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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...

R. Lewis Dark
Founder & Publisher

Pathologists Have Their 'Carpe Diem' Opportunity!

FOR MORE THAN TWO DECADES, leaders and forward-thinkers in the pathology profession bemoaned the fact that lab tests and anatomic pathology services were priced as commodities. From the podiums of various lab and healthcare conferences, they urged their peers to identify, document, and educate health insurers and others about the true value of lab tests.

All of this talk about why it was important for pathologists to demonstrate the value of their services started in the early 1990s. At that time, health maintenance organizations began using capitated, full-risk contracts to slash prices paid to providers, including payments to anatomic pathology (AP) groups and clinical laboratories. Payers also used narrow networks to exclude many pathology groups, resulting in further revenue losses for these groups and labs.

Over the past 20 years, pathologists have made little progress educating payers and the public about the substantial value that AP services contribute. Pathologists know how their services improve patient care and help reduce the overall costs as well. But few hospital administrators or health insurance executives understand how they could leverage anatomic pathology services in useful ways—and pay pathologists more because of these contributions.

However, there is good news for the pathology profession. The health system is transforming, giving pathologists a once-in-a-career opportunity to educate payers, patients, and other providers about their value. As health insurers and employers experiment with value-based payment models, pathologists have a chance to educate decision-makers about the specific ways that pathology services add value.

For this educational effort, THE DARK REPORT is doing its part. On pages 10-13, Robert H. Tessier, an experienced reimbursement consultant with **HPB Services**, explains how his clients are educating hospital administrators about the value of the pathology services they provide and he identifies simple steps every group can take. One such step is to be diligent about preparing an annual report for the hospital that details the time and contributions made by the group, along with its proposals on how the group can add value and be paid for it.

But Tessier also has a warning. Failure to act now means that hospitals and health plans will decide, on their own, how to pay pathologists for value. For all these reasons, it's now time for the pathology profession to seize the day! TDR

Do Hospitals Want to Sell or Outsource Their Labs?

Wall Street is often told that many hospitals have reasons to sell or outsource their laboratories

CEO SUMMARY: Common wisdom on Wall Street is that many hospitals and health systems question the value of continuing in the lab outreach business or continuing to manage their inpatient laboratories. These questions lead them to explore selling their outreach labs or consider having a commercial lab manage their inpatient labs. This year, however, there have been few such deals announced and the recent lab joint venture involving ProMedica and Sonic challenges that popular wisdom.

NEWS OF A NEW LABORATORY JOINT VENTURE involving **ProMedica Health** of Toledo, Ohio, and **Sonic Healthcare USA**, of Austin, Texas, should be of interest to lab administrators and pathologists managing hospital or health system laboratories.

This joint venture is evidence that forward-looking health systems and hospitals recognize the importance not only of retaining control of their laboratory services, but of leveraging and expanding lab testing to support integrated clinical care in all locations.

Stated differently, this laboratory joint venture is evidence that the health system partner is making a substantial commitment in capital and resources to establish a truly-integrated lab testing service that brings together inpatient, outpatient, and outreach lab tests in ways designed to meet the needs of value-based care and precision medicine. The other notable aspect of this joint venture, as we report in the following articles, is that ProMedica wants to expand its laboratory outreach business in two neighboring states.

Another interesting attribute of this partnership involves how ProMedica decided to buck the conventional wisdom by forming a laboratory joint venture with Sonic Healthcare USA and thus retain control of its inpatient laboratories and its outreach laboratory business.

After all, the oft-repeated message of national lab firms to Wall Street analysts and investors in recent years is that hospitals and health systems want to sell their lab outreach businesses and outsource their inpatient labs to commercial lab companies.

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This message is based on the assertion that many hospitals and health systems do not see their labs as either a core competency or a profitable clinical service line. Therefore, they would be better off selling their labs or outsourcing management of these labs to enterprises that can run them more efficiently.

In presentations to Wall Street investors, and in their quarterly conference calls to report earnings, executives at **Laboratory Corporation of America** and **Quest Diagnostics** regularly state that they each have opportunities to buy hospital laboratory outreach businesses and enter into management contracts to operate the inpatient labs of hospitals and health systems.

LabCorp's Outlook

For example, last year, *360Dx.com* published a story and quoted LabCorp's Chairman and CEO Dave King saying that, in conversations with hospitals, "We're seeing a big push to being able to procure [hospital lab] services, the highest quality [lab] services at the most effective cost. And as hospitals and smaller laboratories are recognizing that trend, I think a lot of them are relooking at, do we belong in this business? Is it a core competency? Are we bringing value to the patient?"

But how many health networks and hospitals are actually in the market to sell or outsource their lab testing services? Even as Medicare was preparing to implement deep price cuts on Jan. 1 of this year, in the past 24 months, there were fewer than 15 transactions in which a hospital or health system contracted with a commercial lab company to sell its lab outreach business or have a commercial lab manage its inpatient laboratory.

During 2018, significantly fewer contracts have been announced involving a hospital or health system and a commercial lab company. If many health systems and hospitals are questioning whether they should unload their labs in some fashion, then why has there not been a steady regular stream of such deals?

Substantial Lab Commitment

For these reasons, THE DARK REPORT considers this latest pact involving ProMedica and Sonic to be significant for four reasons. First, this top-tier health system (with 13 hospitals in multiple states) is making a substantial commitment to ensure that its laboratory continues to be a key clinical service into the future.

Second, ProMedica is putting up substantial capital as its part of the new lab joint venture, an indication it expects the outreach laboratory business to be financially-viable, even as payers continue to pay less for lab tests.

Third, its lab joint venture with Sonic aims to reduce lab costs, but the goal of serving inpatient, outpatient, and outreach patients with a standard menu of tests and reference ranges can result in a unified patient lab test record. Such a lab test database will give ProMedica competitive advantage in the coming era of integrated care and precision medicine.

