Volume XXV, Number 4 Monday, March 5, 2018

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

Two Major, Disruptive Changes Coming to Labs

TWO MAJOR, DISRUPTIVE CHANGES lie ahead for both clinical laboratories and anatomic pathology group practices. Each disruptive factor has nothing to do with how payers select in-network labs or reimburse for lab testing services.

Rather, one of these two major changes involves fundamental advances in the diagnostic technologies used by labs to diagnose disease and guide physicians. The other major change centers upon control of the lab testing marketplace by a new group of deep-pocketed corporate entities.

These important developments will be discussed in detail at the upcoming 23rd annual *Executive War College on Lab and Pathology Management*, which takes place on May 1-2 in New Orleans. *(Visit: www.executivewarcollege.com.)*

At the general session on Wednesday, May 2, keynote Speaker Mara Aspinall, CEO of **Health Catalysts** in Boston, Mass., will take up the first major disruptive trend. She will discuss how the flood of data from gene sequencing and other fast-developing sources of biomarkers is poised to transform how laboratories are organized. Her presentation is titled, "Big Changes in Clinical Diagnostics: Why Your Lab is Now in the Information Business, with a Wet Lab on the Side."

The following keynote speaker will address the second major disruptive trend. William G. Morice II, MD, PhD, is Chair of the Department of Laboratory Medicine and Pathology at **Mayo Clinic** in Rochester, Minn. He will explain why pharmaceutical companies are starting to pour huge dollars into clinical diagnostics. Their money is buying control of intellectual property, not to mention ownership of lab companies with proprietary, high-value genetic and molecular tests.

Morice's presentation has the title, "How Pharma Money and Private Equity Investors Are Poised to Use the Coming Generation of Genetic Testing and Clinical Diagnostics to Reshape the Lab Test Marketplace."

Another major topic at this year's *Executive War College* is the actual decline in Medicare revenue experienced by both hospital/health system labs and independent labs since the Part B lab test fee cuts took effect on Jan. 1. Collectively, just these three topics will have immense value in helping lab executives and pathologists develop effective strategies that allow their labs to deliver innovative lab test services while preserving financial stability. TDR

Anthem Seeks $13.5M from California Hospital

Threatens lawsuit over pass-through billing scheme, stops payment for urine drug tests

CEO SUMMARY: Anthem charged 37-bed Sonoma West Medical Center in Sebastopol, Calif., of engaging in an improper billing scheme to defraud Anthem and its affiliated Blue Cross and Blue Shield plans. In effect, the charge is a notification to SWMC that Anthem intends to sue SWMC and its owner if it does not recover the $13.5 million in a timely fashion. On Feb. 23, the hospital board voted unanimously to reject Anthem's claims, saying the hospital does "quality legal and morally correct work."

IN WHAT APPEARS TO BE A NEW CASE of "illegal pass-through billing" of lab claims by a small hospital, 37-bed **Sonoma West Medical Center** (SWMC) in Sebastopol, Calif., received a letter, dated Jan. 9, from health insurer **Anthem** demanding repayment of $13.5 million that the insurer had paid the hospital for urine drug test claims.

One of the nation's largest health insurers, Anthem alleged in the letter that the Sonoma West Medical Center 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. A DNV-accredited hospital, SWMC opened in October 2015 and has insurance contracts with Medicare, Medi-Cal, **Western Health Advantage**, **SCAN**, and **Health Net**. It added **Blue Shield of California** in August 2016.

The effect of the letter is to notify SWMC and its owner, Palm Drive Health Care District, that Anthem intends to file a lawsuit. "Although it is reluctant to do so, Anthem is fully prepared to initiate litigation to recover these funds following the time provided [under California law]," the letter said. In the letter, SWMC had until Feb. 23 to respond to the charges.

During a special meeting Feb. 23, the five-member district's Board of Directors voted unanimously to reject Anthem's $13.5 million claim, according to reporting by E.I. Hillin, a staff writer for the *Sonoma West Times*. Board President Dennis Colthurst labeled Anthem's letter a "false claim" and said the hospital does

THE DARK REPORT Intelligence Briefings for Laboratory CEOs, COOs, CFOs, and Pathologists are sent 17 times per year by The Dark Group, Inc., 21806 Briarcliff Drive, Spicewood, Texas, 78669, Voice 1.800.560.6363, Fax 512.264.0969. (ISSN 1097-2919.)

R. Lewis Dark, Founder & Publisher. Robert L. Michel, Editor.

SUBSCRIPTION TO THE DARK REPORT INTELLIGENCE SERVICE, which includes THE DARK REPORT plus timely briefings and private teleconferences, is $15.27 per week in the US, $15.27 per week in Canada, $16.05 per week elsewhere (billed semi-annually).

"quality legal and morally correct work." *(See sidebar on page 5.)*

Formerly known as **Palm Drive Hospital**, SWMC is owned and managed by the publicly funded Palm Drive Health Care District. In the *Times,* staff writer Rollie Atkinson reported that, since the hospital reopened in October 2015, it has never reported a monthly profit and operated on private loans and donations.

In April 2017, cash-starved SWMC was about to close when **Durall Capital Holdings** promised $1 million and planned to bring expanded laboratory testing to the hospital and provide what SWMC President John Peleuses called "intellectual capital" for vendor negotiations, billings, and collections, Atkinson reported.

In its letter, Anthem said it was aware that SWMC partnered with Durall Capital and also was working with **Reliance Laboratory Testing** of Sunrise, Fla., and **Medivance Billing Service**, also of Sunrise.

A Conspiracy Alleged

"Sonoma West appears to have conspired with several third parties to fabricate or misrepresent claims for toxicology testing services that were improperly billed to Anthem," said the letter from Steven M. Cohen, Anthem's Senior Associate General Counsel. "This scheme has resulted in more than $13.5 million in payments to Sonoma West. Sonoma West had no right to that reimbursement and obtained it only through material misrepresentations in the claims it submitted."

