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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

Restricted information, see page 3

COMMENTARY & OPINION by...

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Of Theranos, ADLTs, and Surgical Pathology Errors

THESE DAYS, IT SURE FEELS LIKE CLINICAL LABS AND PATHOLOGY GROUPS are under constant siege. Every month seems to bring one or more new developments that rock the clinical lab industry.

Theranos, Inc. is a prime example of this phenomenon. Almost every month there are new disclosures about problems plaguing this high-profile lab company. As you will read on pages 3-9 of this issue, CMS has imposed the most serious sanctions available under CLIA. In response, Theranos is taking actions that indicate it may be preparing to drop its clinical lab and direct-to-consumer strategies. Instead, it seems to be repositioning to focus on developing its diagnostic instruments and technologies for other purposes, while also pursuing FDA clearance for its devices and methodologies.

Meanwhile, CMS has issued the final rule to implement the lab test market reporting and ADLT sections of the PAMA statute. In this issue, we provide useful insights about the rule that addresses ADLTs. On pages 10-13, you'll learn how experts in this field recommend that labs offering ADLTs assess their options. They point out that pricing decisions about a lab's ADLT are about to become more complex. When Medicare sets a price for an ADLT in one year, that price will be published and known to private health plans. Thus, a lab's proportion of public and private payers must be known to establish a pricing strategy for each ADLT that will produce optimal revenue.

Next in our line-up of intelligence briefings is coverage of a surgical pathology scandal unfolding in Kansas City. THE DARK REPORT is first in the lab industry to cover this story. According to a lawsuit filed by a whistleblower-pathologist at a major university medical center, the chair of pathology at that institution misdiagnosed a patient's cancer, causing a healthy and essential organ to be surgically removed. Post-surgery, the lawsuit alleges the chair of pathology changed hospital records to cover up the error.

Court documents indicate that the hospital is pressuring the whistleblower-pathologist, while not acknowledging the medical error affecting this patient. Do **The Joint Commission** and the **College of American Pathologists** (accreditors of the hospital and the lab, respectively), know about the whistleblower's complaint? Are they investigating? You'll need to read pages 14-18 to learn the answers to those questions and more. TDR

Theranos Now Scrambling To Save What It Can

In a first after 13 years, lab will have experienced executives handling regulatory compliance, quality

CEO SUMMARY: On July 7, CMS imposed severe sanctions on Theranos for CLIA violations. Included is a two-year ban on owning and operating a clinical laboratory for Theranos, CEO Elizabeth Holmes, the former COO, and the former medical director. Theranos appears to be pivoting away from a clinical lab testing business strategy and back to development of its proprietary diagnostic analyzers and test methodologies. Meanwhile, a congressional committee is asking Theranos for information.

PLENTY OF BAD NEWS HAS DOGGED **Theranos, Inc.**, in recent months. Now, in a series of announcements, the company is providing hints of how it may want to move forward. Based on these public statements, it could be that Theranos will put its clinical laboratory testing strategy on the back burner for the moment.

Instead, there are indications that Theranos intends to emphasize developing its diagnostic technologies so that it can obtain regulatory clearance. This would be logical, for a simple reason. Gaining FDA clearance for its proprietary specimen collection devices, diagnostic analyzers, and test methodologies would go a long way to restoring the confidence of both investors and the public in the lab company and its products.

Should the controversial lab company's prime strategy now be to obtain regulatory review and clearance of its diagnostic inventions and innovations, this would be a significant departure from the business course that Theranos has followed since the fall of 2013.

That's when Theranos, based in Palo Alto, Calif., announced it would provide consumers with low-cost clinical laboratory tests and charge just half of Medicare Part B lab test prices. At the same time, Theranos also announced its agreement with **Walgreens** to do lab testing in Walgreens' pharmacies nationwide. *(See TDR, September 30, 2013.)*

The thrust of this business strategy was to take on the entire clinical laboratory industry directly. In fact, between 2013 and 2015, Theranos CEO Elizabeth

Holmes regularly commented that Theranos was determined to disrupt the entire clinical laboratory industry.

That bold talk suddenly changed last October, when *The Wall Street Journal* published the first of a series of devastating exposés of Theranos. The latest hammer to drop on the beleaguered lab company came on July 7. That's when CMS sent a letter that imposed severe CLIA sanctions on Theranos.

Theranos reacted by making several important announcements last week as it struggles to find the right response to the steady stream of negative news stories that have plagued the company for the past 10 months.

Last week, for example, Theranos took steps to improve its regulatory, quality, and compliance efforts when it named two new executives to report directly to CEO Elizabeth Holmes. The two executives, experienced in medical compliance, are joining the company immediately.

Theranos announced on July 21 that Dave Wurtz will be the Vice President, Regulatory and Quality. Wurtz has extensive experience in the *in vitro* diagnostics (IVD) industry. At **ThermoFisher Scientific**, he was Senior Director of Regulatory, Quality and Compliance. In this role, Wurtz managed FDA inspections, and headed up the company's pre- and post-market regulatory activities worldwide. Wurtz also has worked in compliance at **Beckman Coulter Inc.**, and held positions at **Osmetech** and **G.D. Searle**.

New Compliance Officer

On the same day, Theranos tapped Daniel Guggenheim to be Chief Compliance Officer. Before joining Theranos, Guggenheim worked as assistant general counsel for regulatory law at **McKesson Corp.** where he was the chief regulatory and compliance counsel and senior counsel for its pharmaceutical division. Guggenheim was thus involved with the sale of medical devices, the marketing and sale of drugs, and the sales of health care information technology.

In another move to boost compliance, last week the lab company's board of directors created a Compliance and Quality Committee to oversee and advise the board and the company's executives on regulatory compliance and quality systems.

"The new executive appointments and the creation of the committee are the latest in a series of significant actions Theranos has taken to ensure that it meets the highest standards in its laboratories, medical products, and operations," Theranos said in its announcement.

