G2 INTELLIGENCE
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LABORATORY INDUSTRY REPORT™

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HIGHLIGHTS

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Upcoming G2 Events

Lab Institute 2016
Oct. 26-28, Hyatt Regency
Washington on Capitol Hill
www.labinstitute.com

Webinar:
Lab and Pathology Coding and Billing Update for 2017
Diana W. Voorhees, M.A., CLS, MT, SH, CLCP
Nov. 9, 2016, 2–3:30pm EST

Are Commercial Payers Citing Proposed CMS Gapfill Rates, Trying to Negotiate Lower Reimbursement?

During the summer, the Centers for Medicare & Medicaid Services (CMS) published proposed interim gapfill prices for 15 molecular tests. The agency said it would likely publish final prices later this year for placement on the Clinical Laboratory Fee Schedule.

The proposed prices cut payments to some tests as much as 85 percent from the current rates set by regional Medicare administrative contractors, or MACs, and several tests by more than 70 percent. The proposed rates have been much maligned by the laboratory community as a result, with significant pushback from the sector. Sector advocates such as the Coalition for 21st Century Medicine said at the time the proposed rates were published that they were "inconsistent" with the intent of the Protecting Access to Medicare Act, or PAMA. That law intends to reset some Medicare rates lower to commercial levels, but capped at annual reductions of no more than 10 percent.

But are commercial payers using the proposed rates of reimbursement to push down their own payments?

It depends on with whom you speak.

Continued on page 7

Quest Says Many Americans Are Misusing or Abusing Prescription Drugs

The majority of Americans who take prescription drugs are misusing them, according to a new comprehensive survey by Quest Diagnostics.

Quest, like many laboratories, has an extensive drug monitoring and compliance business. The New Jersey-based company analyzed 3.143 million de-identified test results over several years from 49 states and the District of Columbia to determine the particular issues challenging this patient population. It has performed similar extensive surveys on public health issues such as the prevalence of diabetes and how well it is being managed by specific patient populations.

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■ Quest Says Many Americans Are Misusing or Abusing Prescription Drugs, *from page 1*

The results from the drug survey were sobering: 54 percent of patients misused their drugs in one way or another last year. That's up from 53 percent in 2014, although down from 63 percent in Quest's 2011 survey. The 18-24 age group was the likeliest to have an issue of misuse, although 46 percent of those over the age of 65 also had issues. Medicaid enrollees were the likeliest to have compliance issues, but the rates among enrollees in private plans and Medicare were also relatively high.

"The key takeaway from this massive, nationally representative analysis is that despite some gains, a large number of patients use prescription drugs inappropriately and even dangerously."

— Harvey W. Kaufman, M.D.

The report comes as many parts of America are battling an epidemic of abuse involving prescription opioid painkillers. According to the Centers for Disease Control and Prevention, the number of overdose deaths from prescription opioids has quadrupled since 1999, totaling about 165,000 by 2014. About 1,000 people are treated in hospital emergency departments every day for the abuse of prescription painkillers.

Earlier this year, the CDC issued recommendations about when to prescribe opiate painkillers. Physicians are only supposed to issue a prescription if the benefits outweigh the risk to the patient, and if the patient is tested for the presence of drugs before and after a prescription is issued.

Nevertheless, the epidemic of prescription painkiller abuse has been a boon of sorts for the laboratory sector. There have been many startup labs handling drug monitoring in recent years. For national labs such as Quest, drug monitoring has been among its fastest growing lines of business.

"The key takeaway from this massive, nationally representative analysis is that despite some gains, a large number of patients use prescription drugs inappropriately and even dangerously," said co-researcher Harvey W. Kaufman, M.D., a Quest senior medical director. "The CDC's recent recommendations to physicians to carefully weigh the risks and benefits of opioid drug therapy are a step in the right direction, but clearly more needs to be done to address this public health crisis."

According to the Quest study, the biggest issue involving misuse of prescriptions is the presence of additional drugs that were not prescribed: This occurred in 45 percent of those patients who were having compliance issues. That's up from 32 percent in 2011 and 35 percent in 2014.