Public documents show that healthcare providers from around the United States refer patients' specimens to Reliance Laboratory Testing, and that Reliance Labs distributes those specimens to various labs, including SWMC, for screening, the letter said.

Reliance Labs keeps a portion of the specimens and does testing on those specimens "while purportedly passing on a portion of the same to Sonoma West for additional testing," the letter said.

"Sonoma West bills Anthem for some or all of this testing—representing that it had performed the testing, when, in fact, it had not," the letter added. "Further, it appears that Anthem's review of the claims shows that most of the urine samples for which Sonoma West billed Anthem were collected from patients who had no connection whatsoever with Sonoma West. That is, the patients were not treated at Sonoma West nor were they treated by a physician connected with Sonoma West who orders laboratory services to be performed at Sonoma West.

Hospital Paid More For Tests

"These misrepresentations are not simply administrative—Sonoma West (as a hospital) receives substantially higher amounts for urine drug testing, often 10 times or more, relative to the lesser amount that Anthem would pay Reliance Labs (as a clinical laboratory)," the letter said. "Indeed, it is that reimbursement delta that appears to be the only value that Sonoma West brings to its partners in the scheme."

When Anthem sought to examine medical records for 50 urine drug testing claims that Sonoma West submitted to Anthem, the health insurer learned that the hospital had no records for any of the sample claims, the letter said. "Anthem was subsequently contacted by Neisha Carter Zaffuto, who represented herself as an employee of Sonoma West, and offered to provide the requested records," the letter explained. Since then, Anthem learned that Zaffuto is President of Medivance Billing Service.

Contract Specifics Requested

In the letter, Cohen explained, it is illegal to pass through claims from other labs as if they had originated with SWMC. Such conduct would violate California law, the Anti-Kickback Statute, the False Claims Act, and lead to claims of civil liability under California law, he wrote.

Hospital Board Rejects Anthem's Charges, Says It Complies with Urine Lab Test Rules

IN RESPONSE TO ANTHEM'S ALLEGATIONS, the Palm Drive Health Care District Board of Directors voted unanimously on Feb. 23 to reject the insurer's claims that the Sonoma West Medical Center owes Anthem Blue Cross $13.5 million as a result of allegedly conspiring to fabricate or misrepresent claims for toxicology testing services billed to Anthem. The district owns SWMC and operates in part on public funding.

In rejecting Anthem's charges, board President Dennis Colthurst said SWMC has records to prove that the toxicology testing in question complies with all regulations and requirements and that the medical center can perform laboratory testing legally for non-patients as a reference laboratory under the federal hospital laboratory outreach program, according to reporting by E.I. Hillin, a staff writer for the *Sonoma West Times*.

In June 2017, the governing board of the district and SWMC approved lab management agreements with **Durall Capital Holdings Inc.**, in exchange for a loan of $2.1 million that was used in part to acquire toxicology testing equipment for SWMC's lab, Hillin reported.

"According to SWMC staff reports, the hospital performs initial toxicology screening tests sent by Durall from individuals in drug rehabilitation programs from throughout the country," Hillin added. "When further testing is necessary, those urine samples are sent to Reliance Labs, a Florida laboratory where Aaron Durall also serves as President."

In the article, Hillin included details from an SWMC toxicology report that showed how, on average, the hospital would net revenue on each drug panel of $4,000. "From July to December 2017, SWMC received more than 24,000 screening panels," he wrote. Since then, such testing volume has almost doubled to 7,000 to 8,000 tests each month, he added.

Quoting Colthurst, Hillin wrote, "We are very pleased with the new toxicology program. Our financial stability allows us to move ahead with additional plans, meet our obligations, and lets SWMC reduce its accumulated debt."

In addition, Cohen requested that Sonoma West and Palm Drive provide the following by Feb. 23, as follows:

1. A response detailing the specifics of the arrangement, and any justification that Sonoma West contends allows it to bill Anthem for testing performed on specimens with no connection to Sonoma West.
2. All contracts and agreements between Sonoma West and Durall Capital, Reliance Labs, Medivance, Providica Medical Corp., and Aaron Durall.
3. A list of all laboratory equipment in Sonoma West's facility, including serial numbers.
4. All records identifying the source of all urine specimens billed to Anthem by Sonoma West.

Cohen wrote that he was sending SWMC a flash drive with a spreadsheet that detailed all the urine drug test claims that Anthem believes were tainted by the pass-through billing scheme.

The agreements between SWMC and Aaron Durall's businesses have the characteristics of the hospital outpatient department (HOPD) scheme. More information about the business relationship between SWMC and Durall Capital Holdings, Inc., is on pages 6-8. **TDR**

—Joseph Burns

Hospital Board Expressed Doubts about Lab Billing

In public meetings, board members questioned the ethics, legality of how hospital billed lab tests

CEO SUMMARY: Pass-through billing arrangements, particularly those involving clinical laboratory tests, have long been recognized by healthcare attorneys as having great potential to violate certain federal and state laws. Despite this fact, board members of a financially-struggling community hospital went forward with a pass-through billing agreement that news accounts says committed the hospital to pay monthly fees of $175,000 for lab management and $773,000 for lab maintenance.

ANTHEM IS NOT ALONE IN QUESTIONING the legality of the pass-through laboratory test billing arrangement that exists between **Sonoma West Medical Center** (SWMC) and **Durall Capital Holdings** and its related business, **Reliance Laboratory Testing**. Hospital board members and the public are commenting on the potential legal and ethical issues of this business agreement.

After a December meeting of the **Palm Street Health Care District** board, which owns the financially-troubled 37-bed hospital, the *Sonoma West Times* wrote that district director Eira Klich-Heartt, "was sharply critical of the toxicology lab program brought to the hospital last April by Durall Capital Holdings of Sunrise, Florida. She called it a 'convoluted relationship' that might be supporting 'questionable' business practices."

