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Update on Medicare Lab Price Cuts!

Latest news from Washington, DC on efforts to delay and fix PAMA market price rule.

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...

R. Lewis Dark
Founder & Publisher

2014's PAMA Fix Comes Back to Haunt Big Labs

AS YOU READ THE INTELLIGENCE BRIEFINGS IN THIS ISSUE about lab industry efforts to convince Congress, the administration, and the new leaders of the **Centers for Medicare and Medicaid Services** to delay implementation of the PAMA final rule on market price reporting, keep in mind that—for the nation's two largest public lab companies—there is plenty of irony in current events.

Think back to 2014, when Congress passed the Protecting Access to Medicare Act (PAMA). PAMA's primary goal was to fix the Medicare sustainable growth rate (SGR). Members of Congress needed to identify budget offsets to finance the SGR fix and were in negotiations with the clinical laboratory coalition to identify a mutually-acceptable way for the lab industry to contribute its share of budget offsets to help passage of the legislation.

Several sources familiar with these negotiations say that, independent of the clinical lab coalition, lobbyists for at least one of the two national labs approached senators involved in these negotiations and offered a different way for the legislators to obtain what was calculated to be a reduction in Medicare Part B lab test payments of $2.4 billion over 10 years.

Once the legislators had this budget give-back approach for the lab industry's contribution to the SGR fix, all conversations with the clinical laboratory coalition ceased. Following PAMA's passage into law, the **American Clinical Laboratory Association** (ACLA) announced its support for the legislation.

But the **Association for Molecular Pathology** (AMP) and the **National Association of Independent Laboratories** (NILA) issued statements opposing the law. Their criticisms were essentially the same issues that today, ACLA members **Laboratory Corporation of America** and **Quest Diagnostics** are voicing in their meetings with legislators and government officials in efforts to delay implementation of the PAMA final rule.

That is why there is irony that the public labs find themselves opposing the final rule that CMS crafted to allow it to cut Medicare Part B lab test prices. This is the part of the PAMA law that the national labs are said to have negotiated independent of the clinical lab coalition. And to add to the irony, CMS says that these cuts will total $5 billion over 10 years. That is double the $2.4 billion of budget cuts estimated when PAMA was signed into law in April of 2014! TDR

Delay and Fix Is Message From Labs to Congress

How CMS intends to cut Medicare lab prices is a major concern for clinical laboratory industry

CEO SUMMARY: Only a few months remain before the federal Centers for Medicare and Medicaid Services makes deep price cuts to Medicare Part B clinical laboratory test fees. Before those cuts go into effect, lab associations and lab professionals are educating members of Congress and the new administration about the bias and flaws in CMS' PAMA final rule. The message is that it is best to delay implementing the price cuts and fix the problems in the rule. It is still uncertain whether a delay can be arranged.

COMING TO YOUR LAB in less than 150 days are deep cuts to Medicare Part B lab test fees. The federal **Centers for Medicare and Medicaid Services** is scheduled to implement the most financially-disruptive cuts to clinical laboratory fees in more than 20 years.

If the final rule under the Protecting Access to Medicare Act is implemented as written, experts who understand laboratory medicine and its role in the healthcare system say the rule will have devastating consequences. For one, it will reduce access Medicare beneficiaries have in smaller cities and rural areas to clinical laboratory testing.

The first consequence comes in the short term. Cuts to Medicare lab test fees—which CMS and the **Office of Inspector General** estimate will be about $400 million in 2018—will cause financial havoc to two types of medical laboratories. The first type is the small, independent lab companies that have between $2 million and $20 million in revenue. Many of these labs primarily serve nursing homes. Medicare Part B lab tests make up 40% to 80% of their total revenue.

For these labs, 10% cuts to the Medicare prices of the highest-volume, automated lab tests will take them from break-even or a small annual profit to a significant financial loss. In a study, the **National Independent Laboratory Association** documented that these labs typically operate with net profit margins of 2% to 4%. The decline in Medicare revenue associated with the Part B fee cuts will cause these labs to shut their doors,

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file for bankruptcy protection, or sell out to a larger lab company.

The second type of lab vulnerable to the Medicare lab price cuts is in community and rural hospitals. As with small independent lab companies, these labs usually serve nursing homes and patients in their small towns and rural counties. Medicare Part B lab tests represent a high proportion of the outpatient revenue these labs earn.

Cuts at Rural Hospitals

Reductions in Medicare lab test fees will cause the hospitals operating these labs to slash the number of lab tests they perform in-house, which affect inpatient and outpatient care. More significantly, these hospitals will be forced to stop serving the nursing homes in the small communities and rural areas they serve. The expense of sending phlebotomists and couriers to these facilities cannot be recouped should CMS cut Medicare Part B lab test prices on Jan. 1.

Thus, in the first 36 months from Jan. 1, 2018, the PAMA rule price cuts will cause many of the nation's small community labs to shut down. As this happens, patients and physicians in these cities, towns, and rural areas will lose local access to clinical lab tests.

Of equal significance, the nursing homes in these communities will lose the only local laboratories that provide testing. As noted in THE DARK REPORT's earlier coverage, large public lab companies exited the nursing home business in the 1990s because they considered it unprofitable. Since then, small community labs have filled that need, providing nursing homes with almost 25 years of unbroken service.

In the 36 to 72 months following Jan. 1, 2018, the Part B fee cuts will cause the nation's smaller cities, towns, and rural areas to lose the independent labs and the community and rural hospital lab services that they have relied on for decades. The loss of revenue from Medicare price cuts will cause these labs to close or sell out to other lab companies.

The question that officials at CMS who designed the PAMA market price rule have not answered is: How will they address this problem when it happens? It is short-sighted of bureaucrats to pursue near-term savings on what Medicare spends on lab tests (which is about 3% of Medicare's total healthcare spending), and not see the dilemma that looms in a few years as rural and community hospitals, nursing homes, and physicians in these areas lose access to essential lab tests.