Tough CLIA Lab Sanctions

These steps to beef up compliance come quite late in the 13-year business life of Theranos. They appear to be in response to the severe CLIA sanctions that the federal **Centers for Medicare & Medicaid Services** imposed in a letter it sent to Theranos on July 7.

The biggest sanction CMS imposed is revocation of the company's CLIA license to operate a lab in Newark, Calif., because of unsafe practices. CMS is banning founder Elizabeth Holmes (and two other individuals) from the blood-testing business for at least two years. The CMS letter was addressed to: Holmes; Medical Director Sunil Dhawan, MD; owner Ramesh Balwani; and, Theranos, Inc.

In the letter, CMS said Theranos was out of compliance with Clinical Laboratory Improvement Amendments of 1988 (CLIA) condition-level requirements and had not removed the finding of immediate jeopardy, as CMS had cited in a letter to Theranos on Jan. 25, 2016. That's when CMS listed all of the deficiencies its inspectors identified. In the letter of Jan. 25, CMS notified Theranos that the seriousness of the deficiencies resulted in a finding of "immediate jeopardy to patient health and safety."

CMS requested a response from Theranos to each of the deficiencies it

cited and Theranos provided that response on Feb. 12.

After reviewing Theranos' response, CMS wrote on July 7, "After careful review, we determined that the laboratory's submission did not constitute a credible allegation of compliance and acceptable evidence of correction for the deficiencies cited during the CLIA recertification and complaint survey completed on Dec. 23, 2015, and did not demonstrate that the laboratory had come into condition-level compliance and abated the immediate jeopardy."

As a result of its finding that the lab was out of compliance, the agency imposed the following six sanctions:

1. Revocation of the laboratory's CLIA certificate
2. Limitation of the lab's CLIA certificate for the specialty of hematology
3. A civil money penalty of $10,000 per day for each violation
4. Directed portion of a plan of correction
5. Suspension of the laboratory's approval to receive Medicare and Medicaid payments for any services performed for the specialty of hematology
6. Cancellation of the lab's approval to receive Medicare and Medicaid payments for all laboratory services.

Daily Monetary Fine Of $10K

Most of the sanctions do not take effect for 60 days, which CMS said would be Sept. 5. But one sanction, the monetary fine of $10,000 a day until all deficiencies are corrected, went into effect July 12, *The Wall Street Journal* reported. Until Sept. 5, Theranos can request a hearing before an administrative law judge of the Departmental Appeals Board (DAB), CMS said.

The Wall Street Journal reported that if Theranos cannot reach a settlement with CMS, its options would be limited. Almost any course it takes could dramatically reshape the company, the journal added.

Theranos May Be 'Down,' But Says It Is not Yet 'Out'

After Theranos got its sanctions letter from CMS on July 7, the company outlined the steps it could take to address the agency's concerns, saying it was working closely with CMS.

In a statement issued on July 7, Theranos said, "It's important to note that the CMS review pertained to the operations of the company's Newark lab, not its technologies. Over the last 13 years, Theranos has developed a broad range of technologies, including small-volume sample assays, capillary collection and testing capabilities, the ability to test small-volume samples on a variety of different platforms (high-throughput and field devices), and a software suite for testing analysis and decision support. The clinical lab is just one of Theranos' many opportunities to provide access to high-integrity, affordable and actionable health care information, and the company will continue to carry out its mission under the leadership of its founder and CEO, Elizabeth Holmes."

Theranos also described a path it could take to move forward without testing consumers. "Clinical lab services is one of Theranos' business units. Its research and development unit has developed many technologies that are not dependent on running a clinical laboratory. The company will continue to build infrastructure and build on its mission of improving access through affordable diagnostic testing, and its proprietary technologies and accessible business model. Improving access through innovative technologies is a universal need, with growth opportunities in global and domestic vertical markets," Theranos said.

This Theranos statement describes how the lab company will emphasize development of its diagnostic analyzers and technologies, while jettisoning that part of the business that does the actual testing in compliance with the CLIA sanctions.

In an article published on July 8, the three journal reporters who have covered Theranos closely, John Carreyrou, Michael Siconolfi, and Christopher Weaver, wrote, "The company could appeal the sanctions to an administrative judge, which would put some [sanctions] on hold. Its odds of winning would be slim, according to legal experts and government data. Or it could withdraw from the lab-testing business altogether, focusing on developing devices. That would significantly change its mission."

Would Holmes Leave?

Given that she faces a two-year ban, Holmes could leave the company entirely, they added. In addition, they reported, federal prosecutors have been conducting a criminal probe into whether the company misled investors and regulators.

In response to the sanctions, Holmes said in a statement on July 7, "We accept full responsibility for the issues at our laboratory in Newark, California, and have already worked to undertake comprehensive remedial actions. Those actions include shutting down and subsequently rebuilding the Newark lab from the ground up, rebuilding quality systems, adding highly experienced leadership, personnel and experts, and implementing enhanced quality and training procedures. While we are disappointed by CMS' decision, we take these matters very seriously and are committed to fully resolving all outstanding issues with CMS and to demonstrating our dedication to the highest standards of quality and compliance."

During the 60 days before sanctions take effect, Theranos said it would not conduct any patient testing in the Newark lab until further notice. Also, the company continues to work with CMS, "to resolve and remediate outstanding issues in the Newark lab," and would continue to run its lab in Scottsdale, Ariz. In Arizona, it is outsourcing hematology testing to a reference laboratory in response to the CMS sanction on hematology testing.

Congress Committee Wants Answers from Theranos

IS IT A CASE OF POLITICIANS PILING ON after events have already taken their course? On June 30, three democrats from the House Energy and Commerce Committee sent a letter to Theranos CEO Elizabeth Holmes.

Ranking member Rep. Frank Pallone, along with Diana DeGette and Gene Green, sent the letter to Holmes. It detailed the compliance problems with federal laws uncovered by government agencies.

Pallone, DeGette, and Green then requested that Holmes and Theranos "provide a briefing to committee staff" on a number of issues. One request is for more information on the FDA 483 inspection reports from August and September 2015.