Sonoma West Times further reported that "the Durall toxicology lab also came under repeated attack by members of the public attending the district meeting this week." It wrote, "Former district board member Sandra Bodley and others questioned the 'moral' and 'ethical' basis of running a Florida-based toxicology lab where almost all the test samples are from Florida and testing fees are as much as 10 times higher than prevailing industry standards. 'You may be sacrificing your integrity here,' said Bodley."

Small Hospitals Targeted

In recent years, lab management companies have targeted rural and small community hospitals seeking to get these hospitals to enter into agreements that require the hospitals, as in-network providers, to bill for the toxicology and pain management tests laboratory companies perform.

Often known as hospital outpatient department (HOPD) arrangements, these schemes are designed to enable out-of-network lab companies to bill for the lab tests they perform. The hospital is promised a substantial new source of revenue. However, in practice, the HOPD partner often takes much of the revenue away from the hospital.

Anthem's case against Sonoma West is an example of a hospital outpatient billing department arrangement. The

HOPD scheme is often coupled with healthcare management service organizations (MSOs). *(For more details, see "Lab Fraudsters Recruit Hospitals to Bill as In-Network Providers," TDR, Oct. 30, 2017.)*

This HOPD arrangement appears to be happening at Sonoma West Medical Center. The Anthem letter demanding repayment of $13.5 million from urine drug test payments provides details about the HOPD arrangement between Sonoma West and Durall Capital and Reliance Laboratory.

Additional details about this agreement have been published during the past year by the *Sonoma West Times*. For pathologists and clinical lab managers who want to understand how these HOPD deals are structured, these news stories provide many useful details.

Begins with Bankruptcy

The story starts when **Palm Street Hospital** (now renamed Sonoma West Medical Center) filed for bankruptcy protection in 2015. The hospital owners next went through management partnerships with **Pipeline**, **Americore**, and **KPC Global**. Each failed.

In 2017, Aaron Durall entered the picture. Various news accounts described different aspects of this business relationship, which reportedly include four written contracts involving the toxicology testing program.

On June 22, 2017, the hospital and the healthcare district reportedly approved management and laboratory services agreements with Durall. This happened after Durall "donated $2.1 million to stanch hospital losses in May." It was also stated that the agreements authorized Durall "to manage the hospital and new toxicology laboratory service, which was brought into the hospital under Durall's plan."

In another news story, *Sonoma West Times* said that, as part of the laboratory services agreement, Durall would provide lab specimens, while the hospital was responsible for hiring a marketing company that would provide specimens to SWMC on commission. "It is unknown how much the marketing firm would cost," noted SWT reporter E. I. Hillin.

Durall Capital Invested in Sonoma West Hospital

IN 2015, FOLLOWING THE BANKRUPTCY of Palm Drive Hospital (the previous name of Sonoma West Medical Center), the Palm Drive Health Care District entered into three failed management partnerships with "non-local medical industry entities."

Then, in 2017, as the *Sonoma West Times* reported, "SWMC entered an agreement last June with Aaron Durall and his companies, **Durall Capital Holdings** and **Reliance Laboratory Testing**. Durall forwarded the cash-strapped hospital as much as $2.1 million over the summer and promised enough drug lab testing to pump an average of $2.8 million per month into SWMC's coffers, an estimate later revised to $350,000 per month." Durall and Reliance are located in Sunrise, Fla.

It is unclear how much of this monthly revenue for urine drug test payments the hospital retains. On Aug. 2, 2017, *Sonoma West Times* wrote that, "In October, the hospital billed a net of $5.1 million for just over 5,000 toxicology test panels, according to monthly financial reports and hospital CEO John Peleuses. The windfall was offset by $4.8 million owed to Durall in management fees."

The newspaper described Durall Capital Holdings as a "Florida-based Limited Liability Corporation set up in August 2016. It is led by attorney Aaron Duvall and it owns two hospitals in Georgia and Alabama. Durall also has various management agreements at other southeastern U.S. health institutions. One of its specialties is providing laboratory services to acute care hospitals."

Sonoma West Times also reported that, "through the lab service, SWMC is responsible for billing and will receive all reimbursement, which could be lucrative, depending on the number of tests the hospital performs each month." The paper said that Durell was projecting reimbursement to be $35 for each drug analyte. Estimates were that the hospital would perform as many as 15,000 drug panels each month, with a panel comprised of 10 analytes. This was the basis for Durall projecting that SWMC would gross $2.8 million per month, if reimbursement averaged 80% of the billed amount.

Drug Screens at Hospital Lab

A news article in July stated that, under one agreement, "Durall Capital Holdings will purchase a new blood and urine testing machine for the hospital to conduct preliminary toxicology analysis. SWMC personnel will perform an initial panel of testing on specimens of non-patients—likely individuals in rehabilitation or addiction treatment centers—from around the country. Tests will determine whether one or more broad categories of drugs or chemicals are present. Upon a positive test, SWMC will send the specimen to Reliance Laboratory Testing, a third-party vendor also owned by Aaron Durall, for confirmation testing."

In August 2017, *Sonoma West Times* reported exactly how much money was going to Durall each month. This story included comments from Stewart Goldberg, the financial officer for SWMC's governing board.

Reporter Hillin wrote, "If the trend continues, the new laboratory service could actually cost the hospital money, adding to its negative cash run. According to Goldberg's summary, the hospital has to pay Durall $150,000 a month for managing the toxicology laboratory and an estimated $773,000 a month for lab maintenance. With those numbers, SWMC would need to perform 2,600 panels a month to become profitable on the lab service."