Shared Savings With Payers

Fourth, ProMedica gains access to Sonic's advanced analytics. Sonic has already worked with large physician groups to use its analytical tool and lab test data in ways that improve patient outcomes and generate shared savings payments from certain insurers to itself and the participating physician groups. ProMedica will certainly want to implement similar programs with physician groups, payers, and employers in its communities.

Clearly, ProMedica is not following the popular wisdom that hospitals don't see their labs as essential assets. By placing this bet on the role that lab testing can play in ProMedica's success going forward, this health system is stating clearly that lab testing is a core competency and essential to its success. TDR

—Robert L. Michel

ProMedica, Sonic Form Lab Outreach Joint Venture

After building a new core lab, ProMedica saw opportunity to pursue economies of scale

CEO SUMMARY: Fast-growing ProMedica Health System of Toledo, Ohio, agreed to a laboratory joint venture with Sonic Healthcare USA. As lab budgets and prices for lab tests are squeezed downward, ProMedica sees opportunity to add volume to this new core lab facility to improve efficiency and reduce costs per test. At the same time, it aims to increase its lab outreach business with its joint venture partner to improve laboratory testing services for office-based physicians in a multi-state area.

EARLY THIS MONTH, **ProMedica Health System** in Toledo, Ohio, and **Sonic Healthcare USA** of Austin, Texas, formed a joint venture to provide clinical laboratory services to patients and providers throughout Ohio, Michigan, and into Indiana.

The new venture will be called **ProMedica Pathology Laboratories** (PPL). "Each partner brings an existing book of lab business to the new company," stated Noel Maring, Sonic's Vice President of Hospital Affiliations. "ProMedica will include its already substantial volume of inpatient and outreach lab testing. Sonic will contribute its lab outreach business in the Toledo region.

"In the joint venture, ProMedica and Sonic will provide inpatient reference testing services for ProMedica's hospital laboratories and a comprehensive menu of outreach testing," said Maring. "This includes hospitals in Ohio and Michigan and physician clients in Ohio, Michigan, and parts of northern Indiana. More than 90% of the testing is expected to be done in the core laboratory owned by the JV."

Why is ProMedica developing a bigger laboratory outreach business now? "The most significant benefit expected from this new joint venture with Sonic Healthcare USA is increased efficiency in our laboratory operations," said Gary Akenberger, ProMedica's Senior Vice President, Operations.

Seeking Sustained Quality

"Our goal is to sustain a high-quality laboratory going forward because we recognize that reimbursement will continue to be a challenge and new diagnostic technologies will require substantial capital," he explained.

"In addition to improved sustainability, the other benefits will be improved lab reporting, and increased productivity," he said in an interview with THE DARK REPORT. "From a financial perspective, we look at this joint venture as something that will help us create a strong long-term laboratory testing operation for years to come.

"We want improved sustainability from an economic standpoint," continued

Akenberger. "This deal provides us with an opportunity to lower our overall cost structure and increase our volume while also adding more geographic coverage.

Higher Volume, Lower Costs

"Increased test volume lowers our cost per test," he added. "This makes our lab more efficient, allowing us to enjoy greater economies of scale.

"Together, under this new laboratory joint venture, we will improve lab services in Northwest Ohio and farther south in the state," Akenberger said.

"Also, we will serve the entire state of Michigan and the northern part of Indiana," he added. "Of course, Michigan is a big state, and we intend to serve the entire state, but that will depend on how far we can transport lab specimens.

"In addition to better geographic reach, we expect our work with Sonic will help us with our financial reporting," he said. "Sonic can help us with our managed care contracts by analyzing our lab costs on a per-test basis to give us much greater detail than we have today with our internal systems.

"As a result of being in the lab business for many years, Sonic's systems are specific to the laboratory business line," he explained. "The systems we have as part of a hospital are much broader in nature and provide information not only for our laboratory but also for radiology, respiratory therapy, and all the other ancillary services that we provide.

"The systems that Sonic brings to the table will have much more specific laboratory data available to provide data analytics, from an economic or financial perspective, as well as the ability to improve patient collections, in terms of services that we provide," Akenberger said.

Improved financial data on patients should help ProMedica collect lab test fees from patients, he added. Having patients pay at the point of care is particularly important when so many are enrolled in high-deductible health plans, he said.

Better Financial Data

"We want to make sure that we are paid appropriately for our lab testing services and that our patients know how much they owe in terms of co-payments and deductibles," he added. "Our systems have those capabilities, but Sonic's systems are specifically related to the laboratory business, which are typically high-volume, low-cost test procedures." TDR

—Joseph Burns

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Fast-Growing ProMedica Is Now a Major Health System

RECENT ACQUISITIONS AND ONGOING GROWTH at Toledo, Ohio-based ProMedica Health now put the integrated health system on the list of the 25 largest health systems in the United States.

ProMedica offers acute, post-acute, and ambulatory care services. It owns a health insurance company with a dental plan. The company has more than 70,000 employees, including 2,700 physicians and advanced practice providers. Its ProMedica Physicians division employs more than 900 physicians and other providers.

A nonprofit organization, ProMedica has 13 hospitals in Ohio and Michigan. With its recent acquisition of **HCR ManorCare**, it now operates 450 assisted living facilities, skilled nursing and rehabilitation centers, outpatient rehabilitation clinics, and hospice and home health agencies. Including HCR ManorCare's numbers, ProMedica's revenue is approximately $7 billion annually.

ProMedica's central laboratory facility in Toledo is accredited to CAP 15189.