Other requests are for Theranos to provide information on how it is working with physicians and patients "who may have been harmed by inaccurate test results." The letter also asks for information as to how Theranos determined which patients got inaccurate test results and whether this included results from its Edison device and conventional analyzers. Another request is to "explain how Theranos determined that no patients have been harmed due to inaccurate test results."

Given the subpoena powers available to Congress, this effort may create an opportunity for these three members to put more useful information into the public domain. If this effort leads to a hearing in which Theranos officials testify under oath, the disclosures could be more damaging than the CMS CLIA inspection and sanction documents that have been made public.

What is unknown at this point is whether Theranos will appeal any or all of the sanctions CMS imposed on July 7. On pages 7-9 that follow, THE DARK REPORT interviews two experienced lab industry attorneys about the options available to Theranos, should it decide to appeal. TDR

—Joseph Burns

Lab Compliance Update

CMS CLIA Sanction Letter Sent To Theranos Raises Questions

What options are available to lab company given imposition of severe CLIA sections?

CITING PRACTICES THAT JEOPARDIZE PATIENT SAFETY, the federal **Centers for Medicare & Medicaid Services** decided earlier this month to revoke the CLIA certificate that it granted to **Theranos Inc.** to operate a clinical laboratory in Newark, Calif., and to ban the lab company's founder and CEO Elizabeth Holmes from the operating a clinical laboratory for at least two years.

In its letter to Theranos and three individuals on July 7, CMS said it would fine the company $10,000 per day until Theranos corrects all deficiencies. That fine was scheduled to begin on July 12. The ban on Holmes would not be effective until September. Under that ban, Holmes would not be allowed to own equity in or operate any clinical laboratory for at least two years.

If the sanctions against Theranos are imposed, then the company would need to close or divest both CLIA labs it runs, meaning the one in Newark and a second one it operates in Scottsdale, Ariz.

On July 8, *The Wall Street Journal* reported, "If it fails to reach a settlement with the government, Theranos' options are limited." That was confirmed in a statement published the same day by *The New York Times*, which wrote that "Ms. [Jane Pine] Wood, a partner at the firm **McDonald Hopkins**, said that in cases in which there was no settlement and the appeal went to a hearing before an administrative judge, labs 'almost never win.'"

Meanwhile, the CMS letter imposing the sanctions on Theranos has some ambiguities that puzzle those lab professionals who are familiar with the CLIA sanction process. A careful reading of the sanction letter generates at least two questions, as follows:

1. What does the CMS letter say and not say?
2. What options does Theranos have?

Seeking answers to these questions, THE DARK REPORT interviewed Jane Pine Wood and Rick Cooper, lawyers with McDonald Hopkins who have represented a number of laboratories that faced CLIA sanctions.

Editor While Theranos is appealing the decision, does CMS have the option to hold off on imposing the sanctions?

Wood Yes, and, during this period, the company said it would cease running tests in its Newark lab and would rebuild the lab 'from the ground up,' according to some news coverage.

Editor I saw that in *US News and World Report*, Holmes issued a statement, saying, "We accept full responsibility for the issues at our laboratory in Newark, Calif., and have already worked to undertake comprehensive remedial actions."

Wood One factor that works against Theranos is that CMS may have found the quality of its response to the deficiencies CMS cited following its CLIA inspection was inadequate. The result was the imposition of sanctions.

Editor What level of discretion does CMS have in CLIA enforcement?

Wood Under the TEST Act, which Congress passed in 2012, CMS has some discretion on how to apply sanctions under the CLIA statute. The number of sanctions imposed on Theranos is much greater than we typically see, however.

Editor Please explain.

Wood With most of our clients who have received similar letters, a negotiation process with CMS begins after an appeal is filed on behalf of the client. It is not unusual for the negotiated settlement to include the submission of an acceptable corrective action plan, perhaps retraining over a period of time, and the payment of penalties. These are usually situations where CMS knows that the laboratory operations are fundamentally sound. While there may have been errors, such errors were inadvertent and not reflective of systemic quality issues.

Editor So does CMS recognize that, in some cases, the lab's fundamental operation does not place patients at true risk?

Wood Yes, although CMS will almost always refer to an immediate threat to patient care. In these technical violation situations, while CMS uses the terminology of risk to patients, the course of the negotiations makes clear that CMS recognizes that the errors were isolated and inadvertent. These laboratories received very similar letters from CMS that would ban the owner-operator as Holmes would be banned. The sanctions were similar, but everyone knew once we filed the appeal, we would immediately start negotiating the settlement because the lab could fix (or already had fixed) the deficiencies. When we filed a corrective action plan, CMS accepted our response, essentially agreeing that the lab had addressed the errors successfully.

Cooper The fact that, in this type of case, the laboratories' outcomes were positive may not be a good sign for Theranos. If CMS views the Theranos response to date to be lacking in some way or to be largely nonresponsive, that would put Theranos at a significant disadvantage. That could mean that CMS would be much less likely to settle with Theranos because, in effect, the lab has basically antagonized the agency. On the other hand, the letter said that if Theranos chose to file an appeal within 60 days, then CMS would stay the sanctions.

Wood CMS would not have to stay the sanctions but according to the letter from CMS to Theranos, it could stay the sanctions. We've had a small number of clients who have received letters from CMS in which the agency said it would not stay the sanctions. In one of those situations, a lab closed its doors when CMS didn't offer to stay the sanctions.

Editor Would CMS stay the fines?

Wood The other issue Theranos faces is the fine of $10,000 per day. I'm not sure that CMS would stay that fine because, again, the wording in the letter from CMS to Theranos is unclear. In addition, there's the issue of the threatened ban on the owner-operator. We've had clients where CMS imposed the ban on the owner-operators. However, we were able to negotiate so that selected individuals could run the lab but not the entity itself or any of the entity's owners.

Editor Would that be an option for Theranos, given the CMS sanction letter?

