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From the Desk of R. Lewis Dark...

THE DARK REPORT

RELIABLE BUSINESS INTELLIGENCE, EXCLUSIVELY FOR MEDICAL LAB CEOs / COOs / CFOs / PATHOLOGISTs

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COMMENTARY & OPINION by...

R. Lewis Dark

Founder & Publisher

Helping You Plan Your Lab's Financial Future

WE ARE NOW IN THE NEW YEAR and the 2018 Medicare Clinical Laboratory Fee Schedule (CLFS) is a reality. The dramatic price cuts that the federal **Centers for Medicare and Medicaid Services** has enacted is the single most disruptive financial event the clinical laboratory industry has faced in the past two decades.

As we have reported, these Medicare Part B price cuts will wreak financial havoc among community lab companies and hospital lab outreach programs. But even the two billion-dollar lab companies will feel a major sting from these fee cuts. Some analysts have pointed out that the two national lab companies will no longer be able to use their ample profits from Medicare fee-for-service payments to offset the costs of providing private health insurers with deeply-discounted managed care contract prices.

Now that the 2018 CLFS price cuts are a fact of life, it is imperative that every pathologist, hospital lab administrator, and lab executive understands the specific financial impact that reduced revenue from Medicare fee-for-service payments will have on their respective clinical lab organizations. To assist in that effort, this issue of THE DARK REPORT provides important details about current developments, including the lawsuit by the **American Clinical Laboratory Association** filed Dec. 11 against the federal **Department of Health and Human Services**.

Once again, we are first to bring you not just the news, but useful business intelligence about this lawsuit, what it hopes to accomplish, and the facts the plaintiff intends to present in support of its claims. You will also read the comments from three experienced lab industry attorneys. They were asked to comment on the strengths and weaknesses of ACLA's case and to explain the primary legal strategies that ACLA is using to make its case.

Also of significance are the four declarations by experienced clinical laboratory leaders that were included in ACLA's court papers. You'll learn what the executive director of **Joint Venture Hospital Laboratories** said about the consequences of the 2018 CLFS price cuts on hospital labs. You'll also learn what the CEO of **Aculab**, a lab company that serves 320 nursing homes, has to say about the negative financial impact this CLFS will have, not just on his lab, but all labs that serve nursing homes throughout the United States. TDR

ACLA Suit Challenges HHS' Data-Collection Efforts

Laboratories may face uphill fight because the law specifically bars legal challenge to rates

CEO SUMMARY: In a lawsuit filed last month, the American Clinical Laboratory Association charged that HHS failed to comply with the statutory requirements of the Protecting Access to Medicare Act of 2014 when setting the 2018 Clinical Laboratory Fee Schedule. In the lawsuit, ACLA said HHS disregarded the law's requirement that all applicable laboratories would report relevant data. How HHS and CMS defined "all applicable labs" is the critical issue in this lawsuit, say lawyers familiar with the case.

CLINICAL LABORATORIES enter the new year seeking an answer to a critical question: Will a lawsuit succeed against the federal **Department of Health and Human Services**?

On Dec. 11, the **American Clinical Laboratory Association** sued HHS, charging that the agency failed to comply with the requirements of the Protecting Access to Medicare Act of 2014 (PAMA) which it was to follow to set the 2018 Clinical Laboratory Fee Schedule (CLFS).

In a 32-page filing in the U.S. District Court for the District of Columbia, ACLA charged that HHS disregarded the requirement in PAMA that all applicable laboratories report relevant market-rate data. How HHS and the federal **Centers for Medicare and Medicaid Services** defined "all applicable laboratories" is the critical issue in this lawsuit, said lawyers familiar with the filing. The defendant in the case is Acting HHS Secretary Eric D. Hargan.

Language in the PAMA statute instructed CMS to analyze what commercial health insurers paid clinical labs and to use that private-payer data to set market-based rates for 2018.

When setting the 2018 CLFS prices that went into effect Jan. 1, ACLA charged that HHS instituted a highly flawed data reporting process. More than 99.3% of clinical laboratories in the United States were prohibited from reporting market-rate data on the prices health insurers paid for lab tests, the lawsuit said.

In 2015, the lawsuit alleged, Medicare paid more than 261,500 entities for laboratory services, but only 1,942 laboratories reported market-rate information in 2016 under the PAMA final rule. Those 1,942

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labs that reported market-rate data are about 0.7% of the total number of laboratories serving Medicare beneficiaries.

In addition, the lawsuit alleged, the labs that reported market-rate data did not represent the lab market as a whole. In 2015, 7,000 hospital laboratories billed Medicare for lab testing, accounting for 24% of Medicare payments made under the CLFS, the lawsuit charged. Yet, no more than 21 hospital laboratories (and probably fewer) reported market-rate payments to HHS, leaving hospital labs grossly under-represented, it said.

Hospital Labs Are Different

For many patients, hospital labs are the only ones available in certain areas of the country, the lawsuit said. And, the commercial insurance rates these labs are paid often are much higher than what other labs get, due to differences in competitive markets, service volume, and other factors, it charged.

Given the fact that fewer than 1% of all labs, and only 21 hospital labs, participated in the data-collection effort, the legal arguments are clear: the ACLA's lawyer for the case, Mark D. Polston, will charge that the data-collection effort was flawed.

This argument is important because PAMA prohibits legal challenges to the rates that result from the law. In legal terms, this prohibition is called a review preclusion. Therefore, challenging the data-collection methods may be the strongest legal attack ACLA can bring against the law, said David W. Gee and Jordan B. Keville, partners with the law firm **Davis Wright Tremaine**.

For nearly 30 years, Gee has represented clinical and molecular diagnostic laboratories, pathology groups, hospital lab outreach management companies, hospitals, physicians, and other providers on legal issues, including Medicare and Medicaid compliance. Keville focuses on reimbursement and regulatory issues for healthcare providers and formerly was a partner with **Hooper, Lundy & Bookman**, in Los Angeles, a law practice serving providers in legal challenges involving Medicare and Medicaid payment.

In an interview with THE DARK REPORT, Keville said, "I agree with the way that ACLA framed the complaint. The lawsuit recognizes that there are two parts to PAMA, one of which addresses the information-gathering mandate from all labs for rate-setting. And the second part is the rate-setting based on the data gathered.