As Jan. 1 approaches, several lab associations and companies are meeting with Congress and officials in the new administration. Their message is simple: CMS' PAMA market price reporting rule is deeply flawed. Therefore, the smart course of action is to delay implementation of the final rule and the price cuts to allow time for government officials and clinical lab professionals to work together to address these problems.

Delay and Fix PAMA Rule

Leaders of most national medical laboratory associations are calling on their members and all clinical laboratory managers, scientists, pathologists, and clinical chemists to contact their senators and representatives with a simple message: delay and fix the PAMA market price rule.

The stories that follow provide the latest information about how different lab organizations are working to educate members of Congress and the new administration about the need to delay and fix a biased and deeply-flawed PAMA market price reporting rule.

On pages 5-8, the biases and flaws in the final rule are identified and described. Next, on pages 9-12, the recent comments by certain public lab company executives about their company's respective views on the PAMA final rule are presented. TDR

NILA Asks Labs to Speak about PAMA Rule's Flaws

Lab directors urged: tell Congress to delay PAMA implementation and its revision of rates

CEO SUMMARY: In a call to action, the National Independent Laboratory Association is urging lab owners, lab managers, and pathologists to educate their members of Congress about the biases and deep flaws built into the final rule for PAMA market price reporting and how the rule will result in reduced access to clinical lab testing services for many Medicare beneficiaries. It is also providing an analysis of the problems with the final rule that lab leaders can use when they speak with members of Congress.

IT'S TIME FOR LAB DIRECTORS AND PATHOLOGISTS TO TELL CONGRESS that allowing the federal **Centers for Medicare and Medicaid Services** to implement the final rule on market price reporting under the Patient Access to Medicare Act (PAMA) could have drastic implications for labs, physicians and Medicare beneficiaries.

To help inform lab professionals about the specific problems with CMS' final rule for PAMA market price reporting, THE DARK REPORT has published some of the lab industry's most detailed analyses of the rule, its implications for labs, and why it has a serious bias that will reduce access to clinical laboratory testing for Medicare beneficiaries in many communities.

On July 17, THE DARK REPORT produced a well-attended webinar on the most recent developments involving the PAMA Part B fee cuts that will start on Jan. 1. One of the experts who addressed the webinar was Julie Scott Allen, Senior Vice President of the **District Policy Group** at **Drinker Biddle and Reath**. Allen represents the **National Independent Laboratory Association** (NILA).

In her presentation, Allen explained the multiple and serious problems that CMS wrote into the final rule and outlined how the clinical laboratory profession is working to educate members of Congress and the new administration about the flaws in the rule and why it is necessary to delay and fix the rule.

Message Is: Delay and Fix

Allen pointed out that a delay would allow time for CMS to work with Congress and the clinical laboratory profession to address the flaws and biases in the final rule as currently written. Revisions are needed to protect Medicare beneficiaries' access to lab testing, avoid severe financial disruption for community-based, physician office, and hospital laboratories, and help Medicare achieve savings on Part B clinical laboratory spending.

One of the most significant problems with the final rule is that it excludes

almost all of the nation's 5,000 acute care hospital labs from reporting market-based laboratory prices, Allen explained. Also, it has limitations that threaten to exclude complete rate information and accurate data from physician office laboratories (POLs) and community-based laboratories.

This bias is a huge concern for the clinical laboratory industry. "How can CMS conduct a valid study of the market prices that private health insurers pay for lab tests if it excludes thousands of labs from reporting their private payment rates and those labs serve millions of patients every day?" she asked.

"Those hospital labs, community labs, and physician office labs are essential providers of lab testing in rural areas, towns, and smaller cities throughout the United States," she added. "Private insurers recognize this value. That is why, for decades, private health insurers have paid these labs with test prices that take into consideration higher costs per test, as well as the greater costs these labs have for phlebotomy and specimen transport.

"By requiring only the lab organizations in the United States that have the highest volumes of tests to report their market price data, Medicare officials have introduced a troubling bias into the market price study," Allen explained. "These larger labs have substantially lower costs per test because of their high volumes and, consequently, health plans pay many of these labs lower prices."

Two Major Flaws In Reporting

Next, Allen explained to webinar attendees the two major flaws in the data collection and reporting process. "These flaws not only introduce serious problems in how CMS can use the data for its market price analysis, but they put those labs required to report at high risk of onerous fines and penalties should Medicare auditors determine that they failed to gather and report their private payer price data properly according to the requirements in the final rule."

Also of importance, there are two major flaws with the final rule's requirements in how labs are to collect and report their private payer price data. One is the retrospective reporting process coupled with a short amount of time that CMS allotted for data collection and reporting. The second is the inherent assumptions about how health insurers remit payments to clinical labs—which is by no means consistent and too frequently do not constitute the final and complete payment rates, she said.

Insufficient Time Allowed

"Congress never deliberated on the requirements included in the PAMA statute," Allen explained. "CMS is implementing PAMA in a manner focused only on deriving the highest amount of up-front savings through maximum fee reductions," she said. "No one is addressing the long term effects this rule will have on patient access or market competition.

"There will be significant up-front reductions to the fee schedule, which will result in savings initially to Medicare reimbursement rates," she added. "But those reductions will result in a far greater cost to Medicare down the road. When laboratory professionals talk about their concerns, they need to emphasize this point with members of Congress and the administration.

"In conversations with Congress and their staff, lab directors need to explain how little time labs had to collect and report the market-price data," she said. "The final regulation did not come out until June of last year. Then CMS released guidance in September 2016 that included the codes that laboratories needed to report," she added. Therefore, labs had barely 3.5 months to start reporting data on Jan. 1 of this year.

"CMS required labs to respond to a retrospective reporting process," continued

Allen. "Thus, labs were forced to go back into old records and attempt to get those records to correspond to new requirements that look significantly different from a lab's billing records.