Benzodiazepines, a class of anti-anxiety medications commonly marketed under the Xanax and Valium brands, were the likeliest drug to be misused, according to the study, followed by opiates and oxycodone, a time-released painkiller.

Among those who tested positive for opiates such as heroin, nearly 29 percent also tested positive for benzodiazepines, which can amplify heroin's depressive effects on the nervous and respiratory systems. More than 90 percent of the time, the benzodiazepines were not prescribed by a physician.

"For some patients, opioids and sedatives are co-prescribed which is of concern. The discovery that a growing percentage of people are combining drugs without their physician's knowledge is deeply troubling given the dangers. Perhaps patients do not understand that mixing even small doses of certain drugs is hazardous, or

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they mistakenly believe prescription medications are somehow safe," said co-researcher F. Leland McClure, a Quest medical affairs director.

Among children up to the age of 17, amphetamines were most likely to be misused. In most cases, the drug was prescribed as a treatment for attention deficit disorder.

The rate of drug use was particularly high for patients who had tested positive for hepatitis C. More than two-thirds of those with a positive diagnosis for the disease had additional drugs in their systems that had not been prescribed. The rates of the presence of fentanyl and heroin were nearly twice as high as the average in the rest of the study.

Takeaway: Quest Diagnostics' study of its drug testing division continues to show significant drug abuse issues among a large population of Americans.

G2 INTELLIGENCE

Presents the 34th Annual **LAB INSTITUTE 2016**

Pre-Conference Workshops Open for Registration

G2 Intelligence is pleased to announce that we are conducting two **pre-conference workshops** prior to **Lab Institute 2016**. If you've already registered for Lab Institute 2016 you'll want to add these programs. And if you haven't, why not **register** for both Lab Institute 2016 and one or both of our workshops?

WORKSHOP A

Recruiting and Managing the Lab Workforce of the Future

Wednesday, Oct. 26th, 9:00 a.m. - 12:00 p.m.

SPEAKERS

Leslie Loveless, Chief Executive Officer, Slone Partners
Tara Kochis-Stach, President, Slone Partners
Miriam L. Rosen, Esq., Member, McDonald Hopkins LLC
Lee Hubert, MBA, SPHR-SCP, Principal Consultant, Voltage Leadership Academy

The laboratory industry faces challenges recruiting the next generation of laboratory professionals and leaders who can respond to a changing healthcare environment and the rapidly evolving diagnostics industry. Learn from experts about hiring and compensation trends in the industry, how to identify the right talent to help your lab succeed, and other tips and guidance for developing and managing the laboratory workforce for the future:

- Consider how hiring and compensation trends in the lab industry should affect recruiting efforts and negotiation with prospective lab executives and staff
- Learn the right questions to ask applicants to hire the right talent to meet the lab's needs
- Recognize current HR challenges facing the lab industry and identify best practices for managing the lab workforce

Your Lab's FUTURE SUCCESS Starts at Lab Institute 2016!

We are looking forward to seeing you at Lab Institute 2016. The healthcare industry landscape is changing – and rewarding quality and value over volume is the new order, but labs are also facing more scrutiny than ever.

Reserve Your Spot TODAY!

WORKSHOP B

Improving Laboratory Test Utilization: Strategies for Success

Wednesday, Oct. 26th, 1:00 p.m. - 4:00 p.m.