Sonic Sees a Future in Lab JVs with Hospitals

Collaborations with hospitals and health systems can provide significant clinical, financial benefits

CEO SUMMARY: In every partnership, each member has a unique point of view. Following the announcement of a new laboratory joint venture company involving ProMedica Health System and Sonic Healthcare USA, the Sonic executive who worked with ProMedica's administrators to develop the JV explained why Sonic is bullish on this hospital laboratory outreach joint venture and described why similar lab joint ventures can benefit each partner, both clinically and financially.

A SIGNIFICANT TREND for hospital- and health system-based laboratories may be unfolding in Toledo, Ohio. The newly-formed **ProMedica Pathology Laboratories** (PPL) is a bold statement of confidence in the immediate future of the laboratory outreach business by one of the nation's largest and fastest-growing health systems.

This new laboratory company is a joint venture with **ProMedica Health System** and **Sonic Healthcare USA** as the majority and minority owners, respectively. ProMedica is on track to have annual revenue of $7 billion and Sonic Healthcare USA is itself a billion-dollar lab business.

In the previous article on pages 5-6, the principals involved in this lab joint venture described the details of the partnership. ProMedica's Senior Vice President, Operations, Gary Akenberger, explained why this joint venture is expected to benefit ProMedica and contribute to improving inpatient and outreach lab testing services at a high level going forward.

To provide clients and readers of THE DARK REPORT with Sonic Healthcare USA's perspectives on its endeavor with ProMedica, we interviewed Noel Maring, Sonic's Vice President of Hospital Affiliations.

On behalf of Sonic, Maring played a key role in working with ProMedica administration to develop what will be a large new laboratory company. But Maring's comments should be taken in a larger context.

A Successful Track Record

In recent years, Maring has developed several other lab joint ventures involving Sonic and large health systems. Previously, he served for almost two decades at **Pathology Associates Medical Laboratories** (PAML) in Spokane, Wash., where he worked with PAML's then-CEO Thomas Tiffany, PhD, to establish seven hospital and commercial lab joint ventures involving 37 hospitals in the Pacific Northwest and Rocky Mountain states.

Given his experience and extensive knowledge about what it takes to design,

launch, and sustain a lasting laboratory joint venture involving a hospital or health system and a commercial lab company, his comments about this new venture are important for lab administrators and pathologists in other similar hospitals and health systems.

A Strategic Alignment

"Nationally, ProMedica is recognized as a forward-thinking system," stated Maring. "Its administrative team was deliberate and careful in designing this lab joint venture so that it aligns with their larger strategic plan.

"On the other side of this table, the ProMedica-Sonic lab joint venture fits neatly into Sonic's strategy of partnering with health systems to improve both parties' economies of scale," explained Maring.

"In my opinion, this lab JV is a big deal because ProMedica is one of the largest health systems in Ohio and because this joint venture will involve hospitals in Ohio and Michigan," he noted. "ProMedica's existing progressive and substantial lab outreach program already extends in and around its hospitals.

"By that, I mean this is not the typical small hospital outreach operation because ProMedica's outreach program already performs about two million tests per year," emphasized Maring. "In addition, each year, the core lab handles about 1.9 million inpatient tests coming from ProMedica's 13 hospitals.

"At almost four million tests annually, that level of volume is substantial," he commented. "For its part, Sonic will contribute the more than two million lab tests it currently generates from Toledo, much of northern Ohio (including Cleveland), Columbus, and also from Indiana.

"So here is an immediate benefit for the joint venture," Maring added. "The current ProMedica core laboratory will realize almost a 50% increase in lab test volume by adding the Sonic test volume, when ProMedica's core laboratory becomes part of the joint venture on Sept. 1. At this time, Sonic's existing laboratory in Toledo, called **Pathology Laboratories Inc.** (PLI), and its business will be consolidated into the joint venture's (formerly ProMedica's) new, highly-automated, state-of-the-art laboratory, which opened in April.

"For the better part of two years, Sonic has talked with ProMedica administrators about how we could work together more closely," Maring recalled. "Part of their planning and automation for the newly-expanded lab facility was based on the fact that they saw the opportunity to consolidate the work we do in Toledo with theirs.

"That new lab has about 83,000 square feet of space and will be the core laboratory for this joint venture," he said. "By combining our business with theirs, we expect ProMedica will gain significant economies of scale, which would be important for any health system.

More Capacity and Efficiency

"The lab business responds well to economies of scale and it does so perhaps better than is true of other areas of healthcare," noted Maring. "ProMedica recognizes that its new lab facility of 83,000 square feet has substantial capacity and potential to deliver increased efficiency.

"More specifically, all hospital lab administrators and pathologists know that inpatient testing is performed during the day and test volume falls off dramatically in the evenings and weekends," he added. "That creates the opportunity to use that same lab facility in the evening and weekends to do testing on outreach specimens. That's when a good portion of Sonic's outreach business arrives because some of it is transported to Toledo from distant areas."

Another financial benefit will be combined purchasing. "Over time, Sonic will bring in its global procurement abilities,

which will help to reduce ProMedica's supply and equipment costs," he added. "Those costs won't come down right away, but will be a factor over many months and years.

"These are just a few ways this joint venture with ProMedica demonstrates what we at Sonic want to accomplish as we develop partnerships around the country," Maring explained. "Sonic's goal as it develops these lab joint ventures is not to take testing out of the area so that it can be moved to our distant laboratories.

"Quite the opposite," he added. "The Sonic model is to bring volume and scale into the local market and perform testing in those laboratories. This lab JV will achieve that goal of keeping lab testing local and performed in the health system lab.

Patients Benefit as Well

"ProMedica recognized another benefit from having more volume go through its new core lab," observed Maring. "Not only does the additional specimen volume lower lab costs, but it also benefits patients. This happens because the increased volume of tests makes it feasible to bring more tests in-house. That enables the lab to offer faster turnaround times for inpatient care, potentially contributing to reduced length of stay. This also benefits physicians and their patients.

