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LABORATORY ECONOMICS

Competitive Market Analysis For Laboratory Management Decision Makers

More Inclusive PAMA Reporting Is Top Priority At ACLA Meeting

On March 26, *Laboratory Economics* attended the 2019 American Clinical Lab Association (ACLA) Annual Meeting in Washington, DC, which attracted 223 attendees. ACLA President Julie Khani said that PAMA continues to be ACLA's highest priority and that "we need to make sure hospitals are aware they are required and obligated to report under PAMA."

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What Kind Of Company Is 23andMe?

A study led by researchers at the genetic testing lab company Invitae (San Francisco, CA) found that 23andMe's direct-to-consumer BRCA test for hereditary breast cancer misses almost 90% of BRCA mutation carriers. 23andMe has been criticized for offering the test because it only analyzes three BRCA gene mutations out of a total of 1,000 other known mutations. The study results were presented at the American College of Medical Genetics and Genomics annual meeting in Seattle on April 4.

However, providing clinically relevant information to patients does not seem to be the primary goal of 23andMe. In fact, the company does not even operate a CLIA-certified lab—it subcontracts lab testing services to LabCorp. Rather, *Laboratory Economics* thinks 23andMe is simply a marketing company whose goal is to obtain patient DNA and demographic information which can be sold to pharmaceutical companies to help with drug research.

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DMC Cancels Deal To Sell Outreach Lab To LabCorp

Detroit Medical Center (DMC) has backed out of an agreement to sell its outreach lab business to LabCorp. The transaction was announced in early February (see *LE*, February 2019) and had been expected to close by April 1. DMC says it canceled the deal because it decided that keeping its outreach lab within its overall lab service (DMC University Laboratories) was better for its business. However, a more likely reason is protest from Teamsters Local 283 over union job losses that would have occurred had the sale to LabCorp been finalized, observes *Laboratory Economics*.

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Most Labs Holding Off On Sales Rep Changes In Hope Of EKRA Fix

It's been almost six months since a new opioid law (The Support for Patients and Communities Act) went into effect that bans all CLIA laboratories from paying commissions to sales reps based on the number of patients referred, test volume, or the amount billed to a commercial health plan (see *LE*, December 2018).

More specifically, a section of the new law called the "Eliminating Kickbacks in Recovery Act of 2018" (EKRA), authorizes criminal penalties for the way that most labs incentivize their sales force (including both W2 employees and 1099 contractors).

Despite the threat of substantial fines and/or imprisonment, most labs have not yet changed the way they pay their sales reps in the hope that the law will soon be amended and directed more narrowly to toxicology labs that serve recovery homes and treatment centers.

The implications of EKRA were the focus of a recent webinar sponsored by *Laboratory Economics* titled *Federal Healthcare Laws Take Center Stage: Are Labs Sales & Marketing Practices At Risk Now?* Highlights from the March 27 webinar are summarized below:

Craig Holden

Craig Holden, Shareholder at the law firm Baker Donelson (Baltimore, MD), noted that there is a long and sordid history of improper referral arrangements in the drug and alcohol treatment space. He said that initial drafts of EKRA legislation were focused on banning recovery homes and clinical treatment facilities from engaging in "patient brokering." Patient brokering is when a drug rehab or treatment center pays a third-party marketer for bringing them patients.

However, Holden said that the final EKRA law was written more broadly and applies to recovery homes for addicts, clinical treatment facilities and laboratories.

Furthermore, Holden noted that EKRA applies to all laboratories for all of their business, including basic chemistry testing, genetic testing, anatomic pathology services, et al. "If you're a CLIA laboratory, then you're subject to this statute, even if you don't do any business in the drug and alcohol space."

Holden said that while the existing federal anti-kickback statute (AKS) applies to federal payers (Medicare, Medicaid, Tricare, et al.), the new EKRA law applies to all other payers, including commercial insurance plans and self-paying patients.

Holden noted that the federal AKS allows labs to pay commissions to employed W2 sales reps based on the test volume or revenue they attract. However, EKRA outlaws all volume- and revenue-based commissions to sale reps. "So right now, labs that have a fairly standard sales compensation system for their employed sales reps may be out of compliance with EKRA."