"NILA's member labs told us that this whole experience quickly became, at best an expensive process and, at worst one that was impossible to comply with," she added.

"Another serious problem that labs faced was errors in the data," Allen explained. "Under the provisions of the final rule, labs had to certify the accuracy of the data they were reporting. But given that the process was complex and labs had little time to do it properly, lab directors had serious concerns about the accuracy of the data they were required to submit to CMS. At the same time, labs faced the possibility of serious fines and penalties if they submitted false data or did not submit data.

"These two problems—having little time and the fear of reporting inaccurate data—put labs at a disadvantage," she explained. "On top of those concerns, it is extremely difficult for a lab to set up rules to do a retroactive reporting process. One reason this is difficult is because most laboratories don't have in-depth IT systems or the ability to reconstruct their systems to pull the data together efficiently.

Expensive Manual Review

"For many labs, including NILA members, this process required a manual review of payment data," she said. "A manual review of paper claims was the only way for most labs to pull the data together for submission. That means labs had to spend thousands of dollars either to hire additional help or take their staff off of current billing processes to engage in the PAMA reporting process.

"Another significant issue that lab directors need to explain to their senators and representatives is that many labs do not have formal contracts or agreements with every health insurer," Allen said. "Often, there is no contract rate or fee schedule for a lab to compare against what

A Serious Need to Explain the Threat From Price Cuts

MEMBERS OF CONGRESS ARE UNLIKELY to understand three serious threats that the final rule under the Patient Access to Medicare Act poses to clinical labs, physicians, and Medicare beneficiaries, explained Julie Scott Allen, who represents the National Independent Laboratory Association.

These three threats include loss of access to local lab testing services by Medicare beneficiaries, particularly those living in smaller cities and rural areas; the financial collapse and bankruptcies of many of the nation's smaller labs that service these communities; and, the risk of severe penalties for labs that are later determined to have submitted inaccurate private payer market price data.

This is why lab directors should articulate these three problems to the members of Congress in their districts, while also explaining the threat to their businesses as employers and as an essential part of the public health system, Allen said. "Pathologists and lab directors should demand a delay of PAMA to ensure these problems are fixed," urged Allen.

"I encourage you to raise your voice and be active in this discussion. Make certain that there's an understanding—both in Congress and in the Trump Administration—about the implications of the PAMA rule on the communities you serve," commented Allen. "This program has implications for your customer base, meaning the physicians and patients you serve, and there are serious implications on public health overall.

"More convincing needs to be done to persuade Congress that the implications of the revised Medicare Part B lab test fee schedule could be quite grave," she said.

a payer remits after a laboratory submits its bills. This problem is even more challenging for labs that are out-of-network.

"Therefore, to pull the data together, labs literally had to do a manual review of paper claims to justify differences in how different plans pay and how different plans within the same insurer pay for certain tests," she said. "All of these issues compound the fear of reporting errors.

Lacking Formal Contracts

"Here's an example: When a payer issued a remittance that bundled individual lab tests together into a single payment, PAMA rules prohibit the reporting of bundled payment rates," Allen said. "In addition, CMS told laboratories not to report data that they had to pro-rate in their systems.

"But with a retroactive reporting process, labs had no time to establish a mechanism for identifying which data in their systems was pro-rated or paid in a bundled payment basis versus which data wasn't pro-rated or paid in a bundle," Allen said. "Laboratories concerned about Medicare audits submitted the data anyway because their records reflect those payments, and there was no way to extrapolate those payments from the full data set reported.

"Many labs struggled with what one might assume was the more basic question: Am I required to report?" commented Allen. "There was much discussion among members of the hospital lab community about which ones needed to report and which ones didn't need to report.

Hospital Labs with NPIs

"NILA has learned that even when some hospitals had their own national provider identification number (NPI) for hospital outreach laboratory work, many times they didn't bill through their NPI," she said. "Instead, they did an analysis of whether they had to report based on the health system they belong to. Often, labs in this situation would conclude that they didn't need to submit data.

"Also, it's important to note that the PAMA statute allowed the secretary of the federal **Department of Health and Human Services** to establish a low-volume or low-expenditure threshold so that CMS could allow certain labs not to report their data," she added.

"In the final rule, CMS used this option to establish a low economic threshold, rather than a low volume threshold," she said. "By establishing a low economic threshold, according to the Office of Inspector General, CMS effectively eliminated 96% of physician office labs from reporting and an estimated 52% of independent laboratories from reporting.

"For all these reasons, we encourage lab professionals and pathologists to contact their elected officials in Congress to discuss the significant bias and flaws in the PAMA final rule," Allen concluded. "To be effective in these conversations, lab managers should be prepared to discuss how drastic reductions in reimbursement from a skewed and overly burdensome federal regulation will affect their ability to employ a skilled workforce and care for patients in their communities."

Contact Elected Officials

Every clinical laboratory manager, lab scientist, and pathologist is encouraged to contact their senators and representatives to educate them about the need to delay and fix the PAMA market price reporting final rule. Such contacts will be timely and will reinforce the ongoing educational efforts that are happening in Washington, DC, as representatives from various lab associations and companies meet with elected officials and policymakers. This high-stakes issue needs to be fixed. TDR

—By Joseph Burns

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LabCorp, Quest Talk about Medicare Lab Price Cuts

In calls with analysts, both laboratory companies explain how lab industry is working with Congress

CEO SUMMARY: In an effort to forestall CMS' efforts to implement the PAMA final rule on market price reporting, Laboratory Corporation of America and Quest Diagnostics are meeting with members of Congress, officials in the administration, and the new leadership of CMS. During recent conference calls, executives at both lab companies shared insights about these meetings and the possibility that there could be a delay in implementation of the Part B price cuts.