"In the law, the review preclusion applies only to the rate-setting," commented Keville. "ACLA is not challenging the rates. Instead, ACLA is challenging the data CMS gathered and the way it went about collecting that data. That's a valid argument.

"In response, CMS is likely to say that this argument is a *de facto* attack on the rates and, therefore, the review preclusion in the statute should apply," emphasized Keville.

"But the data-gathering and the rate-setting are separate provisions in PAMA, and the statute says specifically that—as far as the data collection CMS did—the agency had to go through a notice-and-comment process under the Administrative Procedure Act," he added.

Actions Subject to Review

"That's important because notice-and-comment is subject to judicial review. By requiring CMS to go through the comment and rule-making processes, the law separates these processes from the rate-setting part of the law," noted Keville. "That helps the ACLA side.

"There's always a chance that a judge could find the review preclusion bars the whole suit, but I believe the case will at least get over that hurdle," said Keville.

"Under the Administrative Procedure Act, it is typical that when regulations are produced, those actions are subject to review," he added. "That means there is a valid argument to make—as the lawsuit charges—that CMS didn't do the data-col-

ACLA Outlines Importance of PAMA Lawsuit for Clinical Labs Facing Medicare Fee Cuts

WHEN THE AMERICAN CLINICAL LABORATORY ASSOCIATION filed a lawsuit Dec. 11 against the Department of Health and Human Services, ACLA President Julie Khani explained why the case is important to clinical labs.

"We have repeatedly advised CMS that there are significant, substantive deficiencies in the final rule, which fails to follow the specific commands of the PAMA statute," she said in a prepared statement. PAMA is the Protecting Access to Medicare Act of 2014.

'Will Disrupt Lab Market'

"Contrary to Congress' intent, instead of reforming Medicare reimbursement rates to reflect the broad scope of the laboratory market, the Secretary's final rule will disrupt the market and prevent beneficiaries from having access to the essential laboratory services they need," she added.

Under the rules Congress wrote to comply with PAMA, the Centers for Medicare and Medicaid issued the 2018 Clinical Laboratory Fee Schedule, which calls for a cut in what CMS pays of 10% starting Jan. 1. ACLA, the **American Hospital Association**, the **American Medical Association**, and more than 20 other organizations urged CMS not to implement the new CLFS rates, saying the rates would cause clinical laboratories to struggle financially and possibly close, affecting Medicare beneficiaries' access to clinical lab testing, ACLA said.

In the lawsuit, ACLA seeks to require HHS to set aside the provisions in PAMA Section 216 that required labs to report market rate data from private health insurers so that HHS could set payment rates for clinical lab testing that reflect the rates laboratories receive from private payers, the lawsuit said.

When it wrote the regulations for PAMA, however, HHS disregarded Congress' instructions and "unreasonably and arbitrarily exempted significant categories and large numbers of laboratories that meet the statutory definition from the reporting requirements that Congress imposed," the lawsuit said.

ACLA claims CMS did not act in accordance with law, that the law was constructed in an unreasonable manner, and that CMS violated the Administrative Procedure Act.

In its final section, "Prayer for Relief," the lawsuit asks the court to vacate, "any agency action found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;" to require HHS to comply with the statutory requirements, "including faithfully implementing the statutory definition of 'applicable laboratory;'" and enter an "injunction that (1) directs the Secretary to withdraw or suspend his final rule until such time as it can be brought into compliance with the statute, and (2) directs the Secretary to withhold applying the new Clinical Laboratory Fee Schedule until such time as the Secretary has made appropriate revisions to his final rule."

lection process properly, and that data-collection process got us to where we are now.

"When you look at how the data-collection was done, the 99.7% of labs that were not included in the effort is a key fact," Keville explained. "That is a big issue because the PAMA statute instructed CMS to collect data from 'all applicable laboratories.'

Law Gave CMS Discretion

"That is one specific issue ACLA is asking the court to address," he said. "ACLA is saying the phrase—'all applicable labs'—is

clear on its face. In other words, under the law, CMS should have included as many laboratories as possible, including hospital-based labs.

"CMS excluded a large percentage of labs, and that is a big factual nuance that will assist the legal arguments the ACLA lawyers are advancing," he commented. "It doesn't make sense to say, 'collect data from all applicable labs,' and then have CMS collect data only from a small percentage of labs.

"Of course, CMS will challenge this argument too," Keville said. "When it does, it is likely to rely on how the statute gives the agency discretion to exclude low-volume labs. That discretion allows CMS some leverage to define the data-collection effort in a way to carve out some labs.

Statute's Plain Language

"Personally, I think that's a strained argument because it's counter to the plain language of the statute itself, which is what ultimately should control the outcome of this case," he said. "When making decisions, courts review the language in the prevailing statute. That said, courts also give agencies significant discretion unless the agency clearly violated language in the statute."

While these issues are among the strongest ones to pursue, Gee and Keville also pointed out some obstacles to ACLA's case. For example, some labs did not submit data because they found the requirements to do so to be complicated and burdensome. That failure creates an opening for HHS' lawyers, Gee said.

"The fact that many labs, including hospital labs, didn't submit data undermines the ACLA's argument that labs were disadvantaged by the fact that CMS collected data from so few labs," Gee said. "A number of labs didn't submit data, including hospital labs with higher reimbursement experience, in particular, but they had the opportunity to do so.

"I believe the fact that some labs didn't submit data may undermine the claim that CMS' efforts were inadequate," he added. "In addition, CMS may emphasize that it gathered data from the largest participants in the market, namely, **Quest Diagnostics** and **Laboratory Corporation of America**."

How To Respond To PAMA

In addition, the clinical lab industry was aware of the issues and the risk labs faced under PAMA once it became law in April 2014. "Since then, these issues were on the top of everyone's mind," Gee commented. "Everywhere I went, lab professionals wanted to know how to respond to PAMA. This fact may make it more difficult to argue that labs were not given sufficient notice and opportunity to submit data to CMS."

Keville agreed, saying, "If the clinical lab industry complains about the methodology, then the government can argue that labs had the opportunity to submit data but didn't do so."

However, clinical labs had many reasons not to submit market-rate data and chief among them was the fact that they found that doing so was extremely difficult. Another challenge was that CMS decided to have labs submit retrospective data, but CMS did not tell them until after the retrospective-reporting requirement period had passed.