SPEAKERS

Geoffrey Baird, M.D., Ph.D., Associate Professor of Laboratory Medicine & Adjunct Associate Professor of Pathology, University of Washington; Laboratory Director, Northwest Hospital; Director of Clinical Chemistry, Harborview Medical Center
Jeffrey P. Pearson, M.D., System Medical Director of Laboratories and Pathology, Bronson Healthcare

Managing laboratory test utilization offers significant economic benefits, but it is also a powerful tool to improve patient care with shorter times to diagnosis, manage test ordering according to evidence-based guidelines, engage physicians and administrators in clinically appropriate testing, and promote the value of laboratory medicine. This intensive workshop considers the clinical and economic impact of suboptimal test ordering, assess various utilization management strategies, and discuss developing quality measures to address overuse:

- Assess utilization management strategies for hospital laboratories and independent laboratories
- Gain insight into approaches used to most effectively identify tests with a high likelihood of misutilization
- Understand how to implement a successful intervention and how to best work with the various stakeholders involved

For full program agenda and to register, visit **www.LabInstitute.com** or call **1-888-729-2315**

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Inside The Lab Industry

Publicly-Traded Esoteric Laboratories Posted Big Revenue Gains for First Half of 2016

As personalized medicine continues to gain traction in the United States, the publicly-traded esoteric laboratories continue to chug along, with most reporting significantly higher revenue for the second quarter and first half of 2016.

> *"Market share gains continue to drive excellent performance in the base NeoGenomics business, and Clarient test volumes have stabilized nicely."*
>
> — Douglas VanOort, CEO, NeoGenomics

Whereas volume growth of 1 to 2 percent a year among the large national labs has become normalized as a result of a shift of many patients to higher-deductible plans, "esoteric testing remains a source of strength across the lab space," William Blair & Co. analyst Amanda Murphy observed in a recent report.

Florida-based NeoGenomics was among the leaders of the pack in terms of growth, driven in part by its acquisition of cancer testing laboratory Clarient in late 2015. The deal helped drive test volume up 158 percent in the quarter compared to the second quarter of 2015.

The company reported consolidated revenue of $63.1 million, up 159 percent from the $24.4 million reported for the second quarter of 2015. The company also edged into the black, with net income of $413,000, compared to a loss of $176,000 for the year-ago quarter.

"Market share gains continue to drive excellent performance in the base NeoGenomics business, and Clarient test volumes have stabilized nicely," said NeoGenomics Chief Executive Officer Douglas VanOort. "Overall, we are pleased that our revenue growth has been so strong even as we are in the midst of significant integration activities."

For the first half of 2016, NeoGenomics reported net income of $568,000 on revenue of $122.8 million, compared to a loss of $937,000 on revenue of $47.4 million.

OPKO Health, another Florida-based laboratory, has also made progress assimilating its acquisition of BioReference Labs that was announced last year. The company reported net income of $15 million on revenue of $357.1 million for the quarter ending June 30. That compares to a loss of $43.3 million on revenue of $42.4 million for the second quarter of 2015. For the first half of the year, OPKO reported net income of $3.6 million on revenue of $648.1 million. It lost $161.3 million on revenue $72.5 million for the first half of 2015, before it had finalized the deal to acquire the much larger BioReference.

OPKO Chief Executive Officer Phillip Frost, M.D., told analysts that the company's 4KScore prostate cancer test had recently received a CPT code from the

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Inside The Lab Industry

American Medical Association that will go into effect in early 2017. However, Frost suggested that the company has had an uphill battle obtaining Medicare coverage for the assay. Medicare administrative contractor Noridian initially provided a positive local coverage determination, but that was overruled by a negative ruling from Palmetto. "We have since submitted a rebuttal to Palmetto's draft determination and are submitting complete data packages to both MACs," Frost said.

"We believe that our recent accomplishments, which also include our participating in both the Expedited Access Pathway with FDA and Parallel Review with FDA and CMS for FoundationOne, position our company for continued growth and further competitive differentiation."

— Michael Pellini, M.D., CEO, Foundation

Although Massachusetts-based Foundation Medicine has yet to report a profit, it also reported a solid quarter of growth. Although it reported a loss of $29 million for the quarter, revenue reached $28.2 million, up 26 percent. The loss also narrowed from the $33.1 million reported for the second quarter of 2015. The company distributes two versions of its FoundationOne cancer test.

For the first half of the year, Foundation reported a loss of $46.7 million on revenue of $58.6 million. That compares to a loss of $50 million on revenue of $41.8 million for the first half of 2015. Test volume increased 16 percent in the second quarter compared to the second quarter of 2015.