Two Years of Negotiations

"In conclusion, I would say that this joint venture was two years in the making and in that time, it was very thoroughly reviewed by all parties," he said. "As such, it's a good example of a health system taking steps to get the most value from all of its lab data, including inpatient, outpatient, and outreach lab data. Having all that data in one place is very important for health systems like ProMedica." TDR

—Joseph Burns

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Major Healthcare Trends Support Unified Lab Record

BECAUSE OF HEALTHCARE'S TRANSITION to integrated care and value-based payment, health systems have reasons for their laboratories to provide all the testing done for inpatient, outpatient, and outreach testing.

"The Toledo market has plenty of competition for lab tests," noted Noel Maring, Vice President of Hospital Affiliations for Sonic Healthcare USA. "Along with ProMedica, **Mercy Health System** is one of three hospitals in the Toledo market that provides outreach lab testing," he said. "**Laboratory Corporation of America** and **Quest Diagnostics** each have a bit of the outreach market and they do some reference lab work too.

"But most of the outreach testing from physician practices is consolidated in Mercy, ProMedica, and Sonic," he commented. "ProMedica and Mercy have brought in most—if not all—of the outreach testing from the physicians they employ or have affiliations with. By doing that, they ensure that the testing from their employed or affiliated physician practices stays in their system.

"It's likely that the model Mercy and ProMedica are using is similar to the future of where hospital labs are going," he predicted. "That's because health systems recognize the clinical benefits of having the same lab serve inpatient, outpatient, and outreach settings. When health systems do that, they can create a complete patient record with the same methods and reference ranges, which is a benefit when delivering integrated clinical care where providers are participating in value-based payment arrangements.

"Thus, by combining our lab with ProMedica's, when a patient is admitted to the ProMedica hospital, physicians will have access to both the inpatient and outreach lab test results, once the joint venture is fully operational," commented Maring. "In this way, there is a 'big data' benefit to our new laboratory joint venture."

Pathology Groups Should Act Now to Define Value

For AP and CP, value-based payment is coming, creating an opening for pathologists

CEO SUMMARY: Payers and health system administrators generally agree that healthcare is moving away from fee-for-service toward value-based payment. Because adoption of value-based contracts is slower for pathologists than for other providers, pathologists have the opportunity to define how provider systems can pay for value contributed by pathologists. However, to take advantage of this opportunity, pathologists must act before hospitals define value for them, a reimbursement consultant warned.

HEALTHCARE'S TRANSITION to value-based payments is moving forward in many sectors of healthcare. In anatomic pathology, however, the shift away from fee-for-service to value-based contracts has hardly taken hold, according to Robert Tessier, a senior reimbursement consultant with **HBP Services** in Woodbridge, Conn.

"This fact represents a significant opportunity for all pathologists and pathology group administrators," stated Tessier. "The reality is that most health insurers, hospitals, and larger physician groups are still learning how to craft value-based payment arrangements that align the incentives and goals for all parties in ways that improve patient care while lowering costs.

"Such slow movement toward value gives clinical labs and anatomic pathologists an opportunity to get ahead of the value-based reimbursement trend," he added. "Clinical lab directors and pathology group administrators must now begin to define the parameters that health systems use to measure and reward value-driven clinical and anatomic pathology services for their hospital and health system clients.

"As the health system moves away from fee-for-service payment, payers want to reimburse providers for value," Tessier said in an interview with THE DARK REPORT. "For that to happen, value must first be defined.

"However, defining how health systems pay for value delivered by anatomic pathology (AP) and clinical pathology (CP) services has proven to be difficult," he noted. "It's been a challenge to change payer contracts with hospitals and office-based physicians. It is proving to be an even more complex problem to define how to compensate pathologists for value."

Seeking Sustained Quality

Currently, hospitals and health networks typically pay a monthly management fee to pathologists for administrative services. "Unless pathologists can define specific formulas to recognize value, hospitals cannot be expected to incentivize pathologists for that value," stated Tessier.

"Therefore, the smart business strategy going forward is for pathologists to help hospital administrators define value

that meets the clinical, operational, and financial goals of each institution," he explained. "Most hospitals use time studies to document Part A hours, meaning these hospitals are counting hours.

"Some health networks are willing to recognize a competitive $150 hourly rate for pathologists handling non-patient care activities," he added. "We see the $150-per-hour rate as becoming something of a standard.

Counting Hours Is Easy

"For hospital and health system administrators, counting hours is easy, but it also detracts from improving value," commented Tessier, who has consulted to AP and clinical pathology practices for more than 36 years. "Hospitals and health systems define value as reducing overall healthcare costs while improving patient outcomes and patient experience.

"Similarly, when health insurers say they are contracting for value, these are the same parameters they want hospitals and health systems to deliver," he noted.

"Pathologists should prepare to rewrite their contracts with hospitals and health systems," he commented. "When they do so, they will have an important opportunity during these contract negotiations to define value."

Before negotiating a value-based contract with any hospital or health network, Tessier recommended taking one action internally. "After your pathology practice develops and defines the value it intends to deliver to its client hospitals, it is essential to rework your practice management plan to include financial incentives for those pathologists who bring increased value—both to the practice and to the hospitals or health systems the practice serves.

"For this effort, pathology administrators need to devise new mechanisms for payment," Tessier said. "Some practices are willing to consider 'rainmaking' skills as one way to reward value, which is reasonable.

"But rainmaking—the ability to bring in new business—is only one skillset," he continued. "For practices that want to reward all the value pathologists deliver, a more robust program of incentives is required.

"When defining value, most private groups believe that treating all pathologists in the group equally is the right approach, regardless of what they bring to the practice, how much productivity they deliver, or how much innovation they introduce," noted Tessier. "Doing so will work only if all members of the group share the clinical workload equitably and all Part A duties have been distributed equally.