Looking Back Was Difficult

Labs argued that they could have submitted market-rate data if they had known in advance to collect that data for a specific period. Also, labs were concerned about how reporting data incorrectly could trigger CMS audits and steep fines.

Given these concerns among labs, it's reasonable to ask why the ACLA's lawsuit did not address these issues. There is no mention in the lawsuit of the trouble labs had in reporting the market-based rate data. Gee and Keville responded to this point by explaining that legal complaints

are drafted to emphasize the best claims to a judge or jury.

"Lawyers put in what they feel are the strongest arguments because weak arguments tend to distract from the stronger ones," Keville explained. "Clearly, ACLA and its legal team felt that the 'applicable labs' issue was the strongest claim and focused on that."

Another question that clinical labs may have about the lawsuit is why ACLA did not seek an injunction to stop the implementation of the 2018 CLFS. "ACLA's legal team may have reasoned that seeking an injunction was not the strongest strategy," observed Keville. "ACLA would need a temporary restraining order, and, in court, the burden is much higher to prove that a temporary restraining order (or any injunctive relief) is needed.

Needs For An Injunction

"To get such a TRO, ACLA would likely need to show that a certain percentage of labs would go out of business imminently—meaning within a matter of weeks," he explained. "It's not clear at this point that any labs will go out of business in such a short time."

In addition, plaintiffs sometimes do not seek an injunction because such a ruling can be a barrier to getting eventual relief from the same court, Gee added. "Sometimes asking for injunctive review can presage what will happen next," he said. "For example, if the court denies the restraining order, it could be difficult to get the court to move past its prior ruling when deciding the case."

In conclusion, Gee pointed out another factor that may become an issue in this lawsuit. "Given the sensitivity to affordable healthcare, it's always difficult to make the argument that your side is entitled to more money," he said. TDR

—Joseph Burns

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ACLA Lawyer Has Extensive Medicare Experience

TO LEAD ITS CASE AGAINST THE Department of Health and Human Services, the American Clinical Laboratory Association hired a lawyer with deep experience in the workings of the federal Medicare program.

The lawyer, Mark D. Polston, is a partner in the healthcare practice of the **King and Spaulding** law firm in Washington, D.C. The former Chief Litigation counsel for the Centers for Medicare and Medicaid Services, he specializes in representing healthcare providers in cases involving complicated Medicare reimbursement litigation.

Recently, he successfully challenged a proposed rate cut of 0.2% under Medicare's so-called "Two Midnight" rule, a regulation CMS uses to distinguish an inpatient from an outpatient. Under the rule, an inpatient is one whose stay extends over at least two midnights, according to the journal *Health Affairs.*

In the case, Polston represented more than 200 hospitals challenging CMS' decision to cut inpatient Medicare hospital rates. His efforts led to a reversal of the CMS policy, resulting in about $660 million in additional Medicare reimbursement to acute care hospitals, according to King and Spaulding.

Clinical lab directors may be interested to know that Polston also worked with a group of hospitals that lobbied successfully to reform the Medicare Recovery Audit Contractor program. He also led the Stark Reform Coalition, a group of hospitals seeking reform of the Stark physician self-referral law.

In the ACLA lawsuit against HHS, Polston explained why the case against the rules established under the Protecting Access to Medicare Act has merit. "CMS clearly disregarded and violated the statute's specific, unambiguous directives requiring commercial rate information to be reported and collected from a broad, diverse group of market participants," he said. "Instead, information was collected from less than 1% of U.S. labs."

Lab Executives Declare Concerns about Fee Cuts

For some laboratories, what Medicare will pay will be lower than the cost of running lab tests

CEO SUMMARY: Members of Joint Venture Hospital Laboratories in Michigan anticipate that the 2018 Clinical Laboratory Fee Schedule rates being implemented under PAMA will lower payment from Medicare to less than the cost of running tests, especially for rural and critical access hospitals. CMS established the 2018 CLFS under the Patient Access to Medicare Act of 2014 and those rates went into effect Jan. 1. JVHL's executive director explains why hospital labs may be forced to cease offering outreach lab testing services.

IN ITS LAWSUIT AGAINST THE FEDERAL **Department of Health and Human Services**, the **American Clinical Laboratory Association** included declarations from four clinical lab executives and ACLA board members who outlined their concerns about how the 2018 Clinical Laboratory Fee Schedule (CLFS) will affect clinical labs adversely.

Of the four executives, two were lab directors and both expressed concerns that the coming cuts in lab testing rates for this year would not cover the cost of running tests. All four executives said they supported the efforts of the federal **Centers for Medicare and Medicaid Services** to develop a payment system that would be equitable for all labs and they understood that cuts to lab testing rates were inevitable. They also were concerned that the resulting rates were unfair to labs, they said.

The four executives are ACLA President Julie Khani, and two lab directors: Peter Gudaitis, President of **Aculabs** in East Brunswick, N.J.; John Kolozsvary, Chief Executive Officer of **Joint Venture Hospital Laboratories,** (JVHL), in Allen Park, Mich. The fourth executive is Dermot Shorten, Senior Vice President, Strategy, Mergers and Acquisitions, and Ventures for **Quest Diagnostics.** *(For Gudaitis' comments, see, "Medicare Fees Less Than Lab Costs to Serve SNFs," pages 12-14.)*

Market Disruption Expected

Kolozsvary explained in his declaration that many of JVHL's hospital labs expect that the revised Medicare CLFS lab tests will be lower than the cost of running tests, especially for rural and critical access hospitals. CMS established the 2018 CLFS under the Patient Access to Medicare Act of 2014 (PAMA). Those rates went into effect Jan. 1.

In an interview with THE DARK REPORT, Kolozsvary went into more detail. "The potential outcome that we heard in feedback from a number of JVHL labs, particularly our smaller hospital members, was that payment may not cover costs," he said. "These are the observations from lab members of JVHL and the **Great Lakes**

NILA's Attorney Supports ACLA's Legal Strategy in Suit Against HHS over Market Price Reports

ALMOST AS SOON AS THE INK DRIED ON the Protecting Access to Medicare Act of 2014, lawyers for clinical lab associations expressed concern about a clause in the law that prohibited legal challenges to the clinical lab rates that CMS would propose under the law.