Wood From the letter to Theranos, it's unclear if CMS would negotiate with Theranos on this issue. The letter does not entirely make clear if CMS is considering banning Theranos the company or considering banning Holmes and perhaps other executives. Or, is CMS looking at all the individual shareholders of Theranos? The letter does not specify. Another point of distinction is that usually these letters are addressed to the entity and to the lab director only. It's unusual to have a CMS sanction letter addressed to individuals other than the lab director.

Editor Could it be that CMS is seeking to punish the individuals involved, perhaps in part because Holmes has been the face of

the company and has insisted time and again that Theranos' lab operations were fine? At the same time, she has argued that the problems reported in the press were the result of its competitors criticizing its operations. Does that make sense?

Wood Yes, it does, because CMS has discretion under the TEST Act of 2012, which gave CMS more discretion in terms of penalties. Plus, CMS could take into account the fact that certain individuals have culpability.

Editor So, now, assume the sanctions as written in this letter are imposed, then what options do Holmes and Theranos have relative to their ownership of the Newark CLIA lab, which was inspected and found to be deficient, and the Scottsdale CLIA lab which was not found to be deficient?

Cooper Holmes would need to divest her ownership and she would need to remove herself from management of the company since the ban imposed by CMS relates to all laboratories owned by Theranos.

Wood I agree. Holmes could not be an officer or a director.

Editor Does that mean Theranos could continue with its research activities but it would need to divest both CLIA labs?

Wood That depends on how CMS applies the penalties. Will CMS apply the penalties to Theranos, Inc., just to Holmes, or both? That's unclear from the letter.

Cooper The letter is unclear to me on these points as well. If the penalties are against Holmes, then she would have to divest her ownership interests and she could not serve in any management role or board position. But the entity itself—Theranos, Inc.—could continue to operate the Arizona lab where the CLIA certificate wasn't revoked. That's assuming that the sanctions are not against the entity, meaning Theranos, Inc., but are against only the individuals.

Wood That's my reading of it as well. If the sanctions are against the entity, then Theranos as an entity would have to divest itself from the laboratories.

Editor In the letter, CMS said, "We are writing to notify you of the determination by CMS that Theranos Inc., located at the above address," meaning the address for the Newark laboratory, "is not in compliance, has not removed the finding and of the consequent imposition of the following sanctions…" In that part of the letter, Theranos as the corporate entity appears to be the subject of the sanctions. But later in the letter, CMS explains that the three individuals also are named and they would not be able to own a clinical laboratory. So, what does that mean?

Wood I find that part of the letter to be inconsistent. I've looked at it very specifically for this issue. It's unclear. In fact, as we said earlier, this CMS sanction letter is different from other letters we've seen, and Rick and I have dealt with more than a dozen of these letters. Every single time, CMS addresses the letter to the laboratory itself or to the hospital system that runs the laboratory, along with the medical director of the laboratory.

Cooper That's why these negotiations with CMS are so important. If CMS doesn't ban the entity—meaning Theranos—then how will the laboratory community react? If you look up other cases that CMS has had involving the two-year ban on the owner-operator, CMS has gone after the entity. Do you think lab people will ask, "Why is this case different? Why is CMS enforcing CLIA in a way that appears to be inconsistent? Why would CMS go after the entity when it's a not-for-profit health system and not go after the entity when it's a for-profit company, such as Theranos?" I don't have any answers for those questions. TDR

—Joseph Burns

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ADLT Final Rule Creates Tough Questions for Labs

➤Variety of circumstances will affect how labs that offer ADLTs react to the PAMA Final Rule

➤➤CEO SUMMARY: Labs marketing advanced diagnostic laboratory tests will need to watch closely how CMS adjusts what it pays for these tests. Under new federal rules, CMS will set prices close to the market median price level. What's more, a new definition for ADLTs makes a lab's decisions on pricing and contracting more complicated than it has been in the past. Depending on their circumstances, labs will react differently to the various elements of the PAMA Final Rule.

IT'S GOING TO BE A DIFFERENT AND TOUGHER WORLD for laboratory companies that market proprietary molecular and genetic tests. That's the opinion of experts who have studied the final rule governing Advanced Diagnostic Laboratory Tests (ADLTs) that the federal **Centers for Medicare & Medicaid Services** issued in June.

The final rule implements Section 216 of the Protecting Access to Medicare Act of 2014 (PAMA). It had two major parts. One part established the new payment system for the Medicare Part B Clinical Laboratory Fee Schedule. That included lab test price market reporting and THE DARK REPORT provided an analysis of that part of the final rule in its previous issue. *(See TDR, July 5, 2016.)*

The other major part of the final rule defines a new category of assays called ADLTs. These tests are different from other clinical diagnostic laboratory tests (CDLTs) in two significant ways, wrote Charles C. Dunham, IV, an attorney in Houston with **Epstein Becker Green**.

"First, the ADLT must be a CDLT covered under Medicare Part B that is offered and furnished only by a single laboratory," Dunham wrote in a report to EBG's lab clients. "Also, the ADLT is not sold for use by a lab entity other than the original developing lab entity or a successor owner.

➤Criteria for ADLT Status

"Second, the ADLT must be a CDLT that meets one of the following criteria, continued Dunham:

- "The test analyzes multiple biomarkers of DNA, RNA, or proteins combined with a unique algorithm to yield a single patient-specific result, such as a molecular pathology analysis of DNA or RNA;
- "The test is cleared or approved by the **U.S. Food and Drug Administration**; or,
- "The test meets other similar criteria established by the Secretary of the **U.S. Department of Health and Human Services**."

Now That CMS Changed Definition of ADLTs, Lab Companies Need to Take Specific Steps

IN ITS FINAL RULE IMPLEMENTING THE PATIENT ACCESS TO MEDICARE ACT, the federal Centers for Medicare & Medicaid Services set a new definition for advanced diagnostic laboratory tests (ADLTs). Labs seeking to meet this new definition now have specific steps to follow.

"To be designated as an ADLT, a test would need to come from a single laboratory, as defined under the Clinical Laboratory Improvement Amendments of 1988," stated CMS. This definition includes entities that own the laboratory or that the laboratory owns and that may design, offer, and sell the ADLT.