"Be careful, however, because if some members regularly do more than others, this system will fail," he predicted. "It will be unsuccessful because the inherent inequity will penalize those who deliver the most value while unfairly rewarding those who deliver the least.

"Therefore, this model is not value-based," he continued. "Every pathology group needs language in its employment contracts to encourage pathologists to be innovative, to be forward-thinkers, and to be effective at finding new ways to deliver value.

Hospitals Fixate on Dollars

"Currently, I'm working on hospital contracts for three pathology groups," offered Tessier. "At each of these sites, negotiations are centered on how much the hospitals will pay pathologists per hour.

"Another problem is that hospital administrators want to limit what they spend in a given year to a certain dollar figure or number of hours," stated Tessier.

"When contract negotiations center on a fixed payment arrangement, how to pay for value is left out of the discussion," he commented. "For this reason—before going into these negotiations—pathologists should be prepared to present a specific plan on what value they can deliver to the hospital's patients and how they should be rewarded for that value.

"It's distressing that pathologists aren't leading the discussion to define new value paradigms or to ask for value to be

incorporated in their hospital contracts," observed Tessier. "This is the moment when the pathology profession can and should step forward to define value.

Leveraging Pathology

"Health insurers, hospitals, and office-based physicians need to understand how to leverage the power of pathology services to contribute to improved patient outcomes while reducing healthcare costs," he added.

"Pathologists seem hesitant to define value for two reasons," noted Tessier. "First, they are unsure how to describe and measure the value of their clinical services. Second, pathologists worry that any discussion of paying for value will mean a reduction in what hospitals pay for services under Part A. Many are ineffective at explaining what they do across the full range of clinical and management activities.

"The ability to delineate their activities is critically important for pathologists," continued Tessier. "One of the best ways to quantify value is in an annual report. Any comprehensive yearly accounting of services pathologists deliver also allows the group to align its goals and objectives to those of the hospital it serves."

Tessier provided an example of a client in California. "In 2010, the group wrote an annual report on its Part A work," he explained. "This report included a detailed time study we helped them prepare. It documented how many hours the pathologists spent on the various services they delivered.

"In each of the following years, not much changed, so the group saw no need to update its report," he added. "The attitude of many pathologists is that hospital administrators automatically know what they're doing.

"But during the past eight years, there was a complete turnover in the hospital administration," Tessier recalled. "The new administrators didn't understand the role of their pathologists. This became a problem during contract renewal negotiations.

"Every pathology group should prepare their annual report to each hospital," he added. In these reports, he suggested groups include the following:

- The number of hours the group's pathologists spent on Part A activities;
- How many tumor boards and committee meetings they attended;
- Information about the group's improvements and accomplishments; and,
- Details on patient experience or patient satisfaction.

"This is not a complete list of what pathology groups should include in an annual report," noted Tessier. "Going forward, the most important focus should be how the group contributes value.

"Omitting a discussion about value is a pitfall pathology groups must avoid in their annual reports," he said. "There are other pitfalls as well. For example, when a group reports on its fees, it should ensure that its prices are in line with those of other pathology groups in the same area." (*See sidebar on page 13.)*

Attention to Social Media

Another recommendation is to recognize the importance of social media, including patient reviews of pathologists and laboratory services on such websites as **Yelp**, **WebMD**, and **HealthGrades**.

"When talking about patient experience, review the comments patients post on consumer websites where they express their opinions about service in your hospital or health system," he advised. "Pay particular attention to patients' comments about pathology and laboratory services.

"Healthcare today is at the point where there's much talk about providing value," noted Tessier. "It is now time for pathologists to identify the value they contribute, along with how they should be paid for that value. If the pathology profession doesn't figure out how to get paid for value then pathologists will find themselves doing extra work and putting in extra time and effort that generates no return. In turn,

Hospitals and the Pathology Groups Serving Them Will Need to Post Prices They Charge

ONE NEW REQUIREMENT COMING SOON to hospitals and the pathologists who serve them is the requirement that they report the prices they charge to patients for their services, said Robert Tessier, a senior reimbursement consultant with HBP Services in Woodbridge, Conn.

"In April, the federal **Centers for Medicare and Medicaid Services** proposed a rule calling on hospitals to publish their standard charges online," explained Tessier. "The goal is to improve the transparency of hospital prices and to empower patients to choose where to go for treatment.

"When your pathology group must post its prices, it would be a smart strategy to ensure that its fees are usual and customary—meaning not excessive," he advised. "To do so, it will be necessary to know what other anatomic pathology (AP) labs and pathology groups charge in your community and region.

"Today, there is an excellent resource for studying pathology prices in each area of the country," he continued. "It is a well-kept secret, however, as most pathology groups are unaware of its existence. Moreover, in the past, fee data was confidential and never discussed. That meant hospitals were not able to determine what was usual and customary for services the pathologists and other providers delivered to patients.

"That changed in 2012 when the federal **Centers for Medicare and Medicaid Services** (CMS) released data on what it paid all providers—including pathologists," noted Tessier. "CMS now releases this payment data annually. It is a resource that savvy pathology practice administrators should use to understand what prices are being charged by other pathology groups in their state or region.

"When CMS first released its fee data in 2012, those data were difficult to extract," he recalled. "But beginning in 2014, the data became more accessible. Now it's possible to use that fee data to see what pathologists get paid for a wide variety of services.

"The data is based on payment codes and it's easier to extract reports showing which providers charge 50% or more than other providers in the same area," he observed.

"I know of a hospital system, for example, that compared hospital-based physician fees to others in the same state," said Tessier. "It then suggested that the median would be its guideline for acceptable pricing. Today, patients with high-deductible health plans want to know what comparable institutions charge for the same services.