Payment for Lab Oversight

If these numbers are accurate, this is a staggeringly high sum of money for the oversight and the maintenance of a clinical laboratory in a 37-bed community hospital. It calls into question the decisions of the hospital board and administrators when they reviewed and signed these contracts.

Also notable is Durall's representation that payer reimbursement would average $4,000 for a drugs of abuse test panel with 10 analytes. Why did the board and administration's due diligence fail to question these revenue projections?

It is a rare opportunity to have public access to so many details about an HOPD pass-through billing arrangement for lab tests such as the one between Sonoma West Medical Center and Durall Capital Holdings. In combination, the Anthem demand letter of Jan. 22 and the various news stories reported by the *Sonoma West Times* and other media outlets document facts that often remain hidden until cases like this are litigated in court.

Small Hospitals Targeted

There is a key element that connects all these events at Sonoma West Medical Center. It is the ongoing financial losses the hospital has incurred since it filed a bankruptcy action in 2015. As a small and struggling hospital, administrators and hospital board members are motivated to keep the institution open and maintain clinical services to the community it serves. That need to fill the revenue shortfall is what motivates them to consider HOPD arrangements like the one offered them by Durall.

Pathologists and lab managers should consider sharing this information with their hospital CEOs and administrators. It is knowledge that could help them identify and avoid similar HOPD schemes involving lab tests. TDR

Lab Briefs

DUBAI TO TEST DNA OF ITS 3 MILLION CITIZENS

RECENTLY, GOVERNMENT OFFICIALS in Dubai announced a plan to conduct genetic testing on all three million residents. Experts say this is an unprecedented decision by any national government.

This human genome project will be part of the Dubai 10X initiative. "The authority is looking to target all residents of the emirate of Dubai, focusing on UAE nationals in the first phase of implementation," stated Humaid Al Qatami, Director General of DHA.

"The project's timetable extends over 24 months, during which we will be collecting samples, analysing DNA sequences, and recording the results in the data bank," he continued. "The following phase involves automated learning and artificial intelligence to issue reports that support research, forecast future disorders and epidemics, and plan preventive measures."

The practical goals are to use the genetic information to proactively improve clinical care. Officials in charge of the project say that the genetic data will be used to detect changes in the genes, chromosomes, and proteins that can lead to genetic diseases. They hope this information will help researchers to prevent and eradicate chronic diseases and cancer, and reduce the financial burden for treating chronic diseases.

MICRO HOSPITALS ARE POPPING UP ACROSS THE UNITED STATES

MICRO HOSPITALS ARE A GROWING TREND. These are facilities that may be between 15,000 and 60,000 square feet, with as few as eight beds.

Surprisingly, reducing the cost of inpatient care is only one reason driving this trend. Another is easier access and patient convenience.

That's the opinion of Tory Wolff, Co-founder of Massachusetts-based **Recon Strategy**. He says most of these micro hospitals are being located in suburbs and exurbs. "You want to be readily accessible so that patients will want to—when it's appropriate—come in to see a doctor or a nurse so they don't wait and wait and wait and end up in an [emergency department] with something that's very serious," he observed.

"Micro hospitals are the decentralization of healthcare," stated Richard Zane, MD, Chair of the Department of Emergency Medicine at the **University of Colorado**. "You can match the cost of care to the perfect environment."

Micro hospitals will add an interesting dimension in how hospital lab managers supervise clinical lab testing that is provided at these sites. This is a trend that will also further encourage more point-of-care testing solutions.

ROCHE ACQUIRES FLATIRON HEALTH FOR $1.9 BILLION

ON FEBRUARY 15, **Roche** announced that it would pay $1.9 billion to acquire **Flatiron Health** of New York City. Roche had previously held 12.6% of Flatiron's shares.

Flatiron Health has an interesting focus on oncology. According to *Forbes*, "The Flatiron platform captures and normalizes both structured and unstructured oncology data from diverse source systems. It also captures unstructured data from sources such as labs, research repositories, payer networks, among others, and its analytics engine pulls out relevant insights from the unstructured data, which, when combined with electronic medical records (EMR) data, generate the real-world evidence."

LEGAL CHALLENGE TO PAMA PRIVATE PAYER PRICE STUDY

ACLA Sues HHS, Claims Flaws In How CMS Set 2018 Rates

EVERY CLINICAL LABORATORY in the United States has a substantial interest in the ongoing federal lawsuit that was filed in December by the **American Clinical Laboratory Association** (ACLA) against the **U.S. Department of Health and Human Services**.

At stake are billions of dollars in cuts to the 2018 Medicare Part B Clinical Laboratory Fee Schedule (CLFS). These cuts were implemented by the federal **Centers for Medicare and Medicaid Services** under the Protecting Access to Medicare Act of 2014 (PAMA).

Analysis of Court Documents

Given the national significance of this federal court case to the clinical laboratory industry, THE DARK REPORT is presenting this analysis of the court documents that were filed by ACLA.

To date, supporting amicus briefs have been submitted by **AdvaMed**, the **American Association of Bioanalysts**, the **College of American Pathologists** and the **National Association for the Support of Long Term Care**.

In clear and compelling language, the American Clinical Laboratory Association has laid out in a 52-page lawsuit why a federal district court should overturn the payment-data-collection system the U.S. Department of Health and Human Services (HHS) established in 2016.

CEO SUMMARY: When the American Clinical Laboratory Association filed its lawsuit Dec. 11 against the Secretary of Health and Human Services, one of its main claims is that HHS collected payment data on the clinical laboratory testing business in a manner that was deeply flawed. HHS then used that flawed data to set payment rates under the 2018 Clinical Laboratory Fee Schedule. Those rates went into effect Jan. 1 and could force some clinical laboratories to close, the lawsuit says. This would reduce the access many Medicare beneficiaries have to quality lab testing.