DURING THEIR RESPECTIVE SECOND QUARTER CONFERENCE CALLS with financial analysts, executives at **Laboratory Corporation of America** and **Quest Diagnostics** spoke about the PAMA market price reporting rule and lab industry efforts to delay and fix the rule before a new Medicare Part B clinical lab fee schedule is implemented Jan. 1.

Lab industry representatives are having ongoing meetings with members of Congress, with the new administration, and with CMS officials to discuss industry concerns about the PAMA final rule. Comments made during the two conference calls provide lab administrators and pathologists with an understanding about the possibility that implementation of the new Medicare Part B lab fee cuts could be delayed.

Efforts to Delay and Fix

During their conference calls, the executives at the two lab companies discussed the coming Medicare Part B lab test price cuts and efforts to work with Congress and the new administration to fix the most egregious aspects of the PAMA market price reporting rule crafted by Medicare officials.

Quest Diagnostics Incorporated
Comments about CMS Final Rule

On July 25, Quest was first to conduct its quarterly earnings conference call. In his opening comments, Quest CEO Stephen H. Rusckowski said, "I'd like to briefly discuss PAMA. This month, a number of ACLA board members met with the executive branch as well as key members of the Senate Finance Committee and both the Ways and Means and the Energy and Commerce subcommittees to reiterate our belief that the current regulation effectively excludes hospital outreach labs, which are a significant segment of the laboratory marketplace.

"Last month, our trade associations sent a letter to CMS recommending it postpone the calculation and publication of the new clinical lab fee schedule," continued Rusckowski. This would give CMS time to "redefine the definition of the applicable laboratory [for market price

reporting] to ensure it includes hospital outreach laboratories."

The lab trade associations recommend that CMS, after "...gathering data from hospital outreach laboratories, publish new clinical lab fee schedule rates effective not earlier than July 1, 2018," he stated. "While we support reform of the Medicare payment system, we believe any modification [of Medicare Part B lab prices] should be market based and appropriately include all applicable independent and hospital outreach labs.

Strong Case To Congress

"At this point, we have made a strong case to CMS and Congress," emphasized Rusckowski. "While we continue to believe that CMS has not carried out the congressional intent of PAMA, we recognize that a new [Part B] clinical laboratory fee schedule could be in place by January of 2018 and we will be prepared."

Later, in an answer to an analyst's question, Rusckowski stated, "We have shared with them [CMS] that we believe several things are going on with the data they had collected. One is they haven't included all the [private health insurer price] data from those laboratories from whom they buy, typically hospital [lab] outreach.

"We believe their approach still limits the size of the sample, and we shared that," he added. "This has been also reinforced by the **Office of the Inspector General** when it said [in a report last fall] that only 5% of the laboratories [in the United States] are being asked to submit data, which is about 69% of what they [Medicare] actually buy from.

"The second is what we have heard from some of the smaller laboratory associations that affect some of the data input [to CMS]," he said. "So we have shared this with them because some of the smaller laboratories did not have good access to retrospective data.

"Our concern is that if they [CMS] use that data for the basis of publishing a tentative clinical lab fee schedule in the fall, it won't be right," noted Rusckowski. "So our strong recommendation to them—and we have got support from Congress broadly, many different leaders of Congress as well as the **Centers for Medicare and Medicaid Services**—we believe the best thing for us all is to take some time to get it right. So our recommendation is to postpone it [implementation of the final rule].

"We have made a recommendation of how we believe they could collect the [expanded sets of] data. That will take some time," he added. "We think if they [CMS] work aggressively, they possibly could publish the new clinical and fee schedule no earlier than July of 2018.

"So that is the path we are on," he said. "...but [we are] working hard because we believe it [the rule as currently written] does not reflect the impression or intent [of Congress with the PAMA statute] to get a full sampling of the marketplace and get that data in a good form and get good quality data to establish a rate. So we are pushing that in a big way across the trade association."

Laboratory Corporation of America
Comments about CMS Final Rule

During LabCorp's conference call which took place on July 27, financial analysts had several questions about the PAMA final rule. In response, LabCorp executives offered comments.

"We sent a letter to CMS, met with the CMS Administrator, have had multiple legislative and executive branch meetings, [all to] explain that the data set that CMS is reviewing includes only approximately 5% of the [outreach lab test] volume that goes through hospital labs" stated David P. King, CEO of LabCorp.

"As we know, there is a significant delta between what hospitals get paid by commercial insurance and what independent laboratories get paid," he noted. "So, as we've said from the very beginning,

Medicare Beneficiaries in Rural Areas, Small Towns at Risk of Losing Access to Laboratory Testing

IN MEETINGS WITH MEMBERS OF CONGRESS AND THE ADMINISTRATION, representatives of the clinical laboratory industry are communicating their concerns about the consequences of implementing Medicare Part B lab test fee cuts that are based on a flawed study of private payer lab test prices.

During their second quarter conference calls, the CEOs of Quest Diagnostics and Laboratory Corporation of America described some of the problems for Medicare beneficiaries that CMS will create if it implements its PAMA final rule as written.

Quest Comments

Quest CEO Stephen H. Rusckowski said, "We have also met a couple of times with the leadership at CMS. The leadership at CMS understands this well, understands that the current approach [the CMS final rule] has issues associated with it. Our simple messaging on this is take the time to get it right. We continue to support the idea of paying or having CMS pay market-based pricing. To get the right [private payer lab price] data, take the right approach to bringing on those rates is important for all of us.

"And what we remind them is the reason why we have PAMA is reflective of the law's name, that it is called the Protecting Access to Medicare Act, and it's important for Congress—and it's part of their congressional [intent]—not to just pay at the lowest rates, but to make sure that they pay for what they use," continued Rusckowski.

"And the reason for this is there are many parts of this country that are not served by the large national laboratories," he said. "The concern that they [legislators and government officials] are now aware of is, if in fact, this is not done in the right way, [Part B lab test] rates could be cut, smaller labs that are very necessary in smaller rural areas—that in some segments of the marketplace are providing the majority of lab testing [for Medicare beneficiaries]... could be substantially cut. The example is what's happening in nursing homes, where a majority of their testing is basically the most routine tests that are done by many small clinical laboratories all over this country."