"There are other reasons for any local lab to access Medicare data to compare its rates with those of commercial labs and of hospital practices with aggressive outreach programs," he advised. "As an example, data shows that one of the largest commercial lab providers of CPT 88305 billed Medicare for 273,000 such services and charged $315 for each claim, a price well above average!

"For anatomic pathologists, these data provide an opportunity to show how your group's fees compare with those of other pathology groups," noted Tessier. "Of course, you want your group's fees to be inline with those of other pathology groups in your area."

there won't be any net benefit for the pathology group itself, or for the hospitals the group serves." TDR

—Joseph Burns

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Regulatory Update

FDA Issues Response to Draft Legislation to Regulate LDTs

In its comments, FDA said it favored a risk-based approach to regulating LDTs, in vitro tests

DURING HER ADDRESS TO THE ANNUAL MEETING of the **American Clinical Laboratory Association** meeting in March, Rep. Diana DeGette (D-Colo.) explained why she and others in Congress had developed the Diagnostic Accuracy and Innovation Act (DAIA), a discussion draft that would give the FDA authority to regulate laboratory developed and *in vitro* diagnostic tests. At the time, she and other members of Congress wanted the FDA to respond to the draft, she said.

Tests in a Gray Area

Earlier this month, the FDA responded to her request. It provided an overview and technical comments on LDTs and *in vitro* tests. These are tests that fall into a gray regulatory area because CMS oversees labs but the FDA regulates tests.

In its comments on DeGette's proposal, the FDA said it favored a risk-based approach under which it would monitor assays marketed as *in vitro* clinical tests and oversee premarket authorization. It would also ensure that, in the future, tests labs develop will have a path to market. The FDA further said it wants the authority to remove tests from being sold if they pose risks to public health.

DeGette wants the legislation passed by year end, which would be a challenge for Congress given the workload it would need to finish by then, according to published reports. A spokesperson for Larry Bucshon (R-Indiana), a heart surgeon who is DeGette's co-sponsor, said, "We are working diligently with the goal of getting this done this year," according to reporting from Sarah Owermohle at *Politico*.

The FDA's proposals depart from the language DeGette and Bucshon proposed in the DAIA, according to reporting from Turna Ray at *GenomeWeb*. DAIA was drafted with extensive input from stakeholders, she wrote.

On Aug. 3, the FDA said it wanted a bill that would include provisions related to premarket and provisional approvals and a precertification program for certain tests. Also, it wanted explicit authority to revoke approvals and to take corrective action against test developers to protect the public, Ray reported.

The FDA favors a regulatory approach that would allow the agency to monitor tests that are currently on the market while also ensuring that labs can bring new tests to market under what it calls a flexible and efficient pathway, she added.

"According to the FDA, its proposals aim to establish a framework that doesn't hinder access to tests already on the market or for rare diseases, for example, but where the agency also has the power to remove tests from the market that put the public health at risk," Ray wrote.

Some experts in health policy said the FDA's proposal was more than a reaction to the DAIA and was instead an entirely new bill, Ray reported.

Those in the clinical lab industry who have seen the FDA's proposal said they needed more time to review the agency's detailed recommendations and had been expecting line edits to what DeGette and Bucshon proposed last year in their working draft of the DAIA.

The FDA's proposal includes a definition for *in vitro* clinical tests (IVCTs) that is different from that included in the draft bill that DeGette and Bucshon proposed, Ray reported. Their draft bill defines an IVCT as a laboratory test protocol or a finished product (test kit) used in disease detection, screening, prediction, and monitoring, and for selecting treatment based on analysis of human samples, she wrote.

But the FDA's response includes a definition in which the agency said it would consider test protocols, test platforms, and software used for these same purposes to be IVCTs, Ray explained. The FDA has told legislators that, as the draft bill from DeGette and Bucshon is written, it could leave test platforms with insufficient regulatory oversight, she added.

"Notably, the FDA does not specifically mention the terms 'finished product,' 'laboratory test protocol,' or 'laboratory-developed test' in its definition of IVCTs or anywhere in its legislative proposals," Ray reported.

Regulating LDTs

In 2014, the FDA released draft guidelines outlining a risk-based approach to regulate LDTs, saying it would introduce this approach over nine years. Historically, the federal **Centers for Medicare and Medicaid Services** have regulated LDTs under CLIA. The 2014 proposal got heavy criticism from clinical labs and other stakeholders and was later withdrawn. In January 2017, the FDA said it would not finalize guidance on the regulation of lab-developed tests (LDTs). It has now responded to requests from the lab industry and others to develop a new regulatory approach. TDR

—Joseph Burns

13 Groups Issue Statement about FDA's Comments

IN RESPONSE TO THE FDA'S COMMENTS to the draft language in the proposed Diagnostic Accuracy and Innovation Act (DAIA), a group of 13 organizations, including the American Clinical Laboratory Association, the **Clinical Laboratory Management Association**, and the **American Society of Clinical Oncology**, had nothing but praise for the FDA but said little about the specifics in the FDA's proposal.

"We are committed to continuing to work with the House Committee on Energy and Commerce and the Senate Committee on Health, Education, Labor and Pensions to advance diagnostic reform legislation expeditiously so that comprehensive reform may be enacted in 2018, the group said in a letter to members of the leadership of both committees.

The FDA proposal, "represents an important and necessary next step in the pursuit of comprehensive legislative reform," the group added.

The group of organizations that represent clinical labs, patient advocates, providers, and diagnostic manufacturers said they support "modernizing the regulatory framework for clinical laboratory diagnostics, including laboratory-developed tests (LDTs) and *in vitro* diagnostics (IVDs). Such reform is critical to ensure that patients and providers have access to innovative and high quality laboratory diagnostics, they added.