Originally filed Dec. 11, the lawsuit asks the U.S. District Court for the District of Columbia to order Secretary of Health and Human Services Alex M. Azar to withdraw or suspend the Medicare Clinical Diagnostic Laboratory Tests Payment System Final Rule published in the *Federal Register* June 23, 2016. By instituting the final rule, HHS violated the Administrative Procedure Act and the Social Security Act, ACLA argued.

HHS wrote the final rule in an effort to comply with the Proctecting Access to Medicare Act (PAMA) of 2014. In PAMA Section 216, Congress instructed HHS to develop a new market-based payment system for clinical labs, but, the lawsuit explains, HHS did not comply with Congress' intent when it collected the private insurer payment data used to develop the new payment system, which became effective Jan. 1 under the 2018 Clinical Laboratory Fee Schedule.

After Congress passed PAMA in 2014, the Congressional Budget Office estimated that Medicare payments made under the CLFS would decline by about $100 million in the first year of the implementation of PAMA Section 216. "But that estimate assumed that the Secretary would comply with the statute and collect information from the market as a whole," the ACLA lawsuit says. "By excluding virtually all hospital laboratories from the data-reporting requirements, the Secretary's final rule has resulted in an industry-crippling reduction in Medicare payments by more than $600 million."

Required Data Collection

Under the final rule, HHS collected data on the prices commercial health insurers pay for clinical laboratory test services nationwide. But, by excluding hospitals labs, it did not collect payment data on the second largest and the highest-paid segment of the clinical lab industry, the ACLA argues.

HHS then used that flawed data to set payment rates under the CLFS that could force some clinical diagnostic laboratories to close and others to reduce lab testing services, especially in remote and rural areas. Labs in these areas are the only source of such testing for elderly and disabled Medicare beneficiaries, ACLA wrote in its lawsuit.

The effects of not collecting market data as Congress instructed are particularly acute for small community and rural hospital laboratories, the lawsuit says. Those laboratories will be forced to significantly scale back their operations or eliminate the outreach laboratory services they provide

because they will no longer be able to afford to provide those services to non-hospital patients, it adds.

Also, laboratories that serve non-ambulatory patients in skilled nursing facilities (SNFs) and nursing homes will be forced to cut back their services significantly, and many of these laboratories will be forced out of business, it says.

Nursing Homes, SNFs

Providing lab testing services to nursing homes and SNFs is a costly endeavor that larger laboratories will not be willing to provide, the lawsuit adds. "As laboratories close or are required to scale back services, Medicare beneficiaries and other patients will suffer by being deprived of the essential laboratory services they need," it says.

The ACLA lawsuit also described one of the chief reasons the data were flawed. This was because, under HHS' payment-data-collection system, only 21 of the nation's 7,000 hospital laboratories submitted data.

Yet, those 7,000 hospital labs represent 26% of Medicare spending on clinical lab testing, and, by one estimate, commercial insurers often pay hospital labs 1.5 to four times more than what they pay large independent labs for the same laboratory tests, the lawsuit explains. By another estimate, some private payers pay hospital labs 160% more than Medicare pays, while other labs get paid much less than Medicare pays, the lawsuit adds.

Data Skewed In HHS' Favor

By using data that came overwhelmingly from independent and physician office labs, the payment-data-collection program skewed the data in HHS' favor, noted ACLA in its lawsuit. The federal Centers for Medicare and Medicaid Services (CMS) used that flawed data to set the 2018 Clinical Laboratory Fee Schedule, which went into effect on Jan. 1.

Written by lawyers Mark D. Polston and Ashley C. Parrish of the law firm **King & Spaulding** in Washington, D.C., the ACLA lawsuit says it seeks to prevent significant disruptions to the nation's healthcare system by correcting the Secretary of Health and Human Service's refusal to comply with an unambiguous directive by Congress.

In 2014, Congress passed PAMA to permanently replace the sustainable growth rate (SGR) formula used to set Medicare payment rates for physician services. Congress used PAMA to also modernize the Medicare program by ensuring that reimbursement from CMS to clinical diagnostic laboratories closely reflected the payments that laboratories receive from commercial payers.

"One of PAMA's central features is a congressional mandate that the secretary collect information from all 'applicable laboratories' regarding the private-sector payments they receive," the lawsuit says.

Defining 'Applicable Lab'

The definition of the term "applicable laboratory" is a central part of the ACLA's argument and is critical to the success of the ACLA's lawsuit. PAMA was unambiguous in that it said all "applicable labs" should have been included in the payment-data-collection effort, the lawsuit explains. THE DARK REPORT has reported on these facts extensively since CMS announced and published the final rule to implement the payment-data-collection program. *(See TDRs, July 5, Nov. 7, and Nov. 28, 2016; Feb. 21, Apr. 3, and Oct. 9, 2017.)*

"The statute defines 'applicable laboratory' broadly to include any laboratory that obtains a majority of its Medicare revenues from fee schedules used to reimburse laboratories for testing services provided to beneficiaries who are not registered hospital patients," the lawsuit says. "As the Secretary has acknowledged, Congress designed the statute to require the Secretary to collect private-sector information from all significant partici-

In ACLA Lawsuit, Lawyers Outline Three Reasons Why PAMA Market Price Rule Should be Withdrawn

IN CONCLUDING THE INTRODUCTION to its federal lawsuit against the Secretary of Health and Human Services, the lawyers for the American Laboratory Association offer three reasons why the final rule should be vacated.

"First, the final rule is contrary to and cannot be reconciled with the plain statutory requirements. Indeed, the rule is such a clear violation of Congress's unequivocal commands and so exceeds the express limits that Congress imposed on the Secretary's authority, it should be struck down as *ultra vires*," the lawsuit says. *Dictionary.com* defines *ultra vires* as being beyond one's legal power or authority.

"Second, the final rule is unreasonable. The Secretary's attempt to rewrite the statute to exempt hospital laboratories from the reporting requirements is inconsistent with the statute's design, structure, and purpose.