Furthermore, Holden warned, "EKRA is a criminal statute and this is serious stuff, including fines of up to $200,000 and/or 10 years in jail per occurrence."

"Ultimately when things are clarified, I suspect that the same safe harbors for the anti-kickback

statute are going to end up applying to EKRA." But Holden said the EKRA law is not something that the Department of Health & Human Services (HHS) or anyone else can change by regulation. "It's going to require a statutory amendment."

The American Clinical Laboratory Association (ACLA) is lobbying Congress for changes to EKRA. But it is uncertain if and when an amendment might get passed. In the meantime, labs are caught in a quandary of what to do with their sales rep compensation plans?

"You probably don't have to worry about whistleblower lawsuits, as any enforcement of the existing EKRA statute is going to come from the federal government. And because of that, I think it's unlikely that we are going to have any federal enforcement of this statute until we get more clarity, including the issuance of implementing regulations and potential legislative amendments," answered Holden. "I would venture to say that relief is likely with respect to the ability to pay commissions to employed sales reps who are W2 employees."

On the other hand, Holden believes that labs that contract with independent sales reps on a 1099 basis are treading on more shaky ground. "Frankly, I believe the safest way to proceed would be to come up with an alternative arrangement, such as a fixed salary arrangement, over the short term with the ability to switch back to commissions, if the law is amended."

Separately, Jane Pine Wood, Chief Legal Counsel at BioReference Laboratories (Elmwood Park, NJ), said that too often a healthcare company will engage in questionable sales practices and set aside a reserve for paying the fines or penalties if they are caught. "Some healthcare companies weigh the risk of getting caught and view paying fines as a cost of doing business," according to Pine Wood. But within the past few years, she said that the government has recognized that in order to change behavior it must target the individuals behind the wrong-doing.

Jane Pine Wood

For example, Pine Wood cited Biodiagnostic Laboratory Services (BLS-Parsippany, NJ), which was charged with paying kickbacks (e.g., phony leases for space in doctors' offices and fake consulting agreements), to physicians in exchange for patient referrals. In the BLS case, the government brought criminal convictions against not only the company, but also its owners, sales reps and 38 physician clients that received kickbacks. "Nothing that anyone is offering in terms of kickbacks is going to be worth what these doctors went through [fines, loss of medical licenses, jail sentences, et al.]." One New Jersey doctor, for example, was sentenced to 63 months in prison and forfeited $1.8 million as part of his plea agreement.

Dana Simonds

Finally, Dana Simonds, Chief Compliance and Ethics Officer at Inform Diagnostics (Irving, TX), outlined the ways that new ownership upgraded InformDx's compliance program after its predecessor company, Miraca Life Sciences, and previous owners paid $63.5 million to settle false claims charges (see *LE*, February 2019). Simonds, who was formerly Chief Compliance Officer at Sonic Healthcare USA, joined InformDx in early 2018. Key changes include fostering an environment where employees can seek guidance and report unethical behavior without fear of retaliation. In addition, Simonds reports directly to the company's board of directors and manages an expanded compliance staff of nine employees.

Spotlight Interview with Northwell Health's James Crawford

Northwell Health Laboratories (New York) recently opened two new laboratories with NYC Health + Hospitals, as part of their Clinical Laboratory of New York (CLNY) Alliance. The first lab is in Little Neck, Queens, NY – a $47.4 million, 36,000-square-foot facility for Infectious Diseases Diagnostics. The second is a $59.6 million, 101,000 square-foot core lab within the Northwell Center for Advanced Medicine (CFAM) in Lake Success, NY. These replace Northwell's current core lab in Lake Success, and together create the largest nonprofit, hospital-operated laboratory in the nation. *Laboratory Economics* recently spoke with James Crawford, MD, PhD, Senior Vice President of Laboratory Services and Chair of Pathology and Laboratory Medicine at Northwell Health, about the expansion.

James Crawford, MD

Why did you decide to expand?

We have had a 20-plus-year period of growth, and have served both the Northwell Health system, and since April 2014, an alliance with New York City Health + Hospitals. We also have been successful in building our outreach program in the New York region. We had the volumes and the operational justifications to expand from the space where we've been since March 1998.