Among lawyers, this prohibition is known as a "review preclusion." If labs cannot challenge the rates that CMS issued in the 2018 Clinical Laboratory Fee Schedule, then perhaps the best legal strategy is to challenge the data-collection methods that CMS used when implementing the rates, lawyers told THE DARK REPORT.

One of the first lawyers to express a concern about the review preclusion was Jeffrey J. Sherrin, President of **O'Connell & Aronowitz** in Albany, N.Y. Sherrin represents the **National Independent Laboratory Association**.

In an interview with THE DARK REPORT after ACLA filed its lawsuit on Dec. 11, Sherrin agreed with the legal strategy ACLA's legal team is pursuing. "I think ACLA took exactly the right position," he said. "They are challenging the methodology and not the rates themselves. And, I think they are entitled to do that because the methodology was faulty. Although it will be a difficult case, I think there is merit in the ACLA challenge."

Asked if he was willing to predict an outcome in the case, he said, "It's not only hard to predict what will happen, it's impossible.

"That said, there are short- and long-term ways to look at this case," he explained. "In the short term, nothing in the litigation is likely to happen immediately. A court is not likely to step in and issue an order in the coming weeks because ACLA didn't seek a preliminary injunction.

"So, in the long term, it comes down to three questions," he offered. "First, who wins? Second, if ACLA wins, what relief does the court order? We can't say what that order will be right now. And, three, will the lawsuit stimulate some action from Congress to fix this problem statutorily?"

While the wheels of justice turn slowly, the clinical lab industry must meanwhile deal with the Medicare Part B price cuts that became effective on Jan. 1. Labs will soon see declines in their Medicare payments.

Laboratory Network (GLN). GLN is a JVHL hospital laboratory network member representing more than 40 hospitals mostly located in western and northern Michigan.

"The cost for hospitals to provide clinical lab services almost always exceeds those of the large commercial laboratories," he added. "As acute care facilities, our hospital labs are staffed 24 hours a day so that they can serve inpatients, surgery suites, and emergency rooms.

"Also, our members must meet accreditation and conditions of participation standards requiring them to have blood banks and other critical services in place," he added. "All of those services drive up costs.

"Plus, from a sheer volume perspective, hospital labs—despite group purchasing arrangements—don't have the scale that large commercial labs use to buy supplies and equipment," he said. "Commercial lab costs are probably as much as 30% less than those of hospital laboratories.

Will Labs End Outreach?

"My concern is that some JVHL members may need to discontinue offering outreach lab services," Kolozsvary added. "At the moment, it's too soon to know how

many labs may need to stop doing outreach testing.

"Currently, we're looking at just the first round of cuts in the Medicare fee schedule that was published Dec. 11," he explained. "Labs face a 10% cut this year, 10% next year, and 10% again in 2020. In 2021, we'll see a 15% cut and then 15% again in 2022.

"Once reimbursement goes below what it costs the hospital to provide outreach laboratory services, some will be forced to decide whether they can continue to offer those services or not," he said.

"It's too early to say now but some of those decisions may involve reducing staff, scaling back, or closing certain operations," he added. "Left unchallenged, those cuts will reach over 30% or more by the end of the PAMA implementation period.

"In rural areas in Michigan and in other markets, hospitals are the primary providers of healthcare services, and in those markets, you don't have commercial laboratories," Kolozsvary explained. "That means that ultimately, when the hospitals make decisions that they can't afford to provide some vital services—meaning X-rays, emergency rooms, and clinical lab testing—it's going to affect access to care for Medicare members.

Continuity Of Care Issue

"Another factor to consider is continuity of patient care," he commented. "If some hospitals stop offering lab services, it will affect hospital medical records. There is a risk that hospital records may not contain a patient's vital diagnostic testing information. That will have an effect on timeliness and possibly overall medical decision-making if those patients go to other places for lab services."

For Kolozsvary, hospital labs were disadvantaged when CMS excluded most hospitals from participating in the market-based rate-setting process that CMS established under PAMA. CMS then used that flawed process to set the CLFS rates for 2018, he said.

"Hospitals provide 26% of the total spent on the clinical laboratory fee schedule," he said. "If you take that out, a significant voice goes unheard. And it's a significant amount of data that should have been used to determine the rates. We knew cuts were inevitable, but they've simply gone after the lowest price, in my opinion.

A Result Contrary to Intent

"That was not the intent of the lab section in PAMA," he added. "Section 216 of PAMA was to come up with a market-based payment solution that would phase in payment reductions over time. But it was supposed to be based on the entire industry or an applicable portion of the industry, including hospitals.

"I believe the end result is totally biased," he said. "Initially, CMS based its projections on having 12,500 entities report data in the initial reporting period. But in the end, there were fewer than 1,200 and only 20 hospitals participated.

"When you consider that there are more than 200,000 CLIA-certified laboratories in the country, including around 7,000 hospitals, and only about 20 hospital labs were included in CMS' calculations, that's a problem," he added. "Under CMS' definition of 'applicable lab' we know of only two that reported from Michigan. That's less than 1% of our membership and less than 1% of the hospitals in Michigan.

Desire For Equitable Solution

"From this rate-setting process, we just wanted fairness," concluded Kolozsvary. "Again, we recognized that cuts in reimbursement were inevitable. Given that, we wanted an equitable solution from CMS based on the legislative intent of PAMA Section 216. Personally, I do not believe we got that." TDR

—Joseph Burns

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Executives from ACLA and Quest Diagnostics Explain How HHS' Data-Collection Effort Failed

IN TWO DECLARATIONS IN A LAWSUIT ACLA filed against the department of Health and Human Services, executives from American Clinical Laboratory Association and Quest Diagnostics explain how HHS failed to implement the Patient Access to Medicare Act according to the law's intent. The executives are ACLA President Julie Khani and Quest Diagnostics' Dermot Shorten.

Khani joined ACLA in 2013. She has seen firsthand how and why Congress passed the Patient Access to Medicare Act in 2014 and why Section 216 would be of significant importance to ACLA's members. In her 381-page declaration, she explained that she was directly involved in the negotiations with the Centers for Medicare and Medicaid Services over how CMS would gather the data for its market-based reporting project and set the clinical laboratory test rates based on that data for 2018.

"I have been directly involved in ACLA's many efforts to work with government officials to implement PAMA Section 216, including officials and executive-level staff at HHS, CMS, and other federal agencies," she said in the declaration.