Attorney Charles C. Dunham, with Epstein Becker Green of Houston, wrote that, "This change [in the final rule] allows multiple laboratories located in different locations throughout the country, under common ownership, to qualify as a single laboratory and furnish the ADLT at each laboratory site.

"A lab will need to apply to CMS for ADLT status and submit documentation that demonstrates that the CDLT meets the two-part test to be determined an ADLT," added Dunham. "In the final rules, unfortunately, CMS did not include detailed instructions for lab entities. Instead, CMS said all instructions will be provided through sub-regulatory guidance by Jan. 1, 2018.

"CMS has said it will keep information in a lab's ADLT applications as confidential and proprietary," he noted. "But that information may still be subject to disclosure under PAMA, the Freedom of Information Act, and other federal laws.

"The same data collection periods for new and existing CDLTs will apply to existing ADLTs, except that labs will need to report private payer rates for ADLTs annually using data from the first six months of the year (meaning January 1 to June 31) immediately preceding the data reporting year," explained Dunham.

Now that CMS has issued this new definition of ADLTs, labs must answer a number of questions concerning how to develop pricing and marketing strategies for tests, according to Bruce Quinn, MD, PhD, a senior director with **FaegreBD**, a consulting firm in Washington, DC.

"Probably the most important question a lab must answer is whether its tests could meet the definition of an ADLT," continued Quinn. "If so, the next question is whether the lab wants their tests to be classified as an ADLT."

What CMS Pays for ADLTs

In an interview with THE DARK REPORT, Quinn explained that labs currently marketing or planning to develop multi-analyte assays with algorithmic analyses (MAAAs) will want to watch closely how CMS adjusts what it pays for ADLTs. That is because, under PAMA, CMS will set prices annually and close to the market median price level.

"PAMA and the new definition for ADLTs has made pricing and contracting a lot more complicated," declared Quinn. "It therefore has created a whole new world for labs marketing ALDTs. In many ways, running a lab offering ADLTs will become like a circus act where you must run to keep all the plates spinning."

Depending on their circumstances, labs will react differently to the various elements of the PAMA Final Rule, particularly those elements that involve ADLTs.

"Some lab companies have extensive data on how different payer segments behave and how their hospital and physician clients use their ADLTs," Quinn explained. "But other labs have much less understanding about their clients' use of their tests.

"Labs in the first category are ahead of the game in making long-range pricing and marketing decisions about ADLTs," he noted. "But labs in the second category are making up their marketing strategies as sales opportunities arise. Those labs will need a consultant with a math background to understand the impact of PAMA for them.

Contracting Strategies

"Under the new definition of ADLTs, labs will need to develop more sophisticated contracting strategies," said Quinn. "Labs will perhaps want to craft multi-year pricing strategies as well.

"Currently, most labs with ADLTs instruct their sales teams to sell as many tests as possible," explained Quinn. "Then the labs send out claims. But they don't find out for three months or more if the health plans getting their claims will pay for these tests. Most health insurers don't pay for these tests. However, now that Medicare will establish a public price for ADLTs, that may encourage more insurers to pay relative to those fee schedules.

"The final rule requires labs to triangulate what a lab's ADLT Medicare price is under PAMA and what commercial insurers pay for in-network versus out-of-network claims," he continued. "That is why labs will need to determine an optimal pricing and contracting strategy for each of their ADLTs.

Multi-Year Pricing Strategy

"A lab suddenly faces a multi-year pricing strategy because its prices from commercial payers this year will affect what Medicare pays next year," he emphasized. "And next year, Medicare will publish what it pays for these tests, meaning all commercial payers will know your lab's average price for each test it offers.

"For a lab company that gets about 10% of its lab business from Medicare, that federal price won't matter much," Quinn explained. "But if its Medicare business is 60% or 70% of total volume, then it has some math to do.

"Keep in mind that the lab's pricing and contracting strategies are not likely to remain static over time," he advised. "For example, over time and with more clinical acceptance, commercial payers adopt payment policies for these tests.

"When that happens, the lab's Medicare volume will decline as a percentage of its total volume and that factor will affect the lab's pricing strategy for each of its different ADLTs," he said. "Under PAMA, if a lab accepts lower prices from commercial payers, that will automatically shrink their Medicare price.

"On the other hand, if a lab makes its commercial prices too high, those plans won't contract with the lab and that could cause the lab's commercial revenue to drop to zero, or to low levels because of out-of-network rates.

Consider Going Unlisted

"For some labs, there's another strategy to consider," he advised. "Today, there are still quite a few MAAA tests (Multianalyte Assays with Algorithmic Analyses) that don't have a specific code and the lab might prefer to use an unlisted code.

"This strategy might be more common than many people realize," he added "If a lab does not apply for an MAAA code or for ADLT status, then it may be possible to stay with an unlisted code forever. Some labs have done that for several years.

"CMS will not make a company follow the ADLT rules," Quinn said. "That's because a lab company has to apply to get ADLT status. By choosing not to apply for a test to be an ADLT, the lab could use an unlisted code or a CPT code.

"If a laboratory uses an unlisted code, that lab will remain outside of the PAMA reporting rules," added Quinn. "In that case, there's nothing to do. I don't know how many labs will choose this option but it's a possibility.

"For a lab that has a sole-source test that is not an MAAA, there's still another avenue to consider. That test could become an MAAA if it gets FDA approval. So then the lab has a number of new questions to answer. For one, should the lab seek FDA approval?" he asked.

Costs Versus Benefits

"If the lab seeks such approval, what's the cost to do so and how long will it take?" continued Quinn. "What are the advantages and disadvantages? How will that FDA approval affect what the lab can charge for that test to have its own code and then what affect will PAMA have on that test each year?

"There are many issues to consider. Is it worth the risk of having to stay within FDA labeling?" asked Quinn. "If so, how does the lab make that determination?

"I know several labs that are trying to decide whether to get FDA approval, whether to get an ADLT code, and whether all that is worth the extra costs," he said. "Much of this decision-making will depend on how CMS prices the genomic sequencing codes. If CMS prices the CPT code for 51+ tumor genes at $4,000, then, there's no need to get FDA approval.