In addition to the ACLA, the CLMA, and ASCO, other groups that signed the letter are **AdvaMedDx**, the **American Cancer Society Cancer Action Network**, the **Biotechnology Innovation Organization**, the **Coalition for 21st Century Medicine**, the **Diabetes Patient Advocacy Coalition**, **Friends of Cancer Research**, **LUNGevity Foundation**, the **National Alliance on Mental Illness**, and the **Society for Women's Health Research**.

Anthem Alleges $16M in Calif. Hospital Lab Fraud

In lawsuit, Anthem and nine BCBS plans describe elaborate clinical lab-testing scheme

CEO SUMMARY: In a lawsuit filed in the U.S. District Court for the Central District of California, Anthem and affiliated Blue Cross Blue Shield plans alleged that 37-bed Sonoma West Medical Center, a Florida lab testing company, a medical billing company, and others used a pass-through lab test billing scheme to defraud Anthem and its BCBS plans to produce more than $16 million in net proceeds. That income came by deceiving Anthem and its affiliated plans, the lawsuit said.

PASS-THROUGH BILLING INVOLVING MILLIONS OF DOLLARS of toxicology laboratory tests by a small, financially-troubled hospital is the central issue of a lawsuit filed in June. **Anthem Inc.** sued **Sonoma West Medical Center** (SWMC), four companies, and two individuals who had previously managed the medical center lab's toxicology-testing program.

The 37-bed hospital in Sebastopol, Calif., has struggled financially since it reopened in Nov. 4, 2015 after being closed for 18 months. It closed on April 28, 2014, when debt far exceeded its income. On Aug. 17, the **Palm Drive Health Care District** (PDHCD), which runs the hospital, voted to replace the administrative staff and convert the facility to serve patients needing long-term and urgent care.

Last year, SWMC was seeking to shore up its finances and contracted with a lab management company, a deal that led to the Anthem lawsuit. In the lawsuit, Anthem alleges in detail how the medical center used toxicology testing and a pass-through billing scheme to defraud Anthem and the other BCBS plans. *(See TDR, March 5 and May 7, 2018.)*

In the lawsuit filed June 1 in the U.S. District Court for the Central District of California, Anthem and nine of its affiliated **Blue Cross Blue Shield** plans alleged that SWMC, a Florida lab testing company, a medical billing company, and others used a pass-through billing scheme to defraud Anthem and its BCBS plans to produce more than $16 million in net proceeds by deceiving Anthem and its affiliated plans, the lawsuit said. Earlier his year, Anthem said it was seeking recoupment $13.5 million from SWMC for what it says was fraudulent lab testing.

'We're Not Scheming...'

In response to the lawsuit, the medical center's CEO John Peleuses rejected the claim that the hospital was being used as a front to bill for testing it had not performed. "We're not scheming with anyone to do anything other than to provide patient care," he added.

After emerging from bankruptcy protection early in 2017, SWMC was cited in

Lawsuit: Hospital Got Toxicology Test Specimens from Patients Who Were Thousands of Miles Away

IN A LAWSUIT FILED JUNE 1, lawyers for Anthem Inc. and nine affiliated Blue Cross Blue Shield plans explained an alleged scheme to defraud the insurers of $16 million. The following is taken from the court documents:

"The distance this urine had to travel as part of this scheme was remarkable. Approximately 90% of [lab] specimens originated in Orange County, California–nearly 500 miles from Sonoma West. The remaining 10% originated in states other than California.

"But that was just the beginning of their journey. After they were collected from patients, the urine samples did not go directly to Sonoma West, but instead travelled 2,300 miles east to Reliance Labs, in Sunrise, Florida. There the specimens were divided into two portions, with one remaining at Reliance Labs and the other boarding a plane to fly 2,600 miles back to Sebastopol where, purportedly, a basic screening test would be performed—one that Reliance Labs was more than capable of conducting and, indeed, Reliance Labs was the entity who most physicians had ordered to perform the testing.

"These nearly 5,000 miles were a trip not just around the country, but the end-run on Anthem's professional fee schedule.

"The conspiracy was remarkably successful—delivering on Durall Capital's promise of swift wealth. In the 18 months prior to the conspiracy, Sonoma West submitted just 50 claims for urine toxicology testing to Anthem in total. In the first nine months of the scheme, that number ballooned to more than 15,000 claims; more than 50 claims per day," said the lawsuit.

September of that year in a 62-page statement of deficiencies report from the federal **Centers for Medicare and Medicaid Services** for "inability to ensure the provision of quality health care and services in a safe environment."

In addition to SWMC, the other defendants in the Anthem lawsuit are four companies and two individuals:

- **DL Investment Holdings LLC** (formerly known as **Durall Capital Holdings LLC**;
- **Reliance Laboratory Testing Inc.**;
- **Medivance Billing Service Inc.**;
- Aaron Durall who owns DL Investment Holdings; and,
- Neisha Carter Zaffuto who is the president of Medivance Billing, court documents show.

In May, THE DARK REPORT reported that SWMC dropped its controversial drugs-of-abuse testing program. *(See TDR, May 7, 2018.)*

Court documents explained that SWMC stopped its toxicology testing program earlier this year after Anthem sent the medical center a letter on Jan. 9 demanding repayment of $13.5 million that the insurer paid the hospital for urine drug test claims. In the letter, Anthem alleged that SWMC and the **Palm Drive Health Care District** engaged in an improper billing scheme to defraud Anthem and its affiliated Blue Cross and Blue Shield entities beginning in April 2017.

Defendants' Conspiracy

In the most recent court filing, Anthem said Aaron Durall was primarily responsible for the defendants' conspiracy to commit the alleged fraudulent scheme by entering into an agreement between SWMC and Durall Capital, engaging Reliance Labs to do some of the testing, and by having Medivance do some of the billing for the scheme, Anthem charged.