"CMS proposed and then finalized a regulatory definition of 'applicable laboratory' that is contrary to the statutory definition. Instead of requiring all 'applicable laboratories' to report private payer information, as Congress directed," she noted, "CMS' regulations carve out thousands of laboratories from the statutory requirements, effectively excluding hospital laboratories and many other laboratories from the obligation to report information.

"ACLA and its members repeatedly urged CMS to comply with the statutory requirements and explained why the agency's revised regulatory definition was unlawful, unreasonable, and improper," added Khani. "ACLA and its members also identified alternative approaches that would allow the agency to comply with the statutory requirements.

"Between 2014 and today, ACLA had at least 42 separate interactions with HHS, CMS, and federal executive-level staff related to the implementation of PAMA Section 216 and specifically the regulatory definition of 'applicable laboratory,'" she explained. Those interactions included:

- 22 in-person meetings;
- 14 letters;
- 1 presentation at a public meeting;
- 3 teleconferences; and
- 2 comments submitted to CMS proposed rulemaking/rates.

Letters Support Declaration

Those letters and other documents are included in the declaration and lay out ACLA's case in great detail.

Like Khani, Shorten has a view of the clinical lab industry that is unique. He has worked at Quest for nine years in a variety of senior management positions, most recently as Senior Vice President, strategy, mergers and acquisitions, and ventures. In this role, he has prepared an annual lab services market model that includes multiple market segments, including Medicare, Medicaid, and commercial payers. Using this model, he predicts where and why the lab market is growing or shrinking by payer type. These data are then consolidated for Quest's use in decision support, he said. Clearly, Shorten has a thorough understanding of the market for lab services.

From what he saw about how HHS collected data to comply with PAMA Section 216, he said in his declaration that the Secretary of HHS did not collect private payer data from all applicable labs as Congress intended. By excluding almost all hospital labs, the data do not accurately reflect the lab market as a whole, stated Shorten.

Medicare Fees Less Than Lab Costs to Serve SNFs?

➤Even without PAMA price cuts, labs struggle to serve nursing homes, assisted-living facilities

➤➤CEO SUMMARY: Anticipating the negative financial impact of the Medicare 2018 Clinical Laboratory Fee Schedule, a community lab company serving 24 nursing homes on the Jersey Shore stopped offering such services at the end of last year, a lab director told THE DARK REPORT. "The same forces driving this laboratory to close its nursing home business will cause many more nursing home laboratories to follow," stated Aculabs CEO Peter Gudaitis during his interview with THE DARK REPORT.

NURSING HOMES AND LONG-TERM-CARE FACILITIES are considered to be probably the most difficult healthcare sectors for clinical labs to serve efficiently. The costs to collect patients' specimens and run the tests often are perilously close to the existing payment these labs get from Medicare, Medicaid, and commercial health insurers, lab directors say.

In his declaration supporting the **American Clinical Laboratory Association's** lawsuit against the federal **Department of Health and Human Services**, Peter Gudaitis, President of **Aculabs** in East Brunswick, N.J., explained how his lab has served this market since 1972 and how the latest rates from Medicare threaten this segment of the clinical lab testing business.

"In fact, the tough finances and imminent cuts to Medicare Part B clinical laboratory test prices in 2018 caused at least one laboratory serving 24 nursing homes on the Jersey Shore to stop offering such services at the end of last year," noted Gudaitis in a telephone interview with THE DARK REPORT. "The same forces driving this laboratory to close its nursing home business will cause many more nursing home laboratories to follow.

"If our lab and other labs like ours are not around to do this work, I have no idea who will step in to serve nursing homes and LTC facilities," he commented. "To service our clients, my lab needs 200 people driving around to collect the samples from patients in the nursing homes and the assisted-living facilities we serve."

➤Few Labs Serve This Market

Aculabs performs more than 10 million tests annually. It serves 750,000 patients each year in 320 skilled nursing and assisted-living facilities in New Jersey, Pennsylvania, Maryland, and Delaware. It runs these tests in two laboratory facilities, one in East Brunswick and one in Cherry Hill, N.J.

"Less than 100 lab companies provide services to the majority of skilled nursing and assisted living facilities nationwide," observed Gudaitis. "Like Aculabs, these community lab companies are heavily

ACLA's Lawsuit Lists 'Flaws in CMS Data,' Claim Is that CMS Did Not Meet PAMA Statute

CONTAINED IN THE LAWSUIT recently filed by the American Clinical Laboratory Association against the Department of Health and Human Services is a list of what ACLA alleges are flaws in how the Centers for Medicare and Medicaid Services conducted its market price study of the lab test prices paid by private health insurers.

Many pathologists and lab administrators are familiar with the well-publicized fact that CMS used data submitted by just 0.07% (or 1,942 labs) of the nation's 261,500 lab entities that were paid Part B lab test reimbursement in 2016. They may also know that, of the 7,000 hospital labs that were paid for Part B lab tests in 2016—representing 26% of all Part B payments—no more than 21 hospitals provided data to CMS.

But there are some little-known facts about the CMS data collection process of equal interest. One is that 2.4 million data points were submitted by labs showing $0.00 prices! Another is that 3.7 million data points are "unlikely outliers," being less than $1.00 and more than $10,000.

Here are seven flaws identified by ACLA that are described in the lawsuit, as follows:

- Hospital labs only contributed 1% of the data compared to 26% share of Medicare CLFS spending.
- Physician Office Labs (POLs) only contributed 7.5% of data compared to 18% share of Medicare CLFS spending.
- 2.4 million $0.00 prices were submitted as compared to 2.3 million data points from all reporting hospital NPIs.
- 3.7 million data points are likely inaccurate outliers, creating questions of pricing errors which are not obvious as outliers (outlier defined as less than $1.00 and greater than $10,000).
- Alternative CMS simulations incorrectly assume additional hospital labs and physician office labs would report pricing volume and distribution identical to data already captured.
- CMS selectively corrected or omitted data that would have resulted in higher than expected weighted medians.

dependent on Medicare beneficiaries for their customer base."

Of those 100 labs, Aculabs is one of four that provide 30% to 40% of all lab testing services to nursing homes and LTC facilities nationwide, he added. All of Gudaitis' comments below come from his declaration in the ACLA lawsuit.