We couldn't put the whole lab in one site, so we decided to split the lab in two and put clinical microbiology at the Little Neck site and everything else at a new core lab site in Lake Success. Our clinical trials partner, BARC, will continue to use the existing lab space.

Are volumes and revenues growing?

Northwell is a private nonprofit, and New York City Health + Hospitals is a publicly-owned charitable organization, so we don't look at it as growing revenues. We look at operational savings achieved across both organizations. Through 2018, the CLNY Alliance has saved NYC Health + Hospitals over $12 million and Northwell over $5 million; when fully operationalized, the alliance should save Health + Hospitals over $20 million annually and Northwell over $15 million annually. Northwell Health also has a separate business unit that consists of in-system reference laboratory work, clinical trials work and outreach. Annualized over the past 10 years, Northwell Health Laboratories has grown outreach volumes at 4.5% per year and net revenues by 16% per year. For 2018, our system-wide volumes were 30.8 million tests, with 13.6 million of those through core lab.

What do you project going forward?

We are anticipating significant growth. We are pursuing affiliations beyond our initial market. We began discussions with Kaleida Health System in 2016 and formalized our relationship with them in 2017. Northwell is now the reference lab for Kaleida, but more importantly, we are partners with them. We are also in conversations with other health systems regarding affiliations. These are not takeovers, they are partnerships.

Do you anticipate hiring additional employees?

So far, we've moved laterally, holding to our usual rate of annual growth for our workforce. But we have gone from having 50,000 square feet to roughly twice that. If you add in automated technologies, we are more than quadrupling our capacity. We have built capacity for the future and hope to be an employer-of-choice for laboratory professionals.

What are your thoughts on the cuts to Medicare CLFS under PAMA?

At the very least, PAMA is a stark reminder that laboratory services are viewed as a commodity, and that we have to distinguish ourselves on the basis of access and service. I have been very vocal at the

national level about the need for laboratory professionals to provide leadership in establishing the value-added statements for laboratory services, and build the evidence base to support those statements. Our Project Santa Fe group, of which I am a founding member, has termed this "Clinical Laboratory 2.0." It is our hope that Clinical Lab 2.0 will both enhance the contribution that clinical laboratories can make to the effective delivery of healthcare and enable revenue diversification to support these activities. Specific to Northwell, PAMA has had an impact, but much less than that seen by independent laboratories whose primary client base is the ambulatory market.

What is your long-term outlook for the hospital laboratory outreach business?
If the clinical laboratory is viewed – and acts – only as a commodity, then that commodity is moveable, and hospital-based laboratory outreach is at high risk. But hospital-based (or rather, "health-system-based") clinical laboratories are the first to "see" the whole gamut of inpatient-to-outpatient/ambulatory laboratory data. If that information is leveraged to deliver better, more cost-effective health care for their health systems, then health system-based laboratories are empowered to have robust outreach programs. Since I believe that healthcare is ultimately delivered in local settings – close to the patient, I believe that Clinical Lab 2.0 is a mechanism that can empower health system-based laboratories to achieve sustainable value in the eyes of their health system stakeholders.

DMC Cancels Deal To Sell Outreach Lab To LabCorp (*cont'd from page 1*)

LabCorp had been expected to transition most of the acquired DMC outreach test volume now performed at a core lab based at DMC University Health Center to a nearby regional LabCorp facility—most likely in Dublin, Ohio (190 miles south of Detroit). The sale of the outreach lab and relocation of test volume threatened approximately 90 unionized outreach lab and courier employees.

"We came to the conclusion that it was in DMC's best interests for our outreach lab business to remain with DMC University Laboratories. This was a business decision made in consideration of what's best for DMC and not driven by the actions of the union. We will continue to provide our physicians and patients with quality care to meet their needs for these services," according to a statement from DMC.

However, Teamsters Local 283 President Steve Hicks tells *Laboratory Economics* that the sale to LabCorp was terminated because his union filed a complaint with the National Labor Relations Board (NLRB). Hicks believes that DMC was seeking to replace the 90 union outreach lab employees with lower-paid non-union LabCorp workers. "It was nothing but subcontracting to replace our employees. Our union workers put their applications in with LabCorp and weren't being considered," according to Hicks. He says that the Teamsters would have been on board with the sale to LabCorp if the union jobs were kept intact. The Teamsters have withdrawn their NLRB charges now that the deal is off, notes Hicks.