Also, Durall enrolled Zaffuto to participate, court records showed.

Under the scheme, court documents showed, Durall, "has personally received a substantial portion of the amount paid by Anthem and the BCBS plans as a result of this fraudulent scheme…"

In the 107-page lawsuit, Anthem's lawyers, the law firm of **Robins Kaplan LLP** of Los Angeles and Minneapolis, explain the pass-through billing scheme in great detail.

'Deceptive Scheme'

"In 2017, a personal injury lawyer from Florida approached a failing, 37-bed hospital in northern California with an idea he claimed could enrich them both virtually overnight," the lawsuit said. "The lawyer, Aaron Durall, under the guise of a corporate shell, would acquire urine [specimens] through a network of marketers and physicians from around the country; he would consolidate that urine through a toxicology lab in Florida that he owned; and the hospital would bill insurers for the [toxicology lab] testing even though other labs had been ordered to perform it. With that simple but deceptive scheme, the hospital could increase the insurance payments for those services up to 100 fold."

As a result, the lawsuit said, the hospital could generate reimbursement from insurers, "that would be orders of magnitude greater than Aaron Durall's laboratory, Reliance Laboratory Testing, Inc., could."

$32 Claim Goes to $3,500

Anthem's fee schedule showed that Anthem paid about $32 for each claim for urine toxicology test. "But, if the co-conspirators could make it appear to Anthem that an out-of-network hospital was providing the services for the hospital's patients, they could bypass the $32-reimbursement cap. With that simple deception, they could transform a $32 claim into a $3,500 claim, because hospitals were paid as a function of their billed charges," the lawsuit explained.

In 18 months before Durall and SWMC worked together, the medical center billed urine testing claims at an average of $118 per test. After the scheme was in place, the same testing was billed at $3,500, the lawsuit said.

Also, before the scheme, SWMC had submitted only 50 claims for urine toxicology testing over 18 months. In the first nine months of the scheme, billing for urine testing rose to more than 50 claims each day for a total of 15,000 claims, the lawsuit said.

Given the lawsuit and other pressures, the directors of SWMC voted Aug. 17 to convert the hospital into a long-term, acute-care facility and urgent-care center. It will no longer operate as a hospital, the *Sonoma West Times and News* reported.

During a special meeting the PDHCD also voted to accept an offer from **American Advanced Management Group** of Modesto, Calif., to replace the administrative staff of the hospital. Earlier this month, the PDHCD announced that SWMC would run out of money by Aug. 31.

By no means is the example of Sonoma West Medical Center's involvement in a pass-through billing scheme involving toxicology lab testing an isolated example of this type of alleged fraud. Over the past several years, THE DARK REPORT has published stories of other similar arrangements, typically involving small rural hospitals and community hospitals that are at the point of financial collapse and desperate for more revenue.

These stories are intended to help lab administrators and pathologists—particularly those working in hospital and health network laboratories—to understand the scale of lab test fraud that is widespread in this sector of the hospital industry. **TDR**

—Joseph Burns

Contact Robins Kaplan attorneys Roman Silberfeld at rsilberfeld@robinskaplan.com; David Martinez at dmartinez@robinskaplan.com or 310-229-5800.

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

There is a new sector in the clinical laboratory industry. It is called "global direct-to-consumer (DTC) genetic health testing" by **Kalorama Information**, a market research firm based in Rockville, Md. In a recent report, Kalorama says this sector is comprised of the direct-to-consumer genetic tests which are initiated by the consumer, meaning that the consumer decides and orders the genetic tests. According to Kalorama, during 2017, revenue in this sector totalled $99 million and the company predicts it will top $310 million by 2022. It also predicts that government regulation of DTC genetic tests will ease during the next four years and that will stimulate growth in this sector.

MORE ON: *DTC Testing*

Kalorama identifies **23andMe** as the leader in this market sector. It lists other key players offering DTC genetic tests as **EasyDNA** of Elk Grove, Calif.; **Eastern Biotech and Life Sciences** of Dubai, UAE; and, **Mapmygenome** of Madhapur, Hyderabad, India.

APPLE TO DEVELOP CHIPS FOR HEALTH INFORMATION

Apple is developing a custom chip that would specifically handle health information tracking and related applications. On August 14, *MDLinx* reported that Apple's Health Sensing hardware team was hiring engineers for this project. The Apple iPhone and watch currently have health monitoring features. *MDLinx* said that, by designing a custom chip, Apple could better protect its intellectual property. Another goal would be to design a chip function that could continuously monitor blood sugar. Also competing in this market segment are **Alphabet** (parent of **Google**), **Amazon**, and **Microsoft**.

TRANSITIONS

• Paul Mango was appointed Chief Principal Deputy Administrator and Chief of Staff at the **Center for Medicare and Medicaid Services**. Earlier this year, Mango was a candidate for the Governor of Pennsylvania. Previously, Mango held executive positions at **McKinsey and Company** and **The Institute for Transfusion Medicine**.

• Anne T. Daley now serves as the Quality Officer for **ARUP Laboratories**. She formerly worked with **Daley Consulting**, **Chi Solutions**, **Ascendium**, **Roche Diagnostics**, **University of Phoenix**, **Sonora Laboratory Services**, **Maricopa Health**, and **Hartford Memorial Hospital**.

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That's all the insider intelligence for this report. Look for the next briefing on Monday, September 10, 2018.

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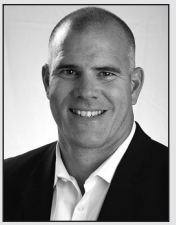

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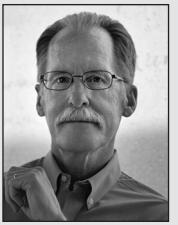

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