Geography-Specific Work

"Each of the four [community labs] is concentrated in certain geographic areas with little overlap," he said. "Because services to long-term care facilities are directly tethered to the location of each laboratory's testing facilities and its ability to get specimens there within hours, these laboratories are unlikely to step into the shoes of another, should one [lab] exit the marketplace.

"Moreover, if one of these laboratories were to exit the marketplace, the likely reason is that the marketplace was no longer profitable for Medicare patients, making it unlikely that other [labs] would attempt to enter in its stead," he explained.

The reason labs serving nursing homes and LTC facilities may exit the market is that they have much higher costs to provide laboratory test services to their patients than large commercial lab companies have.

"The vast majority of tests that Aculabs performs yield some of the lower reimbursement rates paid by Medicare,"

Gudaitis said. He identified the following four basic tests as representing about 75% of Aculabs' tests:

1. Complete blood count (CPT code 80025),
2. Prothrombin time (CPT code 85610),
3. Basic metabolic panel (CPT code 80048), and,
4. Comprehensive metabolic panel (CPT code 80053).

"Aculabs' patient population does not require many of the costlier tests used for diagnosis, including molecular testing and advanced testing," he explained.

In the declaration, Gudaitis further stated that, should labs serving nursing home and LTC facilities close, other labs are not likely to assume that work.

"Because of the unique medical needs of patients in long-term care facilities and the accompanying costs and challenges of providing clinical laboratory services to them, laboratories that operate in other sectors of the market—like independent laboratories or hospital laboratories—are unlikely to step in to provide services," he said.

"If they did enter the long-term care market, other labs would provide significantly reduced services at the ultimate expense of patient health," Gudaitis said.

"For example, a large independent laboratory—with limited direct specimen collection ability, specified travel routes, and less of an ability to provide quick turnaround test results—would not be able to provide the services demanded by long-term care patients without changing its business model," he added.

Non-Complex Lab Tests

"Moreover, it is unlikely that the skilled nursing facility laboratories themselves, which typically provide only limited, simple, non-complex clinical laboratory testing, will be able to dramatically increase the services offered," noted Gudaitis.

"To do so would require additional accreditation, staffing, and equipment, which, given the small, fixed patient population at the facilities, is unlikely to be financially reasonable. This is the reason why these institutions typically contract with laboratories like Aculabs.

"If laboratories serving skilled nursing facilities, nursing homes, and other LTC facilities do not leave the marketplace (or if another type of laboratory were to enter the market), they will be forced to reduce the services they provide which, in turn, poses a very real and substantial threat to beneficiary health and safety," he said.

Adverse Effects on Care

"For example, laboratories like Aculabs will not be able to send phlebotomists to the facility for direct collection as frequently and, as a result, patients will have to wait longer for test results," Gudaitis said.

"There is a direct correlation between delayed laboratory results and poor health outcomes for people who rely on regular diagnostic testing for maintaining their chronic conditions," Gudaitis explained. "The sick and elderly patient population is unlikely to be able to tolerate a slower service model.

"Many patients who require 'STAT' testing will not be able to wait for a phlebotomist to arrive, and the facility will have no other option but to request ambulance transportation for that patient to the hospital emergency room solely for the purpose of swift diagnostic testing that otherwise could have been provided by a phlebotomist on a 'STAT' run," he said.

"Not only does this increase the cost of providing clinical laboratory services to those patients, it also increases the risks of collateral harm that could result from transporting frail and elderly patients to the emergency room (including exposing them to infection)." Patients in rural areas will feel the effects of such cuts in lab test rates hardest, he concluded. TDR

—Joseph Burns

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Managed Care Update

In Florida, More Tests Added to UHC's Decision-Support Program

IN THE FIRST BROAD EXPANSION OF ITS pilot decision-support program for clinical lab testing in Florida, **UnitedHealthcare** (UHC) will add genetic and molecular tests, drug tests, and pathology procedures, among other assays starting in two months.

On March 1, UHC will expand its laboratory benefit management program in Florida beyond the initial 80 routine anatomical and clinical pathology tests. To be added are 40 genetic and molecular diagnostic assays, some name-brand tests, and broad categories of testing such as drug tests and pathology procedures, according to a one-page summary in UnitedHealthcare's December network bulletin report to providers.

In April 2015, UHC and **Beacon Laboratory Benefit Solutions,** a division of **Laboratory Corporation of America,** started the lab benefit program in Florida for its fully-insured commercial members in the Sunshine State. *(See TDR, March 9, 2015.)*

In its latest announcement, UHC said it aims, "to improve the care provider experience," by revising the list of tests that require physicians to use the BeaconLBS decision support system. Also, UHC will make, "Accommodations for CLIA and referring physician claim submission requirements for physician offices." In addition, UHC and BeaconLBS will add "new decision support features," additional integration between electronic health record and laboratory ordering systems, and improve the design of the "physician decision support platform."

An email inquiry from THE DARK REPORT seeking more information from UHC was not returned by press time.

CPT Codes Not Identified

"It's interesting to note that UHC is not specific regarding which CPT codes will be involved," said one lab director who saw the announcement. "All we know is there are broadly-listed test categories.

"With a projected start date of March 1, it may be that the lack of specificity is designed to alleviate an onslaught of torches and pitchforks from specialty labs seeking to appeal for removal from the projected test listing," the lab director added. "It's likely that the CPT codes will be revealed sometime in late February."

In its announcement, UHC said it was making the changes based on feedback from care providers and evaluation of pilot results. UHC has referred to the initiative in Florida as a pilot program since it was started in 2015.

Note that some of the tests being added are specific brand-name tests (such as MammaPrint assay from **Agendia**) and others are general categories of testing such as "drug testing: presumptive and definitive." It is likely that these broad categories of testing will generate the most controversy among clinical lab directors and pathologists.

For example, one category of testing being added on March 1 is "Pathology—dermatopathology, hematopathology, all other." This category is so broad it appears to encompass all work by all pathologists. Another broad category is "drug testing: presumptive and defini-

UHC Publishes First List of Tests for LBMP

HERE'S A LIST OF THE TESTS AND broad categories of laboratory tests that UnitedHealthcare is adding to its decision support program in Florida. This list of tests is available on the UHC website.