LabCorp Comments

LabCorp CEO David P. King commented that, "I would also say that I think that would be—from my perspective—a serious mistake if CMS does it. I don't think it's been well thought through. I don't think they've thought about the implications.

"I was just reading an article that came out in *CAP TODAY*... [about] a hospital system in New Mexico that serves 125 nursing homes in highly rural areas," he noted. "And if there are significant cuts to what they get paid by Medicare for those services, we're going to see significant beneficiary access issues in my view.

"...this statute was called the Protecting Access to Medicare Act, not the Diminishing Access to Medicare Act," emphasized King. "We made that point to CMS and they told us that Congress didn't tell them to take it as a consideration in the statute.

"So this is a very, very important policy decision that CMS is going to make," concluded King. "I hope that they, and Health and Human Services and the legislative branch will be able to come to some understanding that they need to do this right as opposed to just do it and get it done with."

Congress intended to have a market-based approach, and the rule that CMS wrote—and we said this in our initial comments of the rule and we've said it ever since—the

rule that CMS wrote looks at a highly-selective portion of the clinical lab market in a way that doesn't reflect the true market.

Requested Six-Month Delay

"So we've asked for a six-month delay for them to fix the rule to allow for inclusion of the hospital outreach laboratories and the commercial pricing [for those labs] that is not included [in the current PAMA final rule]," stated King.

"I don't have insight on whether that would be permitted, other than to say that ACLA and all of our colleagues in the industry, other laboratory trade associations, and the hospital trade associations have been involved in discussions with CMS and with the legislative and executive branches about trying to make this proposal work the way that it was intended to work," summarized King. "So I am hopeful that we will get a better resolution than what we have seen to date."

Another interesting point emerged during the question-and-answer session of the conference call. Apparently LabCorp encountered problems with the CMS website when it attempted to upload its lab price data. It said that it requested that CMS extend the reporting deadline. If true, this means that CMS recognized that it was unable to get data from a major lab company that was expected to provide it with the lowest market prices.

CMS Extends Deadline

"When we were having trouble loading the data in the portal, we made multiple requests for an extension of the deadline," King explained during the conference call. "We didn't hear [from CMS] for quite a while, and then they agreed to extend the deadline, pretty close to the initial deadline, which, as I recall, was in March, and they gave us a 60-day extension."

Do the two CEOs have any expectations that, among Congress, the administration, and the new leaders at CMS, that a decision will be made or an action will be taken to delay implementation so as to allow time to fix the problems with the PAMA final rule?

During his conference call, LabCorp's King said, "We're optimistic that they'll respond in a timely fashion. I will say, though, we are obviously preparing for next year [2018] on the assumption that there is not going to be any change in the implementation [of the existing PAMA final rule] and that we need to take the appropriate actions to manage whatever will come out in September."

Optimism And Uncertainty

That optimism, tempered with uncertainty, was also true in comments from Quest's Rusckowski. "We remind Congress and we remind CMS of where we started and why we believe paying market-based price is quite important," he commented. "So, what I'll share is we think they are very, very responsive to listening to our concerns. We realize there is an element of administration. They realize what was put in place was put in place over the last couple of years. They realize there is an opportunity to work with us to get it right. So we remain hopeful but I can't handicap the possible outcome."

These comments from the two lab companies' conference calls with analysts provide useful insights for pathologists and lab administrators about the efforts of the clinical lab industry to get Congress, the administration, and CMS leadership to understand the serious biases and flaws that exist with the existing PAMA market price reporting rule.

It is important for lab managers and pathologists to contact their senators and representatives to express concerns about the PAMA final rule. Legislators pay attention to the largest employers in their states and districts, as well as issues that might reduce access by Medicare beneficiaries to health services. Clinical labs certainly employ lots of people, and rural access is always an issue of concern! TDR

Issues Encountered with Anthem's Pre-approval

Laboratories, physicians report challenges with Anthem's genetic test pre-approval program

CEO SUMMARY: Since Anthem and AIM Specialty Health began a prior-authorization program for genetic testing July 1, a Northeast lab has not had any genetic tests approved through the new system. Physicians told the lab that the steps required for prior authorization were disruptive. Those doctors who regularly order genetic tests had not been trained in how to use AIM's genetic testing pre-authorization system and said their training was not scheduled to begin until this month.

LABORATORIES OFFERING MOLECULAR AND GENETIC TESTS have keen interest in the genetic test pre-authorization requirements instituted by both **Anthem** and **UnitedHealthcare** in recent weeks. At stake is access to Anthem's 40 million beneficiaries and the 31 million beneficiaries insured by UnitedHealthcare.

Physicians and genetic testing laboratories share similar concerns about genetic test pre-authorization requirements. They want the procedures and tools that health insurers use in their genetic test pre-authorization programs to be simple to use, speedy, and consistent with established clinical guidelines for genetic tests. Yet, so far, lab directors said, the Anthem program fell short of these goals.

In April, Anthem announced its pre-authorization program—called The Genetic Testing Solution—for genetic tests. **AIM Specialty Health**, a division of Anthem, administers the program. *(See TDR, June 26, 2017.)*

Just weeks later, on June 30, UnitedHealthcare said it would be launching its own pre-authorization initiative for genetic tests. UHC has since said it would delay implementation of that program until Nov. 1.

The actions of the nation's two largest health insurers confirm a prediction THE DARK REPORT made that health insurers' efforts to require pre-authorization of genetic test orders would soon be a mainstream requirement. The similar actions by Anthem and UnitedHealthcare means that by November, 71 million members will be subject to pre-authorization requirements whenever their physicians order genetic tests for them.