"But if CMS prices the CPT code for 51+ tumor genes at $500, then your lab would be bankrupt unless you have your own price as a unique ADLT," observed Quinn. "Then, the question to ask is how much will PAMA pricing affect those genetic CPT codes over time?"

Learning the New Math

As it pertains to ADLTs, the PAMA final rule both giveth some things and taketh away other things. Labs offering ADLTs will gain the benefit of a clear path to obtaining Medicare coverage and payment decisions. But that path has unique obstacles and may complicate how labs negotiate pricing with private payers. TDR

—Joseph Burns

Changes in the ADLT Language Crafted by CMS

THERE ARE SOME CHANGES in the language of the final rule that covers Advanced Diagnostic Laboratory Tests (ADLTs), compared with the draft rule that CMS originally published.

In a commentary about the final rule's language for ADLTs, attorneys at **Covington & Burling LLP**, wrote that, "CMS's proposed rule defined ADLTs as molecular pathology tests and excluded all protein-only tests from the definition. This sparked considerable criticism. Addressing commenter concerns and the recommendations of its Advisory Panel on Clinical Diagnostic Laboratory Tests, CMS modified its proposed definition to align with the statutory criteria. CMS added protein-only tests to its final ADLT definition, but also expressed an expectation that only complex protein-only tests would qualify. As with biomarkers of DNA and RNA, the test's complexity is evaluated through the application of the unique algorithm requirement."

Covington & Burling further wrote, "CMS did not accept commenters' suggestions to rely solely on the statutory language regarding the algorithm requirement. CMS concluded that an ADLT must yield a patient-specific result and provide new clinical diagnostic information that cannot be provided by any other test or combination of tests. The agency finalized its proposal to require that when the test is combined with an empirically-derived algorithm, the test must 'yield a result that predicts the probability a specific individual patient will develop a certain condition(s) or respond to a particular therapy(ies).' CMS also finalized the requirement that the new diagnostic information could not be acquired from other tests."

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Cover-Up Charged After Alleged Surg Path Error

In legal filing, whistleblower says error led to incorrect removal of patient's essential organ

CEO SUMMARY: In an explosive civil case, documents show a pathologist erroneously diagnosed a patient as having cancer of an essential body organ and that the organ was removed unnecessarily, stated an attorney for the whistleblower. The patient has not yet been told of the misdiagnosis or that the essential organ was not cancerous, said the attorney. When the pathologist-whistleblower decided the hospital was not acting to correct the error, he reported the issue to The Joint Commission, the lawyer said.

IN A WHISTLEBLOWER'S LEGAL FILING, a pathologist for the **Kansas University Hospital Authority** claims the head of pathology misdiagnosed a patient as having cancer, causing that patient's essential organ to be incorrectly removed last year.

Submitted July 1, the lawsuit raises troubling questions for the hospital. Court documents show that the pathologist (a former chair of pathology at the institution) challenged the misdiagnosis, claiming the surgery was done in error. The head of pathology and other hospital administrators denied the charges, covered up the misdiagnosis, and refused to conduct a root cause analysis, the court documents show. The petition for judicial review was filed in the civil division of the District Court of Wyandotte County, Kan.

The whistleblower is Lowell L. Tilzer, MD, a pathologist in **Kansas University Medical Center**'s Department of Pathology. He charged that the department chair misdiagnosed a patient's tissue sample as cancerous. The petition does not name the department chair but the current chair is Meenakshi Singh, MD, the Russell J. Eilers, MD, Endowed Chair and Professor of Pathology of KUMC's/KU Hospital's Department of Pathology, said Joseph Colantuono, Tilzer's lawyer. The surgery was done in August 2015, he added.

Report to Joint Commission

Tilzer also has reported his concerns to **The Joint Commission**, a hospital accrediting agency in Oakbrook Village, Ill. As a result of his actions, "…Tilzer has been retaliated against and his job has been threatened…" the petition shows.

"As a result of the misdiagnosis, the patient was erroneously informed that the patient had cancer, and the patient's essential body organ (or a substantial portion of the essential body organ) was removed at the hospital," the petition states.

Court documents further state, "The patient was not told of the misdiagnosis, and was not informed that the essential body organ was not cancerous. For months KUMC/Hospital withheld the correct diagnosis from the patient, and, to the best of Tilzer's knowledge and belief, the patient is still unaware that the patient

did not have cancer." The petition does not name the organ removed, but Colantuono said cancer of that particular organ has a high rate of lethality, and "a patient should not live with the unfounded fear that he or she had a lethal form of cancer."

Hospital Denies All Charges

In its response, the hospital released a statement, saying: "We are not in a position to provide detailed feedback at this time. However, just from a brief review of the allegations made, there is little to nothing in the petition that we believe to be grounded in truth. The patient to whom Dr. Tilzer's petition references was fully informed of the diagnosis and treatment plan after surgery and prior to leaving the hospital and is pleased with the care and clinical outcome."

In a telephone interview with THE DARK REPORT, Colantuono contested the hospital's response: "KU states the patient was 'quote fully informed of the diagnosis and treatment plan after surgery and prior to leaving the hospital unquote.' They do not say that the patient was informed before surgery. Also, KU does not mention that the diagnosis after surgery—that the patient was cancer free—should have been the diagnosis before surgery also."

In what may be the most damaging charges, the petition shows that after being informed of the misdiagnosis, the department chair examined the patient's tissue samples. "The Department Chair did not recognize the difference between acinar cells and islet cells, and covered up her misdiagnosis by placing an addendum to her original report stating the original cancer diagnosis and the normal removed organ matched, thereby concealing her original misdiagnosis and perpetuating the patient's mistaken belief that the patient's removed organ was cancerous," the petition states.

"The Chair of the Pathology Department did not report her misdiagnosis to KU

Who Looks Out For Patient? Accreditors Won't Comment

EVENTS UNFOLDING IN KANSAS CITY demonstrate why the healthcare system is still struggling to cope with how to deal with episodes of medical errors that cause patient harm.