- Ashkenazi Jewish carrier screening
- Breast cancer index
- Chlamydia trachomatis/Neisseria gonorrhoeae with or without Trichomonas vaginalis, NAT
- Chromosome SNP microarray panel
- Cystic fibrosis carrier screening and sequencing
- Cytology (non-gynecology)
- Drug testing: presumptive and definitive
- EndoPredict breast cancer test
- Expanded carrier screening
- Gene expression profile tests for evaluation or management of multiple myeloma
- Gene expression profiling as a technique for colorectal cancer (CRC) risk assessment or management
- Gene expression profiling as a technique of managing the treatment of breast cancer
- Gene expression profiling of cutaneous melanoma
- Gene expression profiling to identify the tissue of origin for cancers of unknown primary site
- Gene-based tests for the screening, detection and management of prostate cancer
- HCV, quantitative, NAT
- Hereditary breast and ovarian cancer testing (BRCA1/2)
- Herpes simplex virus (HSV) antibodies
- HIV-1, quantitative, RNA
- HPV, high-risk (HR) detection
- Leukemia/lymphoma immunophenotyping profile (by flow cytometry)
- MammaPrint breast cancer recurrence assay
- Molecular pathology procedures
- Multi-gene hereditary cancer panels
- Multi-gene pharmacogenetic testing
- Multi-gene tumor panels to guide cancer treatment
- Non-invasive prenatal screening (NIPS/NIPT)
- Oncotype DX Breast Cancer Test
- Pathology, Dermatopathology, Hemato-pathology, all other
- Prosiga Breast Cancer Assay
- Prostate Specific Antigen (PSA) Assay
- Thyroid panel
- Thyroxine (T4), free
- Triiodothyronine (T3), free testosterone
- Topographic genotyping
- UroVysion
- Vitamin B12
- Vitamin D, 25-hydroxy
- Whole exome sequencing
- Whole genome sequencing

tive." Adding "drug testing" in this way suggests that UHC is seeking a way to manage the rapid rise of drug testing nationwide. In addition, UnitedHealthcare may also be seeking a way to manage the fraud that often occurs in the drug testing segment of the clinical laboratory industry.

Note that hereditary breast and ovarian cancer testing (BRCA1/2) require prior authorization, UHC said.

—Joseph Burns

IVD Market Update

Beckman Coulter Sues Quidel for Right to Sell BNP Assay

Beckman says Quidel has rejected its offers to buy the BNP test and rights to the biomarker

THERE IS AN INTERESTING COURT FIGHT UNFOLDING between **Beckman Coulter Corporation** and **Quidel** over the rights to sell a B-type natriuretic peptide (BNP) assay. The lawsuit is a consequence of **Abbott Laboratories'** acquisition of **Alere, Inc.**, last fall.

With that acquisition, Abbott Laboratories became the world's largest manufacturer of point-of-care (POCT) lab tests. But federal anti-trust regulators required Abbott to divest and sell certain Alere assets as a condition for government approval of the merger. *(See TDR, Oct. 30, 2017.)*

That is how the BNP test then became the subject of litigation between Beckman Coulter and Quidel. It is a court fight that should be of particular interest for those clinical labs that currently use Beckman analyzers to run BNP tests.

On November 27, 2017, Beckman Coulter issued a press release in which, among other things, it said it had "requested that the San Diego courts in California clarify and enforce Beckman Coulter's rights to sell a natriuretic peptide assay directly to its customers."

In the lawsuit, filed on Nov. 27, Beckman Coulter said it seeks a court ruling to allow it to sell its own BNP test, using proprietary technology that it had originally developed.

In 1997, **Biosite Diagnostics Inc.**, licensed rights to the BNP marker from **Scios, Inc.** In 2003, in an arrangement with Biosite Diagnostics Inc., Beckman had helped Biosite develop a BNP assay.

The history of this BNP test and technology—and the rights to them—is complex. A timeline on page 18 helps to understand the developments.

Beckman's Plans For BNP

"Beckman Coulter plans in the future to sell directly to its customers a natriuretic peptide assay for its Access Family of Immunoassay Systems," said the company in its November 27 press release. "Currently, Beckman Coulter customers have access to a BNP assay which, although developed and manufactured by Beckman Coulter, is sold exclusively by Quidel and its designated distributors."

Quidel responded in a follow-up press release the same day, stating, "Quidel views Beckman's claims as meritless, and in opposition to Beckman's long-standing strategy of honoring the Supply Agreement with its previous partners—Alere and Biosite—over the last 14 years, and merely a tool in an effort to purchase the BNP assay business from Quidel."

Beckman Coulter is seeking rights to sell B-type natriuretic peptide (BNP) assays directly. Currently, the TRIAGE BNP Assay is sold exclusively by Quidel due to rights obtained in the $680-million October purchase of Alere assay assets.

In the current arrangement, Quidel provides proprietary antibodies to Beckman Coulter under a license from **Scios**. Beckman Coulter then manufac-

tures the assays for sale by Quidel. Quidel then sells these assays for use in its POC instrument. It also sells the assay to labs that perform the BNP test on Beckman Coulter analyzers.

Quidel claims that as long as the Scios license is in effect, the supply agreement previously in place—including a non-compete clause—remains in effect as well.

The agreement initially came from Biosite during its 2007 acquisition by **Inverness Medical Innovations**—who changed its name to Alere in 2010. A potential merger between Biosite and Beckman Coulter was planned. However, Inverness Medical Innovations entered a higher bid.

Alere's recent acquisition by Abbot required divesting of certain assets—one of which is the TRIAGE BNP Assay. Quidel bought the rights to the assay on October 6, 2017, thereby transferring the terms of the supply agreement from Alere to Quidel.

Quidel Rejected Offers

Quidel claims that "in recent weeks," **Danaher**—parent firm of Beckman Coulter—submitted multiple offers to acquire the BNP assay business. The board of directors rejected these offers, citing the potential of their latest acquisition to "create substantial long-term value for Quidel's shareholders."

Analysts at *The Motley Fool* speculate that the recent court filing from Beckman Coulter might be used to increase leverage on the board of directors at Quidel and encourage the sale of the BNP assay assets instead of entering a lengthy—and potentially costly—litigation and defense of their existing rights.