LabCorp would not comment on the canceled deal.

Separately, *Laboratory Economics* notes that this is not the first time a union has protested a hospital outreach lab sale to protect union jobs. For example, in June 2017, Quest Diagnostics announced an agreement to acquire the outreach lab business of Cape Cod Healthcare (Hyannis, MA). The agreement called for outreach testing to be transitioned to Quest's regional lab in Marlborough, Massachusetts (located approximately 100 miles north). 199SEIU United Healthcare Workers East protested the deal to the Massachusetts Health Policy Commission, which must approve healthcare transactions. The union, which argued the sale would result in about 50 lost jobs and increase turnaround time for test results, caused the deal to be delayed by almost one year. However, Quest did complete the cash purchase for $35 million in June 2018.

Publicly-Traded Labs Grew By 2.8% In 2018

On a combined basis, 17 publicly-traded labs grew their revenue by 2.8% to $18.9 billion in 2018 (after adjusting for acquisitions), according to financial reports collected by *Laboratory Economics*.

Revenue growth at the big routine clinical lab companies (Quest, LabCorp, Sonic, BioReference and Enzo) grew by a weighted average of 0.2% last year (after adjusting for acquisitions) to a combined total of $16.3 billion.

Revenue growth was much faster at 12 molecular/genetic-testing lab companies, which grew by a weighted average of 22.3% in 2018 (after adjusting for acquisitions) to a combined total of $2.6 billion.

The fastest revenue growth occurred at CareDx (up 82.1%), which specializes in gene expression tests for heart transplant patients; Guardant Health (up 81.9%), which markets liquid biopsy test panels; and Exact Sciences (up 70.9%), which sells a stool-based DNA test for colorectal cancer screening.

Revenue Growth at 17 Publicly-Traded Lab Companies ($000)

Company	Revenue 2018	Revenue 2017	Reported Change	Pro Forma Change*
Quest Diagnostics	$7,531,000	$7,402,000	1.7%	-1.3%
LabCorp Diagnostics[1]	7,030,700	6,858,200	2.5%	1.2%
Sonic Healthcare USA[2]	877,370	834,000	5.2%	2.0%
Opko/BioReference Labs	813,248	782,710	3.9%	3.9%
Myriad Genetics[3]	772,600	769,900	0.4%	0.4%
Exact Sciences	454,462	265,989	70.9%	70.9%
Genomic Health	394,111	340,750	15.7%	15.7%
NeoGenomics	276,741	240,251	15.2%	15.2%
Natera Inc.	257,654	209,625	22.9%	22.9%
Invitae Corp.	147,699	68,221	116.5%	60.0%
Veracyte	92,008	71,953	27.9%	27.9%
Guardant Health	90,639	49,842	81.9%	81.9%
Enzo Clinical Labs[4]	74,777	77,407	-3.4%	-3.4%
CareDx[5]	60,300	33,106	82.1%	82.1%
Psychemedics	42,674	39,701	7.5%	7.5%
Interpace Diagnostics	21,896	15,897	37.7%	37.7%
Biocept	5,069	3,250	55.9%	55.9%
Total, 17 companies	18,942,948	18,062,802	4.9%	2.8%
5 Routine Labs (Quest, LabCorp, Sonic, BioReference and Enzo)	16,327,095	15,954,317	2.3%	0.2%
12 Molecular/Genetic Labs	$2,615,853	$2,108,485	24.1%	22.3%

*Pro forma change is estimated by *Laboratory Economics* after adjustments for acquisitions.

[1]LabCorp's revenue is for its lab testing business only (excluding clinical trials); [2]Sonic Healthcare USA's revenue is for fiscal year ended June 30, 2018 (using constant exchange rate of 1 AUD = 0.7544 USD); [3]Myriad Genetics' revenue is for fiscal year ended June 30, 2018; [4]Enzo's revenue is for lab services only for fiscal year ended July 30, 2018; [5]CareDx's revenue is for its lab testing business only.