Aiming for Ease of Use

Following Anthem's announcement in April that it would launch a genetic test pre-authorization program, THE DARK REPORT interviewed Karen Lewis, Director for AIM's Genetic Testing Solution.

Anthem and AIM knew of the need for its processes to be easy for physicians to obtain pre-authorization, she said. A benefit to the lab that performed the genetic test is that pre-authorization would allow the lab to know—in advance

of service—that its claim for that genetic test would be paid, she added.

To assess how AIM's Genetic Test Solution is functioning in the early weeks of its launch, and whether it is meeting the needs of physicians, labs, and patients, THE DARK REPORT has heard from a number of genetic testing labs.

A Challenging Process

Executives at several genetic testing lab companies said the program's launch has not gone smoothly in its first month of operation. In an interview with THE DARK REPORT, representatives of one genetic testing lab described Anthem's new pre-authorization process as needlessly complex and difficult to use.

The representatives of this lab, who asked to remain anonymous, described two issues of concern. First, since the program began July 1, the lab has not had any genetic tests approved through the prior-authorization process. Second, physicians are asking the lab to participate in the prior authorization program, but Anthem and AIM have said only physicians can use the pre-approval program. Also, physicians told the lab that doing the prior authorization for lab testing is disruptive. For example, one physician's office needed to call AIM and the lab multiple times to receive approval for what was a simple process previously, the lab representatives said.

Physicians who regularly use the lab's genetic tests had not been trained in how to use AIM's genetic testing pre-authorization system, they added. Physicians told them AIM had not scheduled such training to begin until this month (August), more than 30 days after the pre-authorization requirement became effective.

For this national genetic testing lab company, the AIM program has not improved efficiency and is the source of much frustration. The lab representatives added that other lab test management programs allow labs to submit the prior authorization forms for the physicians' office, the lab's representative said.

Keep in mind that the comments in this article are based on one lab's experience only. Other labs may have had a more positive experience. THE DARK REPORT is interested in interviewing lab directors and other staff in genetic testing labs who have had experience with Anthem's Genetic Testing Solution.

The experience of this genetic lab company is typical, however, when health insurers and health systems attempt to use software algorithms to manage lab test utilization of physicians.

The VP of sales for the national genetics lab described the Anthem program as having similar issues as those identified when UnitedHealthcare implemented its laboratory benefit management program in Florida. **BeaconLBS,** a subsidiary of **Laboratory Corporation of America,** manages that program. Physicians and lab directors complained about that program, which began in 2015, saying it was complex, time-consuming, and difficult to use. Just a few of the 79 lab tests requiring pre-notification or pre-authorization in the BeaconLBS system are genetic in nature.

"For the Anthem program, the physician must enter AIM's website, set up an account, become familiar with the different testing protocols, select the genetic test, and then answer a series of questions before the system issues an approval. Physicians have told the lab that the questions do not always apply to the genetic tests being requested.

Unrelated Questions

"The questions are more complex and relate to the specific process the lab undertakes for the testing and they require the physician to list all the genes being tested along with the CPT and diagnosis codes," said the sales VP. "It's basically a manual administrative process that physicians must complete to get the genetic test order authorized. Once that step is done, Anthem will pay the lab performing the genetic test."

Calling an insurer for approval can delay patient care and inconvenience the

patient. This can affect patient satisfaction scores negatively, the sales VP noted.

"For most labs today, physicians draw the patients' blood and send it into the lab the same day," he said. "The lab handles the specimens and begins the prior authorization process.

"Under the new program for Anthem and AIM, the physician sends the patient away from the office, begins the steps for prior authorization, and hopes to get all the information needed for pre-approval before the patient returns for specimen collection," the sales VP said. "The window of time for appropriate testing varies, thus physicians are concerned that they will not have the approval before it is needed.

New Administrative Burden

"Not only does the process create a new administrative burden for the physician, but the steps of first placing the test order and second receiving the results happen outside of the physicians' electronic health record systems," he continued. "That means the pre-authorization is not part of the normal electronic flow of lab-test ordering for the physician. It also means the new system creates additional work because doctors are entering the same information twice."

This lab's case manager works closely with physicians trying to obtain authorizations on the lab's behalf because the lab staff cannot be involved in ordering, she said. Having the physician get the authorization slows the ordering and can affect patient care, noted the lab's case manager.

"By adding days until the genetic test actually gets run, the patient may need to wait four to six weeks before getting the results," she added. "If we're talking about cancer genetics, that could be a significant delay that would affect medical management and perhaps a pending surgery."

Another problem the lab has is a lack of understanding among AIM staff of Anthem's medical policies, the case manager said. "Recently we've seen some denials where AIM is misinterpreting Anthem's medical policy and denying tests that clearly should be approved. At the same time, other patients receive approval presenting the same medical data to another AIM reviewer," the case manager said. "As a lab, that's frustrating." TDR

—Joseph Burns

Anthem Seeks End to Inappropriate Testing

WHEN ANTHEM AND AIM SPECIALTY HEALTH ANNOUNCED their pre-approval program for genetic tests in April, the companies cited research showing that 30% to 50% of such tests may be ordered inappropriately.

In addition, the companies said physicians today can choose from among more than 70,000 genetic testing products and that clinical labs introduce an average of 10 new products every day. This causes health insurers and providers to struggle to keep pace with the demand for complex and costly genetic and molecular assays. AIM Specialty Health, a division of Anthem, is managing the program.

Physicians in all 14 states where Anthem operates are required to follow Anthem's protocols for ordering any of the tests listed in its 45 genetic testing guidelines. "The Genetic Testing Solution promotes appropriate use and provides education that addresses the clinical and financial complexities of genetic testing," Anthem Blue Cross said last week in its press release announcing the program.

In addition to California, Anthem's divisions serve members in Colorado, Connecticut, Georgia, Indiana, Kentucky, Maine, Missouri, Nevada, New Hampshire, New York, Ohio, Virginia, and Wisconsin.