'Arbitrary and Capricious'

"Third, the final rule is arbitrary and capricious. The Secretary's only reason for exempting hospital laboratories from their statutory reporting obligations—the purported administrative challenges of determining which hospital laboratories meet the statutory requirements—cannot justify his failure to comply with the statute that Congress enacted. The Secretary has also failed to respond meaningfully to comments, brushing off with no reasoned explanation both serious objections to this approach and proposed alternatives that would have complied with Congress' directives," said the lawsuit.

After outlining these three reasons, the lawsuit explains the consequences of leaving the final rule in place. "If the Secretary's statutory violation is not corrected, the consequences will be severe," the lawsuit says.

Far Below Private Rates

"Because the data-collection parameters imposed by the final rule are destined to lead to the Secretary establishing payment rates that are far below private-sector rates, some laboratories will be forced out of business, others will be forced to scale back essential services, and patients will be deprived of the services they need," said the lawsuit. "Instead of modernizing the Medicare program to better reflect the private sector market, as Congress intended, the Secretary's statutory rewrite has put his own parochial interests ahead of the program and subverted Congress' reforms.

"None of this should be allowed to occur. Instead, the court should enforce the statute as written and strike down the Secretary's final rule," the lawsuit adds.

pants in the laboratory market. A major component of that market is the thousands of hospital laboratories that, in addition to serving hospital patients, compete with other laboratories to provide services on an outreach basis to non-hospital patients."

Was Congress Contradicted?

When HHS officials drafted the rules clinical labs needed to follow in their reporting private payer lab test payment data, it contradicted the instructions Congress included in Section 216 of the PAMA statute, the lawsuit argues.

"In implementing his data-collection obligations, the Secretary promulgated a final rule that unlawfully rewrites the definition of 'applicable laboratory' and contradicts Congress' express instructions," the lawsuit says. "HHS did so by defining an 'applicable laboratory' as one that bills Medicare under its own National Provider Identifier (NPI).

Is the 'Hidden Data Tab' the Smoking Gun? What Excel Reveals About HHS' Calculations

In the lawsuit, the lawyers explain that when making its calculations for the 2018 Clinical Laboratory Fee Schedule, Health and Human Services may have inadvertently exposed a bias in the calculations of market price data.

When HHS published the new payment rates for clinical labs under the 2018 Clinical Laboratory Fee Schedule, the department inadvertently failed to delete a "hidden data" tab that was included with the Microsoft Excel file online.

Under this "hidden data" tab, the lawsuit says, were "columns labeled 'payment difference' and 'payment percentage change' comparing what appears to be the 'count' of HCPCS codes when the data from two large independent laboratories is included and excluded. As of March 5, this Excel file was available online on the CMS website, via this link: *https://tinyurl.com/zaawygs.*

By reviewing the data on this tab, it is possible to see how those doing the analysis at HHS viewed the effect of including or excluding data from the two largest independent laboratories. The lawsuit explains that this tab, "shows that the Secretary understood that collecting data principally from large independent laboratories (and excluding hospital laboratories) would result in a data set that would dramatically reduce Medicare payments.

"The consequences of the Secretary's data-collection efforts are significant and underscore just how far he missed the mark set by Congress," the ACLA lawsuit says.

"The Secretary's final rule requires that to qualify as an 'applicable laboratory,' the laboratory must bill the Medicare program under its own National Provider Identifier (NPI)," the lawsuit says. "As the Secretary has acknowledged, that requirement excludes virtually all hospital laboratories from the data-reporting obligations that Congress imposed, because most hospital labs do not have their own NPI. Instead, they bill Medicare for laboratory services under the NPI used by the hospital as whole.

Exempting Hospital Labs

"The Secretary's final rule also effectively reads the 'majority of' Medicare revenues requirement out of the statute, exempting hospital laboratories from their statutory reporting obligations, even when a majority of their Medicare revenues are from the fee schedules that Congress specified," the lawsuit explains.

"This rewrite of the definition of 'applicable laboratory'—excluding by executive fiat an entire category of market participants from the data-reporting requirements—violates the statute and dramatically undermines the purpose of Congress' mandate that the Secretary collect private-sector information," the lawsuit adds.

This argument is important because hospital labs represent more than a quarter of Medicare spending on clinical lab tests. "In 2016, hospital laboratories received approximately 26% of the payments made under Medicare for providing laboratory services to non-hospital patients," the lawsuit says.

"But out of the approximately 7,000 hospital laboratories that billed Medicare for services provided to non-hospital patients, no more than 21 reported information to the Secretary—less than half of one percent of all hospital laboratories in the country," the lawsuit adds. Among payments under the CLFS, independent labs get 55% and physician office labs get 18%, according to data from the HHS Office of Inspector General.

By itself, this flaw in the payment-data-reporting system undermined the entire data-collection effort, as the lawsuit explains. "Because hospital laboratories often receive higher private-sector payments for the testing services they provide—as much as 1.5 to four times higher than the rates paid to large independent laboratories—the Secretary's final rule ensures that, contrary to Congress' intent, the information collected by the Secretary does not reflect the private-sector market as a whole," the lawsuit says.

In the lawsuit, the lawyers asked for a summary judgment, in which a court is asked to rule for the plaintiffs without a full trial. HHS's response to the ACLA motion for summary judgment is due on March 16.

A Way to Challenge the Rule?

In recent months, THE DARK REPORT has interviewed several attorneys knowledgeable about the clinical laboratory industry and federal law to have them comment on what issues would allow labs to challenge how HHS and CMS interpreted the language of the PAMA statute to design a final rule for the private payer market price study, then used those data to set new lab test rates.

The consensus was that, because the PAMA statute and the final rule on market price reporting both have language that prevent a court challenge to the rates published by CMS, labs would be unable to sue on that basis.

