the Houston-area operator of community-based cancer practices. It will operate a laboratory on-site.

MolecularHealth's chief executive officer for its U.S. operations is Lloyd Everson, M.D., U.S. Oncology's former president and a current member of its board of directors. The division's three other top-ranking executives are all from U.S. Oncology.

"This management team brings with it the medical and operational experience needed to commercially launch MolecularHealth here in North America and to make our cancer diagnostics offering available to oncologists, pathologists, patients, and their families," said Friedrich von Bohlen, MolecularHealth's chairman.

Altogether, MolecularHealth expects to have 20 employees by the end of 2013 and 30 by the end of next year, anticipating a staff of 80 by 2017.

The firm has been working for the past several years with the M. D. Anderson Cancer Center in Houston on developing assays and related products. A company spokesperson said it will offer a 500-gene custom panel in the United States, along with a whole-exome test. It projects performing 2,000 tests in the United States next year.

Takeaway: Large European firms see a potential benefit to breaking into the U.S. market.

CMS Releases Final Molecular Prices, but Confusion Over Errors Persists

Call it cloudy with a chance for shortfalls. That might be the best way to describe final 2013-2014 gap-fill pricing on dozens of molecular tests released by the Centers for Medicare and Medicaid Services (CMS) on Sept. 30.

While the numbers contained some hope for the sector and its efforts to lift some prices, some test codes received no definitive pricing at all. And some key tests appeared to be priced dramatically lower in some regions than in others—the apparent result of clerical errors by two of the agency's Medicare administrative contractors (MACs) that left industry observers scratching their heads.

A report by Piper Jaffray said pricing errors were included for BRCA testing in the regions overseen by Noridian and Palmetto, dropping them more than 48 percent than the previous pricing. That would have proven disastrous for Myriad Genetics, the Salt Lake City-based lab that currently performs most of the nation's BRCA testing and relies on the assay for a large part of its revenue.

"Myriad is working with CMS to rectify the erroneous reimbursement information and anticipates corrected rates will be published in the next week or two," Piper Jaffray said in a report.

A statement issued by the American Clinical Laboratory Association appeared to confirm Piper Jaffray's concerns. The organization was "still in the process of reviewing the information that was published . . . but has received several credible reports that there may be clerical errors in the published information that could impact the final pricing for these tests."

> ***"Myriad is working with CMS to rectify the erroneous reimbursement information."***
>
> ***—Piper Jaffray***

Whether CMS has acknowledged or will fix the apparent errors anytime soon remains to be seen. The federal government entered into a massive shutdown on Oct. 1, furloughing thousands of nonessential employees, with many CMS officials among them.

As a result, calls to the CMS press office went into a closed-loop recording that prevented leaving messages. An e-mail to the CMS spokesperson who handles these specific payment issues generated an automated response saying she is on furlough and unable to respond.

65 Codes Priced

Just hours before the shutdown, the agency issued prices for 65 of the 114 codes that were placed on the Clinical Laboratory Fee Schedule earlier this year, replacing the prior code-stacking methodology. For those codes, prices rose an average of 26 percent and a median of 6 percent compared to the proposed prices that had been issued earlier this year.

Altogether, 39 tests received an average nationwide price boost over their proposed price, while 19 saw cuts and six were unchanged. Thirteen tests saw their final prices increased over what would have been paid using code-stacking methodology, while 24 were cut, most by double-digit percentages.

Pricing released by Palmetto GBA, the MAC with jurisdiction over California and Nevada, led to increases of prices on 43 tests and price reductions on 22 others that ranged from nominal to as high as 81 percent.

Some of the tests received pretty dramatic boosts over the proposed prices that had been released in the spring.

NPM1 gene analysis, CPT code 81310, was priced at a national average of $212, up 264 percent from the average proposed price of $58. It was also up 261 percent from the original code-stacked price of $59. It also fared well in California and Utah, where Palmetto GBA serves as the MAC. It priced the test at $249, up 327 percent from the original proposed price.