According to a civil lawsuit described in the accompanying story, a patient at a major university hospital had a healthy and essential organ removed because of a misdiagnosis of cancer by the pathologist. The lawsuit alleges this pathologist then changed health records to cover up the misdiagnosis.

The lawsuit's description of the subsequent events alleges that the hospital did not respond to the complaint of the whistleblower pathologist. In contacting the two accrediting bodies for this hospital, The Joint Commission and, for the laboratory, the **College of American Pathologists**, each told THE DARK REPORT that it could not disclose whether it received a complaint involving this patient's care. Nor could it comment if either organization was investigating the care given this patient as a potential medical error.

According to the whistleblower lawsuit and press accounts of this episode, the patient—still unidentified—has yet to be informed of the facts of his or her medical care: that a pathologist wrongly diagnosed cancer in a healthy and essential organ, and it was only after that healthy organ was removed that the mistake was discovered, then covered up by that pathologist.

In such a case, who speaks for the patient? The hospital has a motive to not let the public know about such an alleged medical error. It also doesn't want the liability of a medical malpractice lawsuit. Accrediting bodies, such as TJC and CAP, have concerns that any failure of their assessment teams to uncover incidents of medical errors would count against them with the Medicare program. Thus, who speaks for the patient in cases of medical errors?

Hospital's Chief Medical Officer, Risk Management Committee or Risk Manager," court documents show. *(See sidebar, "Kansas Court Documents Allege Pathologist Falsified Electronic Record to Cover Up Hospital Error.")*

In September 2015, Tilzer urged hospital administrators to correct the errors and inform the patient of the misdiagnosis, but hospital officials did not do so, the petition shows. "KUMC's and KU Hospital's administrators resisted Tilzer's efforts to thoroughly investigate the matter and conduct a review known as a 'root cause analysis;' and KUMC and KU Hospital did not take corrective action," it says.

What's more, the petition says, the department chair continued to sign off on cytopathology cases despite being told not to do so. Also, the chair of pathology continued to make mistakes on these cases, causing actual and potential harm to patients, the petition states.

Failing to get a response from hospital officials, Tilzer sent an email complaint to The Joint Commission in March of this year, Colantuono said. In that complaint, Tilzer explained the issues about the misdiagnosis and the failure to inform the patient, he added.

A Focus on Process, Policies

The commission's Office of Quality and Patient Safety responded by email on April 1 to Tilzer's report of his concerns, saying, "The Joint Commission does not assess specific care of an individual patient, thus we are unable to tell you if appropriate medical care has been provided. Instead, our evaluation focuses on processes and policies that are required within our standards."

The Joint Commission also said it needed Tilzer's written permission to release his name and share his correspondence with hospital administrators. Tilzer has granted that permission, confirmed Colantuono.

After the surgery, other pathologists in the department examined tissue samples from the removed organ and, "established that the patient's essential body organ was essentially normal and was not cancerous," court documents show. "After the post-surgery examination determined that the patient's essential body organ was not cancerous, the pre-surgery tissue sample was re-examined.

Post-Surgery Examination

"The post-surgery re-examination of the pre-surgery tissue sample established that the pre-surgery sample was not cancerous, and that the pre-surgery tissue sample had been misdiagnosed by the chair of the KUMC/KU Hospital Department of Pathology. The removed essential body organ, in fact, was normal, and should not have been removed," the petition states.

Dan Margolies, a reporter for **NPR** station **KCUR**, reported that Tilzer was the pathology department chair for more than six years until he left that position last year and has been a staff pathologist at the hospital for 25 years.

The petition goes into some detail about a meeting Tilzer had with KU Hospital President Bob Page on May 31. During that meeting, the petition says, "Page reprimanded Tilzer and attempted to intimidate Tilzer by:

- "Asking Tilzer if Tilzer wanted to resign (to which Tilzer stated that he would not resign),
- "Berating Tilzer for contacting the Joint Commission,
- "Accusing Tilzer of lying to the Joint Commission (to which Tilzer responded that his statements to the Joint Commission were truthful),
- "Saying that he (Page) was irritated that Tilzer had contacted the Joint Commission,
- "Asking why Tilzer had 'done this alone' (to which Tilzer responded that others in the department were too scared to act), and,

Kansas Court Records Allege Pathologist Falsified Electronic Health Record to Cover Up Hospital Error

IN A PETITION FOR JUDICIAL REVIEW, Joseph Colantuono, the lawyer for whistleblower Lowell Tilzer, MD, explained how administrators at the Kansas University Hospital have attempted to cover up a pathologist's misdiagnosis and incorrect surgery.

"The Chief Medical Officer stated that the [pathology] chair's original diagnosis was correct because two other pathologists signed the report; but the two other pathologists did not agree with the original diagnosis, and the chair simply wrote their names in the electronic medical record," the petition states.

"The Chief Medical Officer refused Tilzer's requests to talk to any other pathologist. The Chief Medical Officer's failure to interview other pathologists perpetuated the cover up of the misdiagnosis by the hospital," court documents show. A root-cause analysis was never done, it adds.

"In early 2016, the chair of the pathology department instructed others to alter hospital records regarding the chair's misdiagnosis, and to remove from records any reference that a root cause analysis was necessary," the petition adds.

As of July 1, Tilzer believed the patient had not been informed of the misdiagnosis or that it was unnecessary to remove the patient's essential body organ, Colantuono said.

- "Describing Tilzer's report to the Joint Commission as 'pitiful' and 'despicable' behavior."

The petition adds, "Tilzer justifiably perceives Page's May 31 reprimand and attempted intimidation as a serious threat to Tilzer's employment and as an attempt to prevent Tilzer from further reporting to The Joint Commission. On June 4, 2016, KUMC inquired whether Tilzer wanted to take a sabbatical."