Foundation Chief Executive Officer Michael Pellini, M.D., said the company's genomic profiling assay was in parallel review by the U.S. Food and Drug Administration and the Centers for Medicare & Medicaid Services for use in oncology care. The intent is to get the assay approved for Medicare coverage to assist in oncology care.

"We believe that our recent accomplishments, which also include our participating in both the Expedited Access Pathway with FDA and Parallel Review with FDA and CMS for FoundationOne, position our company for continued growth and further competitive differentiation," Pellini said.

The company also announced a $100 million line of credit from Roche Finance (the drug giant Roche owns a stake in Foundation). The credit will be used for product development and for better management of working capital.

California-based Veracyte reported a second quarter increase in revenue of 23 percent, to $14.7 million, compared to $11.9 million for the second quarter of 2015. However, the company reported a widening loss of $11.2 million, up from $9.1 million from the year-ago quarter.

For the first half of 2016, Veracyte lost $21.3 million on revenue of $28.2 million, compared to a loss of $16.7 million on revenue of $23.1 million for the first half of 2015.

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Inside The Lab Industry

In a call with analysts, Veracyte CEO Bonnie Anderson said that the company planned to hire six more sales staff over the second half of 2016. She also indicated that the company had been in talks with officials from CMS regarding its proposed reduction in its reimbursement for the Afirma thyroid test from $3,200 to $2,240. The Medicare program comprises about 20 percent of Afirma's revenue. Anderson said she was "optimistic that the final Medicare reimbursement rate for the Afirma GEC will match the current rate of $3,200," although she did not provide specifics. Anderson said she also believes that CMS is on the brink of approving Medicare coverage for its Percepta lung cancer test.

The company reiterated its revenue guidance of $59 million to $63 million.

Another California-based laboratory, Genomic Health, reported a healthy growth in revenues and narrowed its losses. For the second quarter, it reported a loss of $6.1 million on revenue of $82 million. For the second quarter of 2015, it lost $10.8 million on revenue of $70.6 million.

The company reported increases in test volumes across the board: Oncotype DX breast cancer assays were up 12 percent; invasive breast cancer testing volumes were up 8 percent; and prostate cancer tests were up 13 percent. U.S. test volumes grew by 8 percent. Overseas test volumes grew 23 percent—including a 41 percent growth spurt in Western Europe—and now account for nearly a quarter of Genomic Health's total volume.

Genomic Health Chief Executive Officer Kim Popovits said that the company had recently launched the Oncotype SEQ liquid biopsy test for late stage solid tumor cancers, and entered into an agreement with Epic Sciences to commercialize its blood test for analyzing metastatic prostate cancer.

Popovits also told analysts that the company's market penetration for invasive breast cancer testing can grow from 50 percent to 80 percent.

As a result of the strong numbers, Genomic Health raised its 2016 revenue forecast slightly, from a range of $320 to $335 million to between $325 million and $335 million.

Despite the strong growth, some concerns for the future are present.

"The reported strength in esoteric testing remains juxtaposed with continued investor concern about next-generation sequencing testing's trajectory in the clinic due to increased payer scrutiny and lack of reimbursement structure," William Blair's Murphy noted.

Takeaway: The publicly-traded esoteric laboratories continue to post strong growth numbers, even as some have yet to operate in the black.

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Are Commercial Payers Citing Proposed CMS Gapfill Rates, *from page 1*

Two sources close to the situation have told *Laboratory Industry Report* that some commercial payers are indeed using the proposed rates as leverage to make their own cuts, particularly among Medicare Advantage enrollees. Both asked that their identity be kept anonymous.

> *"As a provider of government-sponsored managed care services, including Medicare Advantage and Medicaid plans, WellCare adheres to the determined CMS Fee Schedule for the appropriate plan year and pays the standard rate for all codes as outlined in our contracts with laboratory providers"*
>
> — WellCare

According to one of the sources, a lab executive, some payers cited a table of proposed rates published in the July 21 issue of *Laboratory Industry Report* that "appeared to be final … and therefore 'justifies' their low pay rate for Medicare Advantage beneficiaries."