Final Molecular Gapfill Pricing Versus Proposed Pricing

CPT Code	Procedure	Final Average Price	Proposed Average Price	Code Stacked Price	% Change From Proposed	Final Change From Code Stacked
81206	BCR/ABL1 Major	$187	$100	$61	87%	208%
81210	BRAF	$162	$88	$259	84%	-38%
81211	BRCA1/2	$2,842	$2,845	$3,340	0%	-15%
81213	BART	$598	$598	$700	0%	-15%
81217	BRCA2 Known Family Variant	$91	$90	NA	-1%	NA
81225	CYP2C19	$275	$223	$290	23%	-5%
81226	CYP2D6	$405	$278	$159	46%	154%
81227	CYP2C9	$153	$126	$219	21%	-30%
81235	EGFR	$279	$185	$302	51%	-7%
81240	F2 Analysis	$62	$43	$136	45%	-55%
81241	F5 Analysis	$77	$73	$136	6%	-43%
81245	FLT3 Analysis	$153	$111	$344	38%	-56%
81256	HFE Analysis	$84	$70	$95	20%	-12%
81261	IGH Gene Rearrangement	$250	$164	$154	52%	62%
81263	IGH Variable Region	$367	$260	$227	45%	62%
81310	NPM1 Gene Analysis	$212	$58	$59	264%	261%
81319	PMS2 Gene Analysis	$216	$413	$462	-50%	-53%
81340	TRB	$260	$147	NA	77%	NA
81342	TRG	$258	$157	$83	64%	212%
81371	HLA Verification	$317	$326	NA	-3%	NA

Sources: Centers for Medicare and Medicaid Services, Piper Jaffray

Chimerism analysis, CPT code 81268, was priced at an average of $312, up 102 percent from the original proposed price of $150. However, it still fell far short of the original code stacking price of $1,109.

Another test that fared well from its proposed to final average price was MLH1 gene analysis familial variant, CPT code 81293. It originally had a proposed price of $91 but came in at $240, a bump of 165 percent. It also fared well in code stacking, where Medicare originally paid $94, representing a bump of 156 percent.

Although industry experts were still poring over the codes as of earlier this week, there were tacit admissions that they had prevailed on lifting some of the prices.

Some Improvement

"The bottom line is there was some improvement," said Michael Arnold, president of the California Clinical Laboratory Association, one of the most vocal of the regional lobbying groups on the molecular coding issue. However, Arnold added that he would have liked to see the prices rise even further.

Not every code emerged unscathed. An MSH2 full sequence gene analysis test, CPT code 81295, was priced at $292, a 64 percent reduction from the proposed price of $809 and a 60 percent drop from the code-stacked price of $730. Palmetto cut pricing on that assay 81 percent from its original proposal, down to $153.

"We are extremely concerned about the apparent lack of coverage for many of these tests."
—Stephen Black-Schaffer, M.D., College of American Pathologists

Meanwhile, some industry experts have expressed concern about what did not receive specific prices: 51 separate tests. They include ASPA gene analysis, CPT code 81200, which was priced at $213 under code stacking, CFTR gene analyses, CPT codes 81220 to 81224, and long QT gene analysis, CPT codes 81280 to 81282.

"We are extremely concerned about the apparent lack of coverage for many of these tests, despite their current use in patient management, the availability of medical literature supporting those uses, and their inclusion in practice guidelines. In many cases, the results and interpretations provided in the reports of these medically necessary tests are used to determine patient treatment," said Stephen Black-Schaffer, M.D., a Massachusetts pathologist who is vice chairman of the economic affairs committee of the College of American Pathologists. "CAP is concerned that many proposed contractor coverage decisions would deny beneficiaries' access to molecular testing that is necessary for their diagnosis and management." He added that the American Medical Association is reporting denials in Indiana, Texas, Tennessee, Ohio, Kentucky, and Wisconsin.

Arnold also expressed concerns about tests being left off the schedule. "It's a giant question mark we have," he said.

Takeaway: The laboratory industry prevailed in some instances to raise prices on dozens of molecular test codes, but errors by the Centers for Medicare and Medicaid Services has clouded just how wide-ranging its successful campaign was.

■ **Health Diagnostic Laboratory Publishes Cost-Effectiveness Data,** *from page 1*

The study followed 229 patients who received two of HDL's cardiometabolic panels between June 2010 and May 2011 and compared them to a 214-patient control group that underwent two lipid panels during the same period of time. The patients in the HDL group also received related wellness services. The health care costs for both groups were then charted over a two-year period.