However, these attorneys generally agreed that there was ample legal precedent for clinical laboratories to file a lawsuit that challenged how the federal agencies interpreted the language of the PAMA statute and used that interpretation to write a final rule and design a program to collect private payer lab test price data—the same data that CMS would use to determine the Part B CLFS prices. TDR

—Joseph Burns

ACLA Explains Why Legal Challenge Is Warranted

WHEN CONGRESS PASSED the Protecting Access to Medicare Act of 2014, it added a section to the law that stated that labs could not challenge the rates that resulted from the law. Those new rates for the Medicare Part B Clinical Laboratory Fee Schedule went into effect on Jan. 1.

In filing its lawsuit against the Secretary of Health and Human Services, the American Clinical Laboratory Association did not challenge the rates that the federal Centers for Medicare and Medicaid Services set under the law. Rather, the lawsuit challenges the way the federal Department of Health and Human Services implemented the law.

"There is no doubt that Congress knows how to bar judicial review when it wants to," the lawsuit explains. "In a separate provision of PAMA, Congress prohibited judicial review of the Secretary's "establishment of payment amounts." But Congress did not state that the payment-data-collection could not be challenged.

"Congress' decision to include an express provision precluding challenges to the 'establishment of payment amounts,' but not to include a provision precluding challenges to the Secretary's final rule establishing the 'parameters for data collection,' demonstrates that Congress did not intend to strip courts of jurisdiction to review the secretary's final rule," the lawsuit explains. "It is axiomatic that '[w]here Congress includes particular language in one section of a statute but omits it in another section of the same act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion."

Since the ACLA filed the lawsuit, amicus briefs in support of ACLA have been filed by AdvaMed, the American Association of Bioanalysts, the College of American Pathologists and the National Association for the Support of Long Term Care.

Sale of Tox Lab Company Attracted Multiple Buyers

When listed for sale, DrugScan drew interest of several investment firms and other clinical labs

CEO SUMMARY: In the midst of expanding their toxicology testing services nationally, DrugScan and DSI Medical Services (collectively Toxicology Holdings Inc.) hired a brokerage firm last year to pursue a sale of the two toxicology companies. Multiple potential buyers responded with interest. The buyer, ACM Global Laboratories—owned by a health system in Rochester, N.Y.—saw the acquisition of THI as a way to grow beyond its existing toxicology testing operations in Upstate New York and Connecticut.

WHEN A TOXICOLOGY LAB COMPANY outside Philadelphia put itself up for sale last year, it got just what any clinical laboratory would want from the offering: stong interest from multiple potential buyers.

That's what happened with the sale of **DrugScan** and its affiliated company, **DSI Medical Services,** to **ACM Global Laboratories** of Rochester, N.Y., last month. *(See TDR, Jan. 22, 2018.)* DrugsScan is a toxicology laboratory, and DSI Medical is a third-party administrator that provides employers with such services as drug testing and physicals.

Having owned the company for nine years, the owners, including DrugScan President and CEO Anthony G. Costantino, PhD, and executives at **Eureka Growth Capital**, decided last year that the time was right to pursue a sale. DrugScan and DSI Medical retained **Lazard Middle Markets** to represent them in the marketplace, Costantino said.

"Lazard found numerous interested parties and we had a competitive process," he explained. "Some were financial backers wanting to invest their capital and some were other lab companies."

Although he would provide no other details and the terms of the final deal were not disclosed, Costantino said, "There was somewhat of a bidding war, and I'm definitely happy with the outcome."

A Deep Pocket Partner

For DrugScan, ACM Global had two factors in its favor: It has deep pockets and was looking to expand nationwide. For ACM Global, DrugScan and DSI Medical had useful assets as well, including contracts with health insurers and operations nationwide.

ACM Global is a clinical and pathology lab affiliated with the **Rochester Regional Health System**, a multi-hospital integrated delivery system with $2.2 billion in annual revenue and 17,000 employees. The lab does 20 million tests annually and operates in more than 65 countries, most of which are for clinical trials.

To support its lab acquisition strategy, ACM Global wanted to expand beyond its operations in upstate New York and

Toxicology Lab Already Sees Less Revenue As Reduced Medicare Part B Rates Kick In

WHILE THE SAMPLE SIZE IS SMALL, it's significant nonetheless that DrugScan has seen slightly lower payments from CMS as 2018 begins.

In 2017, payment rates from the federal **Centers for Medicare and Medicaid Services** ran slightly ahead of what CMS paid in 2016, said DrugScan President and CEO Anthony G. Costantino, PhD.

But this year, revenue is already dropping down again, he added.

"In 2017, our reimbursement levels for toxicology testing were better than we had in 2016," he said. "But now, the reimbursement levels that we see look like they may go down again, just as we thought they might.

"Our first reimbursements from Medicare for toxicology testing this year are in line with what we expected from the 2018 Clinical Laboratory Fee Schedule," he added. "In other words, they are lower than they were last year.

"We see about a 10% drop in the drug screening test codes and about a 2.7% drop in the definitive testing codes," Costantino said.

"But, we're a diversified toxicology laboratory and only about half of our revenue depends on reimbursement from Medicare and private health insurers," he added. "The other half is all business-to-business relationships because we work with other clinical labs, pharmaceutical companies, state licensing boards, police departments, employers, and the like. They all need tox testing and that volume and their payments are holding steady, at least for now."

Connecticut. Those expansion plans made ACM Global an ideal partner for DrugScan and DSI Medical because the two companies in Horsham, Pa., also wanted to grow their toxicology testing business nationwide, Costantino told THE DARK REPORT.

Synergistic Expansion Plans

DrugScan has operations in 23 states and DSI Medical services operates in all 50 states. That national presence enables ACM Global to expand into those markets, said ACM Global President and CEO John Foley. Another key asset that made DrugScan attractive was the contracts it has with 114 health plans, which is four times the number of health insurance contracts ACM Global had before the acquisition, Foley added.