Source: *Laboratory Economics* from company reports

What Kind Of Company Is 23andMe? (*cont'd from page 1*)
23andMe markets two testing services directly to consumers. Its ancestry testing service costs $99 and analyzes saliva samples obtained from at-home collection tubes. The samples are shipped to a LabCorp facility in North Carolina for genotyping. 23andMe takes the data provided by LabCorp to prepare ancestry reports that are made available to customers through online accounts in about 3-5 weeks. The report provides an estimate of your ancestry composition (e.g., 47.4% European, 41.8% East Asian & Native American, 5.2% Sub-Saharan African, et al.).

The company's second product includes an ancestry report plus tests that assess your genetic risk for a variety of diseases (Parkinson's, Alzheimer's, Celiac Disease, breast cancer, et al.) and your carrier status for numerous inheritable diseases (Cystic Fibrosis, Bloom Syndrome, Canavan Disease, et al.). The report also gives generic lifestyle advice such as "avoid eating fast food," and "sleep a healthy amount." The cost for this combined service is $199.

FDA Clearance?
The FDA has granted 23andMe four separate clearances related to sending its genetic testing reports directly to consumers. The clearances did not involve instrument systems or reagents, just the issuance of result reports. FDA clearance was given after 23andMe showed that more than 97% of users understood that they should not use the company's reports to make any changes to their treatment without first consulting their doctor.

Loss-Leader Testing
23andMe is clearly using its ancestry and genetic testing services as loss leaders. Its advertised list prices of $99 and $199 are often discounted by as much as 30% with free shipping. The company has also offered free testing to certain ethnic groups that are underrepresented in its DNA database, which now includes samples from more than five million people around the world. In fact, *Laboratory Economics* thinks that 23andMe is likely to be paying LabCorp close to, if not more than, $199 per specimen tested. LabCorp has stated that it makes above-average margins on testing services provided to 23andMe.

DNA Database For Sale
23andMe says that roughly 80% of the five million people who have purchased its service have given their consent to having their anonymized DNA and demographic data shared with third parties. And this is where 23andMe makes its money. The company has had research partnerships with numerous pharmaceutical companies including Alynlam, Biogen, Pfizer, Roche's Genentech, Johnson & Johnson's Janssen, Denmark-based Lundbeck and Germany-based Grünenthal Group.

And last year it announced its biggest deal to date, a four-year agreement to develop new drugs with GlaxoSmithKline (GSK). The companies agreed to split costs and profits equally, and Glaxo made a $300 million investment in 23andMe.

In addition, GSK contributed its LRRK2 inhibitor, a promising therapeutic target for some forms of Parkinson's disease, into the partnership. GSK thinks 23andMe's database of people who know their LRRK2 variant status will help the Parkinson's program enroll patients on the way to clinical proof of concept.

Who owns 23andMe?
The company was co-founded by its CEO Anne Wojcicki, ex-wife of Google co-founder Sergey Brin, in 2006. Google was an early investor in 23andMe. In addition, 23andMe has raised more than $750 million from a combination of private equity investors (e.g., New Enterprise Associates, Mohr Davidow Ventures, Sequoia Capital) and pharmaceutical companies (e.g., Genentech, GlaxoSmithKline and Johnson & Johnson).

FDA Tells Inova To Stop Marketing Unproven Pharmacogenomic Tests

On April 4, the FDA issued a warning letter to Inova Genomics Laboratory (Falls Church, VA) for illegally marketing genetic tests that claim to predict patients' responses to specific medications (also known as pharmacogenomic tests). Inova Genomics is a CAP-accredited laboratory focused on precision medicine and is part of the Inova Health System, which includes five hospitals with more than 1,700 licensed beds in northern Virginia.

The FDA said claims on the Inova Genomics Laboratory webpage violated regulations by asserting that its MediMap tests can predict patients' responses to specific drugs. The FDA letter noted that Inova Genomics' website markets its MediMap tests as "genetic tests for predicting medication response, reducing negative side effects from certain medications, discovering the right drug and right dose for a patient, and avoiding trial-and-error prescribing by healthcare providers by testing patient receptivity to drugs that treat specific conditions."

"Specifically, we are unaware of data establishing the relationships between the genotypes assessed by your tests and your assertions regarding drug response for multiple drugs," the letter stated. "For example, the relationship between CYP2C19 genotype and drug response to escitalopram [Lexapro] and sertraline [Zoloft] in not established and this relationship is not described in the FDA-approved labeling for these drugs."