The data was striking: The HDL cohort had overall health care costs that were 23 percent lower than the control group. According to the study, the more granular data from HDL's tests and the follow-up disease management led to the cost reductions.

"Interestingly, the reduction in total costs was seen despite higher costs observed in the HDL cohort during the baseline year before the first HDL . . . test panel," noted the study. Its lead author was Steve Thompson, a professor at the University of Richmond, researchers from HealthCore, a Delaware-based company that focuses on health outcomes, and HDL staff.

Monthly Health Care Costs, HDL Vs. Control Group	
Baseline Costs	**Year 1 of Program**
HDL $997	HDL $612
Control $818	Control $652
Sources: Population Management	

The study's introduction focused specifically on the role of laboratory testing in accountable care organizations, a model where the sector's role remains unsettled.

"The findings from this report also suggest that providers and payers that are entering shared savings initiatives should consider the role that ancillary service providers with comprehensive care models such as HDL can bring to both manage costs and improve the health of patients," said Tonya Mallory, the Richmond, Va.-based laboratory's chief executive officer.

Sector observers say the approach could blaze a path for other laboratories.

"This is one of the ways of the future—labs will have to choose from the low-cost or high-value strategy," said Kathy Murphy, chief executive officer of Chi Solutions, a consulting firm in Ann Arbor, Mich.

"This is extremely powerful data, the kind of thing that would support even differential payer reimbursements and networks," said L. Eleanor J. Herriman, M.D., managing director of advisory services for G2 Intelligence.

Herriman added though that HDL's business model is unique, in that it blends laboratory testing with disease-management services. "They have a reason they want to invest in outcome differences," she said.

She also believes that other laboratories will have to take a similar approach.

"What they need to succeed is low cost and quality tied to outcomes and studies, but a lot of labs are not yet thinking that way," Herriman said.

Takeaway: Publishing peer-reviewed data may be an avenue for labs demonstrating their value proposition. G2

INDUSTRY BUZZ

Biodiagnostic: 17 Guilty Pleas and Counting

Less than six months after the first arrests were in announced connection with corruption at Parsippany, N.J.-based Biodiagnostic Laboratory, the pile of guilty pleas is beginning to eclipse the region's collection of smokestacks.

Late last month, Angelo Calabrese, M.D., and Paul Ostergaard, M.D., both pleaded guilty to single charges of violating the U.S. Travel Act—using the Postal Service to commit a crime. A Biodiagnostic employee, David McCann, pleaded guilty to violating both the Travel Act and federal anti-kickback statutes.

Their pleas add up to 17 to date involving Biodiagnostic's business practices, federal officials said.

According to the federal prosecutors, Calabrese accepted at least $130,000 in bribes from Biodiagnostic to refer some $600,000 worth of Medicare and commercial blood testing to its lab. Ostergaard accepted $50,000 in bribes to refer at least $150,000 worth of testing business.

The payments were made through sham consulting, lease, and service agreements that began in 2006. The payments were made by a company called Advantech LLC—an entity formed by Biodiagnostic specifically to disburse illegal payments, according to prosecutors. Calabrese was accepting monthly $4,500 payments from Biodiagnostic as recently as last spring.

Both doctors face up to five years in prison and $250,000 fines when they're sentenced next March. Calabrese will forfeit $334,000 and Ostergaard will forfeit $53,000.

Federal investigators began arresting Biodiagnostic employees—including Chief Executive Officer David Nicoll—and affiliated physicians last April, accusing them of a wide-ranging conspiracy to obtain more than $100 million in claims payments from Medicare and private insurers through the use of provider kickbacks. Some physicians have admitted to receiving kickbacks totaling nearly $2 million.

So far, about $3 million has been recovered through forfeitures. Federal officials say the investigation is continuing and that more guilty pleas should be expected.

Biodiagnostic also continues to limp on, although how the charges have impacted its business is unknown. Several of the links on the home page of its Web site are nonfunctioning.

Takeaway: A kickback scheme involving a single laboratory can entangle numerous providers.

References

American Clinical Laboratory Association
202-637-9466

Biodiagnostic Laboratory
973-677-7822

California Clinical Laboratory Association
916-446-2646

Chi Solutions
800-860-5454

College of American Pathologists
800-323-4040

Health Diagnostic Laboratory
804-343-2718

Mayo Clinic Arizona
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Molecular Health
281-655-3270

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