Another source, who advises laboratories, confirmed that the labs had been under pressure. The sources indicated that the three plans that have advocated for lower rates are UnitedHealth, Humana and WellCare. All three carriers have sizable Medicare Advantage populations.

Laboratory sector observers say that commercial payers have been ratcheting down payments for tests in recent years, using their large patient populations as leverage. In some instances, cuts for some tests have been significantly below Medicare rates.

UnitedHealth and Humana did not respond to requests seeking comment.WellCare denied it was pressuring labs to accept reduced payments.

"As a provider of government-sponsored managed care services, including Medicare Advantage and Medicaid plans, WellCare adheres to the determined CMS Fee Schedule for the appropriate plan year and pays the standard rate for all codes as outlined in our contracts with laboratory providers," said a statement provided by company spokesperson Crystal Warwell Walker.

Meanwhile, at least one lab executive contended they have not been pressured to reduce their commercial reimbursement in line with the proposed Medicare cuts.

"That is not our experience," said Veracyte Chief Executive Officer Bonnie Anderson. The California-based Veracyte is facing a potential 30 percent cut in reimbursement—nearly $1,000—for its Afirma thyroid cancer test. "We negotiate rates for our tests with commercial payers, which are supported with the value we deliver in patient benefit and surgical cost reductions."

Anderson added that "our contracted rates are not tied to CMS rates and we have not had our commercial contracts challenged during this CMS process. We are confident CMS will finalize rates that are consistent with reimbursement rates in place now for Afirma." Veracyte recently won a local coverage determination from the Noridian MAC for its Percepta lung cancer test.

Other labs contacted for this article did not respond to a request seeking comment.

Takeaway: Commercial payers are potentially using the gapfill rates proposed by CMS as a template for cutting their own reimbursement for testing among their Medicare Advantage population, although it is unclear how widespread the practice currently is.

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INDUSTRY BUZZ

HIMSS Says Precision Medicine Adoption Uneven at Hospitals

Precision medicine is slowly taking hold at the nation's hospitals, but the need to build up information technology to make it an organic part of the delivery of medicine would likely prove burdensome.

That's the conclusion of HIMSS Analytics, which surveyed 137 health care organizations last month to gauge their approach toward the use of precision medicine—typically molecular-based tests for identifying specific disease variations in order to tailor care pathways. Respondents included standalone hospitals, academic medical centers, specialty hospitals and integrated delivery networks.

According to the survey, only 29 percent of those providers surveyed conducted precision medicine onsite. Slightly more than a third of large academic medical centers performed it. "The limited adoption of precision medicine programs across the U.S. hospital market is understandable as very few organizations have the funds, technology or expertise to conduct precision medicine on site," the survey said.

As an alternative, 26 percent of respondents said they performed precision medicine through the use of third party laboratories, while a third used a combination of in-house and third-party services.

The primary focus of the precision medicine efforts has been on cancer, with nearly 80 percent of respondents saying they used it for that purpose. HIMSS Analytics noted that the federal Precision Medicine Initiative and its associated funding is among the reasons that the focus has been on cancer. However, it is also being performed in neurology, cardiology and for prenatal screening, among other areas.

Large numbers of the survey respondents said they were challenged with integrating genomic data with a patient's overall clinical data. Nearly 36 percent said they had yet to complete such an integration.

Moreover, many organizations have uncertain plans regarding the future of their precision medicine initiatives. Nearly 43 percent said they had yet to develop a concrete strategy regarding their patients and the use of precision medicine. Another 21.4 percent were unsure about the strategy they would develop. Only 14.3 percent said they planned to develop a comprehensive marketing campaign to tout their precision medicine initiatives.

Takeaway: Precision medicine remains a considerable way from being a stronghold in American hospitals.

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

Veracyte 650-243-6350

WellCare 800-960-2530

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