The FDA also expressed concern that Inova's MediMap tests may be ordered by a lab physician with test results provided directly to patients. "This could lead to patients inappropriately increasing, decreasing, or stopping their medication without a physician's involvement," said FDA.

The FDA initially warned Inova during a March 13 teleconference and asked that the firm change its promotional material and stop providing results directly to patients. Inova initially refused and argued that its MediMap tests are laboratory-developed tests (LDTs) that are not subject to FDA's premarket review or labeling requirements.

But FDA said that there is no regulatory "carve-out" or exemption for LDTs. "Although FDA has generally exercised enforcement discretion for LDTs, the agency always retains discretion to take action when appropriate, such as when it is appropriate to address significant public health concerns."

Within days of receiving the April 4 warning letter from FDA, Inova backed down and has since removed all promotional materials for its MediMap tests from its website.

Late last year, the FDA issued a public warning that the claims for many pharacogenomic tests' ability to predict a patient's response to specific medications lacked clinical evidence and had not been reviewed by the FDA. The FDA then contacted and warned several firms to remove specific medications from their promotional material and patient test reports. Most labs honored the FDA's request, while Inova took extra prodding.

More Inclusive PAMA Reporting Is Top Priority At ACLA *(cont'd from p. 1)*

Khani said that at a recent meeting with 40 hospital executives, she asked if they understood that they now have a mandatory obligation to report their private-payer lab outreach data to CMS, and none raised their hand to indicate they were aware of this requirement.

During the first PAMA reporting cycle, less than 20% (<2,000 labs) of all "applicable" labs (>12,500 labs) that were required to report, actually did so. "What else can be done to get the word out?" Khani asked a CMS official during a panel discussion at the ACLA meeting.

Carol Blackford

Carol Blackford, Director of the Hospital and Ambulatory Policy Group at CMS, which has the responsibility of implementing PAMA, said that the agency's goal was getting as close to 100% compliance as possible without creating an "undue burden" on reporting labs. She noted that CMS has emphasized the new reporting responsibility of hospital outreach labs through a teleconference on January 22, followed by a Medicare Learning Network (MLN) bulletin, and posting of a new Frequently Asked Questions section for PAMA on the CMS website. In addition, CMS has instructed all MACs (April 12: transmittal 2279) to notify all clinical labs and hospitals in their jurisdiction that they may be required to collect (Jan. 1, 2019 to June 30, 2019) and report (Jan. 1, 2020 to March 31, 2020) their private-payer lab payment data under PAMA regulations.

However, Blackford made no mention of whether or not CMS plans to enforce PAMA regulations that authorize it to impose civil monetary penalties of up to $10,000 per day on labs that are required to report their private-payer data, but fail to do so.

Laboratory Economics notes that non-reporting labs got a free pass during the first PAMA reporting cycle. The agency may not be as lenient in the current reporting cycle. The OIG is prodding CMS to threaten penalties to increase reporting compliance (see *LE*, August 2018). In addition, CMS Administrator Seema Verma has mentioned targeted outreach and auditing of labs that may meet the definition of an applicable laboratory.

A Fix To Stop Unbundled Panel Testing

Tamara Syrek Jensen

On a separate topic at the ACLA meeting, Tamara Syrek Jensen, the Director of the Coverage and Analysis Group at CMS, said that the agency will soon fix a glitch that has temporarily allowed labs (since January 1, 2017) to unbundle automated test panels (lipid panels, metabolic panels, electrolyte panels, et al.) and bill for individual CPT codes to get higher reimbursement. "We're working with Medicare Administrative Contractors (MACs) to come up with some automated ways to detect claims that have been inappropriately bundled, which we hope to implement this spring."

Potential FDA Regulation of LDTs

In a panel discussion, Lauren Silvis, Chief of Staff to FDA Commissioner Scott Gottlieb, MD, reiterated that the FDA continues to view regulation of laboratory-developed tests (LDTs) as a high priority. The agency has slowly been working toward establishing a defined role in the regulation of LDTs for at least the past 10 years. Silvis noted that potential FDA regulation would likely grandfather in many LDTs that are already on the market, while requiring premarket review for the highest-risk tests. These would include tests marketed directly to consumers, used at home, and pharmacogenomics tests used in conjunction with prescribing a drug (see related story on page 8).