While DrugScan and DSI Medical were attractive acquisition targets when they were put up for sale last year, their beginnings were more humble. "DrugScan was founded in 1985 by Richard Cohn and Robert Tully," noted Costantino. "They started it as a partnership focused almost exclusively on workplace drug testing with a little bit of forensic testing for police departments.

"Then, in 2008, we (meaning Eureka Growth Capital, Jack Bergstrom, Phil DuBois, Tim Johnson, and me) acquired DrugScan from the founders," he added. "We did so because we saw tremendous opportunity for investment and growth in the toxicology space for a company that would have solid testing methods and high integrity in the marketplace.

Workplace Drug Testing Lab

"At the beginning, our initial plan was to be a workplace drug testing laboratory," said Costantino. "However, the poor economy in 2008 and 2009 caused a dramatic decline in test volume because the majority of DrugScan's work was pre-employment testing. And, because few employers were hiring, there was less demand for those services.

"Seeing these trends, our response was to diversify our mix of clients," recalled Costantino. "To do that, we pursued the credentials to become a clinical laboratory, which DrugScan did not have at the time. We needed CLIA certification and credentials to become a clinical laboratory and bill health insurance companies.

"Those credentials also included becoming a CAP-certified laboratory licensed in Pennsylvania to complement our SAMHSA certification," he said. "Since then, we've expanded and now have a national footprint and a big healthcare and network insurance presence.

"In addition, DrugScan also developed a niche in the drug testing space. We also develop test abuse deterrent formulations of narcotics for pharmaceutical manufacturers," Costantino said. "The FDA requires manufacturers to reformulate narcotic dosages into abuse-deterrent formulations so that they are not easy to crush or get them into an injectable or smokable form. That's an important niche for us, particularly when there's so much interest in that work, given the epidemic of narcotic-related deaths.

Turning Away Business

"One important challenge for any toxicology testing laboratory is to avoid being tainted by the behaviors and business practices of some in the industry, as evidenced by the various lawsuits from health insurers and charges and settlements with federal investigators for fraudulent testing and kickbacks paid to physicians to boost test volume," explained Costantino. "Early on, we implemented a rigorous program to ensure that our business practices complied with relevant laws and regulations.

"From day one, compliance has been our mantra," he added. "When we started, our owners were industry executives who had deep experience in operating clinical laboratories and they wanted to build a solid company that would last.

"As one example, we did not over-test," stated Costantino. "Also, of course, we had a compliance policy, a compliance officer, and ongoing monitoring of operations so that compliance became part of our culture."

Such a focus has not been come without cost. "Our compliance program has caused us to turn away business at times, because there are things we won't do," he explained. "Our compliance program has influenced the culture as well. The benefit is good employee retention because everyone understands the culture we pursue, buys into it, and are proud to work here."

Looking Ahead

For Costantino, the deal was attractive because ACM Global wants to make DrugScan its toxicology center of excellence, which will allow the lab to continue to grow, he said. "We've always been in a growth mode, going from fewer than 30 some employees in 2008 to about 180 now," he said.

"During that same time, our revenue increased more than five-fold," he said. "With an infusion of capital from our new owners, we expect to increase test volume. In turn, that creates stability for our employees.

"That new capital will allow us to build out the space we have here and add new lab equipment," he explained. "Another factor that will help is that ACM Global has significant inroads into various types of toxicology customers. We also expect there to be an expansion in the number of sales reps at DrugScan and ACM. That will allow us to capitalize on the opportunities in the clinical toxicology market."

It is unusual to have a clinical laboratory company owned by an integrated healthcare system wanting to expand its geographical reach with toxicology testing services. This makes Drugscan an interesting lab company to watch. TDR

—Joseph Burns

Contact Anthony Costantino at 267-960-3400 or Anthony.Costantino@drugscan.com.

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

"More people took genetic ancestry tests last year than in all previous years combined," declared Senior Editor Antonio Regalado in a story published on Feb. 18 by *MIT Technology Review*. He wrote that, just in 2017, the number of people who had their DNA analyzed with direct-to-consumer genetic genealogy tests more than doubled. According to industry estimates, 12 million people have now done such testing and most live in the United States. **Ancestry.com** leads the pack. It announced in February that it has done testing on seven million people. Notably, it did two million genetic genealogy tests just during the last four months of 2017.

MORE ON: *Gene Tests*

According to *MIT Technology Review*, **23andMe** is the second largest, having tested more than three million people. Then comes **MyHeritage** and **FamilyTreeDNA**. **Laboratory Corporation of America** does the gene sequencing for 23andMe. **Quest Diagnostics** does the gene sequence testing for Ancestry.com.

PAIGE.AI RAISES $25 MILLION

In New York last month, pathology company **Paige.AI** secured $25 million in Series A funding. It also inked a deal with **Memorial Sloan Kettering Cancer Center** that gives it access to its 25 million pathology slides, as well as MSK's "intellectual property related to computational pathology."

ROSETTA CANCELS DEAL TO ACQUIRE GENOPTIX

On Feb. 23, **Rosetta Genomics** disclosed that its proposed merger with **Genoptix** had been canceled. The financially-struggling genetic testing company said that it had failed to secure the necessary shareholder approval. On that date, Rosetta's share price was $0.30 on the NASDAQ exchange. Because its share price has been less than NASDAQ's minimum $1 bid price requirement since October, it has been out of compliance. The company has until May 29 to return to compliance.

TRANSITIONS

- **Bio-Rad Laboratories** announced that John Goetz, currently Executive Vice President and COO, "will retire and resign from his position effective March 30, 2018." Goetz began his career at Bio-Rad in 1974 and has served the company continuously since that date.

That's all the insider intelligence for this report. Look for the next briefing on Monday, March 26, 2018.