Until an outcome is reached—either in negotiations or a win by Beckman in court—Quidel continues to maintain the exclusive right to sell TRIAGE BNP assays to customers for use on Beckman Coulter analyzers. TDR

—Jon Stone

Timeline Shows BNP Test Development, Licensing

IT WAS ON DEC. 30, 1996, when Biosite Diagnostics Inc.—then a public company based in San Diego—signed an agreement with **Scios, Inc.**, whereby Scios granted Biosite "a semi-exclusive license under the Patent Rights and Know-how to make, have made, use, offer for sale, sell, and import" a diagnostic product using Scios' patents relating to B-type natriuretic peptide (BNP).

In November 2000, Biosite received FDA clearance for the Triage BNP assay of which sales rights are now in question.

In 2003, Beckman entered into a BNP Assay Agreement with Biosite. Beckman developed the BNP assay as part of this agreement. Several years later, Biosite obtained FDA clearance to perform the assay using capillary whole blood. In 2006, the BNP assay received a CLIA waiver.

Beckman Coulter announced its intention to buy Biosite in March 2007. At this time, Biosite had the sales rights to the BNP assay for use with Beckman analyzers. However, Inverness Medical Innovations entered a competing offer. It outbid Beckman Coulter. Inverness paid $1.68 billion to acquire Biosite in mid-2007.

As the new owner of Biosite, Inverness Medical Innovations also acquired the BNP licensing agreement with Scios.

In 2010, Inverness Medical Innovations announced it had changed its name to Alere, Inc. Six years later, Abbott Laboratories initiated talks to buy Alere. To meet antitrust approvals, Alere had to divest its Triage MeterPro and Triage BNP businesses. Abbott also holds a semi-exclusive license with Scios from May 29, 1997.

In October 2017, Quidel acquired these businesses from Alere so as to improve its POCT offerings. This again transferred the Scios BNP license—now to Quidel.

Less than two months later, Beckman Coulter filed its lawsuit against Quidel in a San Diego court. At the time of writing, a hearing is scheduled for February 16, 2018.

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

In Arizona, individuals and patients who paid for clinical laboratory tests performed by **Theranos, Inc.**, are finally getting refunds. These payments are a result of a settlement between the Arizona Attorney General and Theranos. News accounts indicate that, over the time in 2013 through 2016 that Theranos offered lab tests in Arizona through its relationship with **Walgreens**, about 175,000 patients were tested. It is reported that the average refund will be $61. One Arizona resident paid $3,400 to Theranos for clinical laboratory tests.

HEALTH NETWORK LABS EXPANDS INTO FOUR HOSPITALS

In Allentown, Pa., **Health Network Laboratories** (HNL) disclosed last month that it will assume management of inpatient laboratories at four hospitals in northeast Pennsylvania. Each of these hospitals was acquired by HNL's parent, **Lehigh Valley Health Network**. HNL says that it now manages seven hospital laboratories.

GENOPTIX ACQUIRES ROSETTA GENOMICS

Last month, **Genoptix** announced a merger agreement with **Rosetta Genomics**. The acquisition of outstanding Rosetta shares is valued at $10 million, or about 60¢ per share. Rosetta's CEO said that there was only enough cash to fund operations through the end of 2017.

TRANSITIONS

- CEO Khosrow Shotorbani resigned from **TriCore Reference Laboratories** in December to pursue other opportunities. He previously held executive positions at **ARUP Laboratories**.

- Last month, Priscilla Cherry retired from her position as Vice President of Laboratory and Courier Services at **Mission Health Systems**. Formerly, Cherry held administrative positions at **Fairview Health Services**, **Premiere Inc.**, and **Kaiser Permanente**.

- Ana K. Stankovic, MD, retires from **Becton Dickinson** this month. She held positions at the **Centers for Disease Control and Prevention**, **Quest Diagnostics**, **Immucor**, and the **American Red Cross**.

- **Ambry Genetics** announced the selection of Tom Schoenherr as its new Chief Commercial Officer. Schoenherr has had executive positions with **Counsyl**, **Quest Diagnostics**, **Siemens Healthcare**, and **Abbott Diagnostics**.

DARK Daily
Clinical Laboratory and Pathology News/Trends

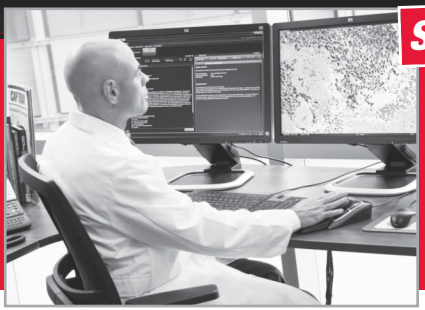
DARK DAILY UPDATE

Have you caught the latest e-briefings from DARK Daily? If so, then you'd know about...

...how researchers in the Netherlands published findings about their verification that at least 30,000 studies published in 33,000 scientific papers included data derived from misidentified or contaminated cell lines. This puts at risk many findings in the fields of oncology, molecular biology, pharmacology, and other cell-centric medical research.

You can get the free DARK Daily e-briefings by signing up at www.darkdaily.com.

That's all the insider intelligence for this report. Look for the next briefing on Monday, January 22, 2018.



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SPECIAL SESSION!

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It was big news last year when the FDA cleared the first digital pathology system for use in the primary diagnosis of most types of biopsies. Now all pathology groups must decide when to take the plunge and invest in digital pathology.

To help you, we've organized a full-day digital pathology summit on May 3, following the two-day *Executive War College* on May 1-2. The event starts with a reception and digital product exhibition on the evening of May 2. This allows you to meet the summit speakers, see the digital pathology products, and get a head start on the summit itself.

Be ready for a full day of learning on May 3 about everything you and your pathology group needs to know about digital pathology. You'll hear clinical, operational, and financial case studies from innovative pathology labs using digital pathology. They will teach you the do's and don'ts, how to gain clinical advantage, plus effective ways to win new clients and develop new streams of revenue. You'll see all the leading digital pathology systems. Register today!

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- ***UnitedHealth vs. Next Health: $100 Million Lawsuit Alleges Lab Test Fraud and Multiple Lab Entities.***
- ***Challenges and Opportunities for Specialty Labs: Why the Market Is Rewarding Some Lab Firms.***
- ***Recent Developments in DOJ, OIG Enforcement of Lab Compliance: What Every Lab Must Know.***