The ACLA meeting also featured a presentation on local coverage determinations (see separate article on page 10).

MolDx Medical Directors: LCDs More Transparent Under New Process

Changes to Medicare's local coverage determination (LCD) process is helping to improve transparency among all Medicare contractors, including Palmetto GBA, which administers the Molecular Diagnostics (MolDx) program.

Speaking at the annual meeting of the American Clinical Laboratory Association (ACLA) on March 26, the new medical directors of the MolDx program, Paul Gerrard, MD, and Gabriel Bien-Willner, MD, PhD noted that they are working to make the MolDx program more user-friendly. Both Gerrard and Bien-Willner began their positions in 2018. Gerrard is a board-certified physiatrist, and Bien-Willner is a molecular pathologist.

"We want to be a more transparent organization that is easier to access by providers," explained Bien-Willner. "We don't want this to be a guessing game."

"We want to be sure that as the LCD process changes, that the MolDx program changes along with it, and so we'll be updating some of the MolDx LCDs to match the spirit and the environment of the new LCD process," added Gerrard.

Under Transmittal 863 (Change Request 10901), issued Feb. 12, 2019, the LCD process has been modified to be in compliance with the 21st Century Cures Act. This requires that each MAC that develops an LCD to make the following available online at least 45 days before the effective date: the proposed determination, when it was first made public, hyperlinks to the proposed determination and a response to comments, a summary of evidence that was considered by the contractor during the development of such determination, and a list of the sources of such evidence and an explanation of the rationale supporting the determination.

One result of these changes to the LCD process is that codes of covered tests will no longer be included in the determination but will be listed in a separate article, explained Bien-Willner. In addition, there is a new formal process for providers to ask for an LCD, as well as a formal process for LCD reconsiderations.

Prior to submitting a formal LCD reconsideration, Palmetto GBA encourages requestors to schedule an information conference call to review the requirements for a valid request. Requests will be considered from beneficiaries residing or receiving care in the contractor's jurisdiction, as well as providers and other interested parties doing business in the jurisdiction. Reconsideration requests are only accepted for LCDs published in final form. If modification of the final LCD would conflict with an NCD, the request will not be valid.

Gerrard also noted that information requirements differ based on the type of test. "If it's a new test, we'll focus more on clinical validity and utility, but if it's an established test, we'll focus more on analytical validity," he said.

Information used to determine an LCD has to be publicly available, added Gerrard. "If you have proprietary data, you need to get it out in the public so we can consider it," he said.

Responding to a question about coordination of LCDs under MolDx, Bien-Willner explained that the Palmetto coordinates with the other MACs on MolDx policy-making. "Some people believe that MolDx writes policies and the other MACs are just along for the ride," he said. "It doesn't work that way. We meet regularly and we must all agree on policies before they are rolled out." In addition, Gerrard said that Palmetto welcomes input from the lab community when developing an LCD, particularly when there are gaps in knowledge.

LabCorp Buys MNG Laboratories

LabCorp acquired MNG Laboratories (Atlanta, GA) on March 1. MNG has approximately 40 employees and operates a CAP-accredited laboratory in Atlanta that specializes in next-generation sequencing (NGS) and testing for neurological disorders such as epilepsy and muscular dystrophy, and mitochondrial disorders such as cellular energetics defects. MNG had been majority-owned by the private equity firm HealthEdge Investment Partners (Tampa, FL), which had acquired its stake from former owner and co-founder John Shoffner, MD, a clinical geneticist, in 2015.

OIG Cracks Down On Specimen Validity Testing

The Office of Inspector General (OIG) for the U.S. Department of Health and Human Services is cracking down on toxicology labs and POLs that improperly billed Medicare for specimen validity tests in combination with urine drug tests. The OIG recently reached settlement agreements with one toxicology lab and three physician groups in MAC Jurisdiction 15 (Kentucky and Ohio) for a total of $434,000, to resolve allegations that they submitted claims to Medicare for non-covered specimen validity testing.