Request For Discovery

In the petition, Tilzer seeks to "conduct discovery," which Colantuono said would allow Colantuono to confirm the name of the pathologist who signed off on the diagnosis and would reveal the names of two other pathologists who signed the report and whether they confirmed the diagnosis or not, he said. "To our knowledge, approval of the other two pathologists was noted incorrectly," he said.

In addition to The Joint Commission, the **Kansas State Board of Healing Arts**, which is the licensing and regulatory board for physicians, could review the underlying issues in the case if it became aware of it, said Kelli J. Stevens, the board's General Counsel.

"I don't know if our board members are aware of this particular issue," she said. "And, we can't confirm or deny if an investigation is ongoing on that particular issue. Those go directly to our investigative department.

"If an investigation reveals a violation of the Kansas State Board of Healing Arts Act, then a disciplinary petition against that physician's license would be filed and that physician would have an opportunity for a hearing to contest allegations and present their own evidence," Stevens explained. "Then the board makes a determination if disciplinary action is warranted against the physician. Disciplinary action could include a suspension or revocation of the physician's license, or sometimes a limitation on the license," she added. "It depends on the specific findings as to what degree of discipline would be warranted." **TDR**

—Joseph Burns

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Compliance Update

What Is CAP's Role When Lab Has a Serious Medical Error?

IT IS CERTAINLY SIGNIFICANT NEWS FOR THE PATHOLOGY PROFESSION that a respected pathologist—indeed a pathology chair—is alleged to be involved in covering up a misdiagnosis of cancer for a patient who then had a healthy essential organ surgically removed.

And the story doesn't end there. It is further alleged in court documents that, when a whistleblower in the pathology department reported this incident to hospital executives, administrators apparently refused to investigate the incident.

Meanwhile, according to a whistleblower's legal filing, the patient has still not been informed that the diagnosis of cancer was wrong and that a healthy organ was surgically removed as a result of the diagnostic error.

News reports and court documents show that the whistleblower notified The Joint Commission, which accredits **Kansas University Medical Center** and **KU Hospital** where these events are alleged to have taken place. Upon inquiry by THE DARK REPORT, the **College of American Pathologists** confirmed that the clinical laboratory at Kansas University Medical Center and KU Hospital is CAP-accredited.

In an email, CAP said that if it were investigating, "Our investigation would not focus on the misdiagnosis specifically. It would focus on ensuring the laboratory is in compliance with our checklist requirements. CAP has checklist requirements that address pathologists' competency and so we routinely ensure that a laboratory is meeting the requirements in that area and within the quality management area."

R. Bruce Williams, MD, CAP's President-Elect, explained that the CAP accreditation means anyone in the KU laboratory could file a complaint with CAP at any time about any issue of concern. He declined to comment on whether an employee at the KU Hospital had notified CAP. Nor would he comment on whether CAP is investigating the alleged misdiagnosis.

"All CAP-accredited labs are required to post a notice in a prominent place in the lab informing employees of the various ways they can make a complaint about a misdiagnosis or any other patient safety or quality issue," stated Williams. "Also, CAP could start an investigation even without a complaint from a staff member of a lab. If CAP learned of a problem at a lab through the media or some other source unaffiliated with the lab, it would certainly investigate.

No Comment on This Case

"We don't comment on ongoing investigations or on potential investigations," Williams explained. "We can talk about the processes we follow, but would not discuss individual cases because of confidentiality requirements.

"In this case, we would want to ensure that there is a review board or internal process that the lab has to review a case like this," Williams said. "There are cases of misdiagnosis. They don't happen often but when they do, the laboratory involved needs a mechanism to address how that misdiagnosis was made and how to prevent a similar misdiagnosis going forward." TDR

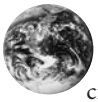
—Joseph Burns

Contact Amy Daniels at accred@cap.org.

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report



Throughout the profession of laboratory medicine, concern is surfacing following publication of a proposed rule by the **Department of Veterans Affairs** (VA) that would expand the authority of Advanced Practice Registered Nurses (APRNs) to supervise and perform laboratory testing. This rule would expand APRNs' authority, currently limited to ordering and interpreting lab tests. In an alert to its members about the proposed rule, the **American Society for Clinical Laboratory Science** (ASCLS) stated, that if adopted as written, the proposed rule would allow an APRN to supervise and direct a clinical laboratory. The proposed rule is §17.415(d)(1)(i) and was posted on May 25, 2016.

MORE ON: *VA Draft Rule*

ASCLS opposes implementation of this draft rule on the grounds that nurses are not educated and trained to work in complex clinical laboratories. ASCLS is encouraging its members to submit comments about the rule. Public comments will be accepted by the VA through July 25, 2016. A little-known fact that is part of this story is how, earlier this spring, according to ASCLS, "the CMS Survey and Certification Group quietly changed the personnel requirement for directing or performing non-waived tests under CLIA. Specifically, CMS said, 'Bachelor's and Associate's degrees in nursing meet the requirement for earning a degree in a biological science for, respectively, high complexity testing personnel and moderate complexity testing personnel.'"

FEW 'CLINICALLY RELEVANT' TESTS

In a news story titled, "ECRI wants to bring transparency to molecular diagnostics, an arena plagued by useless tests," **ECRI Institute**, the 50-year-old not-for-profit based in Plymouth Meeting, Penna., announced that it was establishing a database service for molecular diagnostic tests to help hospitals and physicians identify clinically useful genetic tests. Diane Robertson, the Director of Health Technology Assessment at ECRI, told *Med City News* that, of the 60,000 tests available, "less than 5% of molecular diagnostic tests are clinically relevant."

TRANSITIONS

• Edgar Braendle, MD, PhD, will become the new CEO of **ARUP Laboratories** of Salt Lake City on August 16, 2016. Braendle will leave his current position as Senior Vice President and Head of the Companion Diagnostics Unit of **Novartis**.

That's all the insider intelligence for this report. Look for the next briefing on Monday, August 15, 2016.

★SPECIAL SESSION!★

Designing Optimal Workflow in Molecular & and Genetic Testing Labs: Using Lean Tools in a Dynamic Way

Steve Stone

Managing Director, Argent Global Services

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