The program affects Anthem members who have insurance through their employers in fully-insured and self-insured companies. Anthem plans to add its members in national accounts next year, Anthem Blue Cross said.

Lab Acquisitions Update

LabCorp Spends $1.2 Billion to Acquire UK's Chiltern

LabCorp will pair Chiltern with Covance, another contract research organization it acquired in 2015

IT IS THE NEXT STEP to continue diversifying its business away from clinical laboratory testing. On July 31, **Laboratory Corporation of America** announced that it would acquire **Chiltern**, a specialty contract research organization in London and Wilmington, N.C.

LabCorp valued the all-cash transaction at about $1.2 billion and said it would fund the deal with a combination of bank financing and bonds. The acquisition will close in the fourth quarter pending regulatory approvals.

It's significant that the acquisition allows LabCorp to make Chiltern part of its **Covance** division and thus strengthen its ability to combine diagnostics and drug development. Like Chiltern, Covance is a contract research organization that LabCorp acquired in February 2015. Covance has 16,100 employees worldwide (including 9,100 in the Americas), while Chiltern is much smaller with 4,500 employees worldwide (including 2,000 in the Americas).

The two companies fit together well, analysts said, because Covance serves some of the top biopharma companies and Chiltern works mostly with mid-market and emerging companies. In the past five years, it has produced 1,800 studies for companies in 87 countries, LabCorp said.

This year, Chiltern will have revenue of about $550 million and adjusted EBITDA of approximately $95 million, LabCorp predicted.

At a price of $1.2 billion, the sale suggests LabCorp paid 2.2 times Chiltern's projected revenue and 12.6 times 2017 EBITDA of $95 million, Amanda Murphy wrote in her analysis of the deal for **William Blair.**

A Complement to Covance

Over the past year, LabCorp has said it was pursuing opportunities to expand its contract research offerings. But, Murphy added, LabCorp had passed up the chance to acquire other CRO companies, such as **Parexel** and **inVentive**.

"The acquisition of Chiltern seems to have been worth the wait as it checks all of the company's strategic and financial criteria, and valuation appears to be reasonable," Murphy wrote. In addition, she said, adding Chiltern complements the Covance operation, particularly because Chiltern's strength is in oncology research. Covance has extensive experience in late phase oncology and Chiltern has experience in early clinical development, LabCorp said.

One analyst said LabCorp's acquisition of Chiltern indicates that the company is seeking "to become a $10+ billion clinical laboratory and drug development business." The Covance division is already a $3 billion operation, the analyst said.

With Chiltern, LabCorp acquires more than 130 MDs and 1,700 employees with advanced degrees, the company said. TDR

—Joseph Burns

Lab Informatics Update

Calif. Pathology Labs to Report Data to State's Cancer Registry

Cancer data to be submitted starting in 2019, would support clinical trials and improved care

HEALTHCARE BIG DATA IS ADVANCING in California and all pathologists in the Golden State will be required to submit data to the state's cancer registry beginning in 2019.

California's new law to support the state's cancer registry is the latest example of an effort to ensure the timely collection of complete sets of data needed to foster population health management and personalized medicine. Pathologists and clinical lab administrators outside of California should expect similar initiatives in the coming years.

California took its first steps to develop a registry of cancer cases in the 1970s. Then, in 1985, the California Cancer Reporting Law was signed into law. That same year, the **California Cancer Registry** (CCR) was established.

"The **California Society of Pathologists** (CSP) supported this latest legislation," stated Robert J. Achermann, Executive Director of CSP. "In recent years, the CSP has backed a bill in the California legislature to improve the cancer registry by collecting de-identified patient data on each cancer case. The data would include the diagnosis, when it was made, the treating physician, and other data relevant to researchers and clinicians treating similar patients.

"In the past few years, the CSP board was supportive of reforming the cancer registry process in California," said Achermann. "We recognized that the reporting process for the registry was unfair regarding who was supposed to report. As it was structured at that time, any provider in the care chain could report, meaning there was no consistency in the reports. Also, there were long delays in submission of cancer care reports, sometimes as long as 12 to 18 months.

"This created a problem," he continued. "The cancer registry folks spent considerable time sending staff to hospitals looking through medical records to identify cancer cases. The process was inefficient and ineffective.

Seizing an Opportunity

"Seeing these deficiencies, our members started talking with members of the legislature to improve the process," he explained. "Those conversations led to the creation of the **California Cancer Data Consortium**, which brings together physicians, the cancer registry people, healthcare systems, hospitals, and others to update the registry process.

"Our board saw an opportunity to put pathologists in the proper place in this equation," Achermann said. "Pathologists are often the ones making the diagnosis of cancer; so they should report that data. The **College of American Pathologists** also is active in such reporting efforts and our initiative is similar to theirs.

"Here at CSP, we help pathologists to improve the completeness, accuracy, and usefulness of the data they report," he

noted. "Our goal is to ensure that the data will be retrievable, usable, and searchable in terms of the types of data, location, types of cancer, and the demographics of the patients involved. Getting data reported consistently would make the registry much more powerful and more useful than it has been. In turn, it will support clinical trials and improve patient outcomes as well.

"The CSP also is mindful of any increased burdens on pathologists and for those who may not be using the synoptic reporting process contained in the CAP eCancer checklists," he added. "The goal is to allow pathologists to submit their reports electronically without entering discrete data and working toward possible additional compensation for their reporting efforts.

Cancer Database

"Eventually we expect to have data on every patient diagnosed with cancer," added Achermann. "This data will include when the diagnosis was made, who made the diagnosis, what type of cancer was identified, the treating physician, what treatment the physician prescribed, what care was delivered, the outcome for the patient, and the patient's prognosis over time," Achermann said.

"Having all that data in one place—the California Cancer Registry—will be useful for anyone conducting clinical trials on certain types of cancer or other conditions," he added. "It could become a treasure-trove of data for drug companies developing treatments. We are all enthusiastic about the possibilities that could come from aggregating this data and making it available almost in real time.