- On March 13, 2019, VerraLab (dba Biotap Medical-Louisville, KY) entered into a $125,983 settlement agreement.
- On March 13, 2019, Medical Specialist of Kentuckiana (Louisville, KY) entered into a $69,776 settlement agreement.
- On February 6, 2019, Mohammad Mouhib Kalo, MD, and Wheelersburg Internal Medicine Group (Wheelersburg, OH) entered into a $111,706 settlement agreement.
- On January 24, 2019, Northern Kentucky Center for Pain Relief (Florence, KY) entered into a $126,800 settlement agreement.

Similar OIG's investigations and settlements are almost certain to be reached with other toxicology labs and POLs in other states in the coming months, notes *Laboratory Economics*.

Specimen validity testing is used to analyze urine specimens to determine whether they have been tampered with or adulterated. Common specimen validity tests include urinary pH (CPT 83986) and creatinine (CPT 82570). For example, urine samples typically have a pH of approximately 7--an extremely high or low pH can be an indication of tampering or adulteration.

Since 2010, CMS and Medicare contractors have repeatedly warned that labs that bill Medicare for presumptive drug testing (e.g., CPT 80305-80307) or definitive drug testing (e.g., CPT G0480-G0483) should only be billing for one code per date of service. It's okay to perform specimen validity testing on toxicology samples, but you cannot separately bill for it, according to CMS.

In February 2018, the OIG issued a report that found that Medicare improperly paid 4,480 labs and physician offices a total of $66 million for specimen validity tests billed in combination with urine drug tests between 2014 and 2016. The OIG report recommended that CMS: 1) direct Medicare contractors to recover the $66 million in identified improper payments and 2) strengthen its system edits to prevent improper payment for specimen validity tests.

Finally, *Laboratory Economics* notes that its latest analysis of Medicare Part B payments to toxicology labs (see *LE*, June 2018) found that some tox labs had billed an average of more than 10 CPT codes per patient and received payments averaging $1,000 or more per patient in 2016.

Lab Stocks Up 34% Year To Date

Eighteen lab stocks have risen by an unweighted average of 34% year to date through April 11. In comparison, the S&P 500 Index is up 16% so far this year. The top-performing lab stock thus far in 2019 is Invitae, which has jumped 136%, followed by Veracyte, up 101%, and Guardant Health, up 92%. Shares of LabCorp are up 25%, while Quest Diagnostics is up 8%.

Company (ticker)	Stock Price 4/11/19	Stock Price 12/31/18	2019 Price Change	Enterprise Value ($ millions)	Annual Revenue ($ millions)	Enterp Value/Annual Revenue
LabCorp (LH)	$157.87	$126.36	25%	$21,200	$11,333.4	1.9
Quest Diagnostics (DGX)	89.72	83.27	8%	16,150	7,531.0	2.1
Sonic Healthcare (SHL.AX)	24.57	22.11	11%	13,490	5,770.0	2.3
Exact Sciences (EXAS)	93.72	63.10	49%	11,350	454.5	25.0
Guardant Health (GH)	72.09	37.59	92%	5,820	90.6	64.2
Myriad Genetics (MYGN)	33.56	29.07	15%	2,500	825.0	3.0
Genomic Health (GHDX)	66.60	64.41	3%	2,250	394.1	5.7
NeoGenomics (NEO)	21.83	12.61	73%	2,120	276.7	7.7
Invitae (NVTA)	26.12	11.06	136%	1,880	147.7	12.7
Opko Health (OPK)	2.44	3.01	-19%	1,650	990.3	1.7
Natera (NTRA)	20.39	13.96	46%	1,280	257.7	5.0
CareDx (CDNA)	30.84	25.14	23%	1,170	76.6	15.3
Veracyte (VCYT)	25.24	12.58	101%	995	92.0	10.8
Enzo Biochem (ENZ)	3.46	2.78	24%	118	90.7	1.3
Psychemedics (PMD)	14.35	15.87	-10%	74	42.7	1.7
Interpace Diagnostics (IDXG)	0.74	0.80	-7%	22	21.9	1.0
Cancer Genetics Inc. (CGIX)	0.27	0.24	13%	20	28.2	0.7
Biocept (BIOC)	1.05	0.86	22%	18	3.3	5.6
Unweighted Averages			34%	$82,107	$28,426	2.9

Source: *Laboratory Economics* and Capital IQ

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