"When your data is behind schedule in terms of submission and the quality of the data is poor and not searchable in a meaningful way, you can't answer questions about cancer clusters," he said. "So, just in that one area, improving this registry could help to improve cancer care, patient outcomes, and possibly reduce costs as well.

Pathology Data Is Essential to California Cancer Registry

ONE ISSUE TO BE RESOLVED is whether pathologists who submit information for the California Cancer Data Consortium would need to be paid to ensure that they submit data on every cancer patient.

"Under the new law, there's an obligation for pathologists to report this data directly," stated Robert Achermann, Executive Director of the California Society of Pathologists. "If pathologists support this initiative, does that mean that pathologists should pay for data collection as well?

"Recently, the discussion has been about how to avoid creating an additional burden on pathologists to report discrete data elements as opposed to submitting data electronically by sending in a copy of their pathology report," he added.

"As we look at implementation of this new reporting law, we want to make sure that our members and other pathologists are not unduly burdened by this initiative," Achermann said. "We are still considering whether a financial incentive is needed or not. If we can develop a system that eliminates much of the administrative staff time to send people to hospitals looking through medical records, then there might be funding available to help pathology groups and software vendors to submit the data effectively and efficiently."

"The implementation guide for reporting is near completion and the CSP wants to ensure that practicing pathologists can adapt and comply with any obligations," he added.

"As we begin to collect data from pathologists, in the long-term, we envision that we will capture data from radiation oncologists, medical oncologists, and other physicians," concluded Achermann. TDR

—Joseph Burns

Contact Robert Achermann at 916-446-6001 or bachermann@amgroup.us.

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

PAML of Spokane, Washington, was the subject of an unusual public disclosure recently made by **Laboratory Corp-oration of America**. The lab company sent a statement to the *Spokane Journal of Business* stating its plans to make PAML "its primary lab site in the western U.S. for workplace and toxicology testing." The statement was made to the newspaper by Donald R. Von Hagan, Labcorp's Vice President of Communications. Civic and economic development leaders in Spokane have been concerned about LabCorp's plans for PAML's central laboratory facility that employs 800 FTEs in Spokane County.

MORE ON: *PAML*

Along with the statement that LabCorp intended to use the PAML laboratory as its primary workplace and toxicology testing site for the western United States, Von Hagen stated that "Now that PAML is a LabCorp company, we remain committed to Spokane and the other communities that PAML and its joint ventures serve."

SIX SIGMA GOAL ACHIEVED AT ARUP

At **ARUP Laboratories** in Salt Lake City, the semi-retired Charles Hawker, PhD, MBA, continues to achieve milestones in lab automation. In last month's issue of the *Journal of Applied Laboratory Medicine*, Hawker and his colleagues wrote about their 25-year effort to achieve six sigma performance for lost specimens. ARUP handles 55,000 specimens daily and its use of automation with Lean and process improvement methods has helped it reduce the number of lost specimens to the six sigma rate of 3.4 defects per million events. Hawker believes ARUP is the first medical laboratory in the United States to document Six Sigma performance for a specific laboratory process.

TRANSITIONS

• Haywood D. Cochrane Jr., was elected as Chairman of the **University of North Carolina-Chapel Hill** Board of Trustees. He is a graduate of the university and has held senior leadership positions at **Midatech Pharma US**, **CHD Meridian Corporate Healthcare**, **Laboratory Corporation of America**, **Allied Clinical Laboratories**, and **Roche Biomedical Laboratories**.

CORRECTION

In a story about the acquisition of **Med Fusion** and **ClearPoint Diagnostic Laboratories** by **Quest Diagnostics** that was published by THE DARK REPORT on July 17, Quest did provide a statement after our publication deadline. Here is that statement:

"Med Fusion spearheaded a unique model for standardizing and simplifying precision medicine diagnostics in oncology. Assuming completion of the acquisition, the infusion of Quest's resources, expertise and scale will allow our organizations to work together to further build this model and extend its reach to more physicians, particularly community oncologists, who deliver 70% of the nation's cancer care. Our organizations' shared commitment to innovation and quality provides a foundation from which to generate greater value for physicians and patients."

That's all the insider intelligence for this report. Look for the next briefing on Monday, August 28, 2017.

★ SPECIAL SESSION! ★

Why Medicare's 2018 Lab Price Cuts Make It Smart to Trim Costs Now!

Stephen Stone
Managing Director, Argent Global Services

Protect Your Lab's Financial Stability by Using Cost-per-Test Studies Done the Right Way to Guide Cost-Cutting Efforts

Coming to your lab on Jan. 1, 2018 are deep cuts to Medicare Part B clinical laboratory test prices. Medicare officials say these price cuts will total $400 million just during 2018! You have a valuable window of time to prepare your lab to operate on less revenue while delivering superior clinical testing services.

In this timely session, Stephen Stone will show you the secrets and proven ways to accurately determine a cost-per-test for each assay your lab offers. Next, you'll learn how to use those accurate costs to guide Lean and process improvement methods designed to take out chunks of costs while sustaining quality.

This important session is designed to help you maintain your lab's financial sustainability *before* the Medicare price cuts take effect on Jan. 1. Make your plans today to register and join us at the 11th annual Lab Quality Confab. It will be your smartest management decision of the year!

It's Our 11th Year!

Lab Quality Confab

and Process Improvement Institute

October 24-25, 2017 • Sheraton Hotel • New Orleans

UPCOMING...

- ***Chair of Pathology's Serious Diagnostic Error Makes National News a Second Time.***
- ***Preparing for PAMA Lab Test Price Cuts in 2018: Essential Steps to Prepare Your Lab before Jan. 1.***
- ***Why National Labs Want PSCs in Grocery Stores and How This Raises the Bar for Customer Service.***

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