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YEAR END SPECIAL REPORT!

2016 TOP TEN BIGGEST LAB STORIES

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

Revisiting the 'Substantially in Excess Rule'

BY NOW, NEARLY EVERY LAB MANAGER knows that Medicare lab test fee cuts will commence in just 13 months, on Jan. 1, 2018. The federal **Centers for Medicare & Medicaid Services** estimates that the final rule for PAMA private payer market price reporting will produce cuts of $5.4 billion over 10 years. *(See TDRs, November 7 and November 28, 2016.)*

Thus, CMS is preparing to implement fee cuts that total more than double the $2.4 billion cost cuts that Congress and the **Office of Management and Budget** scored at the time that the Protecting Access to Medicare Act was passed in 2014. As reported by THE DARK REPORT and other lab industry news sources, the aggressive fee cuts planned by CMS will cause a substantial number of the nation's community labs to go out of business. The cuts will also do financial harm to many rural hospitals that depend on the revenue generated by outreach lab tests.

If the clinical laboratory industry wants Congress to derail the PAMA market price reporting program that CMS is implementing, it will need to have an acceptable alternative. The lab industry must show Congress how to achieve the original targeted cost savings by an alternate and credible method. Recently, some lab leaders called our offices to discuss their thoughts about resurrecting the "substantially in excess rule." They think it might be a viable way for Congress to stop the PAMA market price reporting program and replace it with this rule. They also pointed out that Congress can limit this rule to just the clinical laboratory industry (and not all healthcare providers, as was originally proposed).

In 2003, CMS published a proposed "substantially in excess rule," then later withdrew that rule. The core concept was that "substantially in excess" would mean an amount that is 20% greater than the provider's usual charge for a given item or service and this would include negotiated rates that managed care plans pay (capitation excluded).

The lab leaders suggested that crafting a version of the "substantially in excess rule" would give Medicare approximately the same discounted prices that labs offer to managed care plans and would be an equitable way for Congress to realize the cost savings expected from PAMA without putting many of the nation's community labs at risk of financial failure or bankruptcy. If you have thoughts on this problem, please share them with us! TDR

Much Disruption for Labs In 2016's Top 10 Stories

Events set in motion during this year will cause big cuts to Medicare Part B fees beginning in 2018

CEO SUMMARY: Within THE DARK REPORT's list of the Top 10 Lab Industry Stories for 2016 is one story of disruption that might have been and one story of disruption about to happen. The disintegration of Theranos during 2016 is the big story about a self-proclaimed disruptor of the lab industry that finds itself struggling just to survive. The big story about impending financial disruption involves the final rule for PAMA private payer lab test price reporting that CMS issued last June.

IT WAS A YEAR DOMINATED BY TWO BIG LAB INDUSTRY STORIES! One was about **Theranos, Inc.**, the now-discredited lab testing company that said it wanted to disrupt the clinical laboratory industry.

The other big story was about the PAMA final rule that the **Centers for Medicare & Medicaid Services** published on June 17, 2016. Implementation of this final rule is expected to lead to a significant reduction in Medicare Part B lab test fees in 2018 and will thus be financially disruptive to most of the nation's clinical laboratories.

Theranos is one of the big stories on THE DARK REPORT'S list of the Top 10 Lab Industry Stories for 2016 because this was the year when the much-vaunted lab company found itself in deep trouble on multiple fronts. Consequently, it will not be disruptive to the clinical lab industry as it regularly predicted during the years 2013 through 2015. *(See page 5.)*

One reason Theranos was a top 10 story among lab administrators and clinical pathologists is that it was a high-interest story for their hospital and health system CEOs from 2013 through 2015. During that time, Theranos caught the attention of nearly every hospital CEO with its claims that it could perform clinical laboratory tests at half the price of Medicare fees, use a capillary blood specimen collected by finger stick, and return results in four hours.

Hearing these benefits, hospital CEOs regularly asked their lab administrators and clinical pathologists about Theranos and, in some cases, asked these lab professionals to identify ways the hospital could

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do business with Theranos to lower the cost of clinical lab testing.

Most lab administrators and pathologists were skeptical that Theranos had the technology and capability to deliver on its claims. They pointed to the fact that Theranos had not shared its scientific data nor published its data in peer-reviewed journals.

PAMA Market Price Reporting

The other big story on this year's top list is about the final rule for PAMA market price reporting. Every laboratory that does testing for Medicare patients will see a substantial reduction in the prices of Medicare Part B lab test fees in 2018. THE DARK REPORT concurs with a number of lab industry experts that these Medicare fee cuts may be the single most disruptive event to hit the clinical laboratory industry in 40 years. *(See page 5.)*

Each of the other eight stories on this year's list of the major lab industry stories represents a significant development that influences how lab executives and pathologists will operate their clinical labs and pathology groups.

The outcome of this year's federal elections and Republican control of the presidency, the Senate and the House is one of this year' big stories, for a simple reason. The electorate has sent a message to both political parties that the political processes of the last 30 years must be left behind and a new sense of purpose and public service should be the hallmark of the new Congress.

Why this matters for the lab industry is that Congress will consider repeal of the Affordable Care Act and additional reforms to healthcare. The new administration gives the clinical laboratory industry an opportunity to educate this new crop of lawmakers about the value of lab testing and the importance of allowing community labs and hospital labs to have access to patients. *(See page 9.)*

The election outcome is also an important element in our number three biggest story of 2016: **the Food and Drug Administration's** decision to defer going foward with its draft guidance for regulating laboratory-developed tests (LDTs). This is another opportunity for the lab industry to educate federal lawmakers about the complexities of developing LDTs and gathering clinical data necessary to demonstrate the accuracy and clinical value of these assays. *(See page 6.)*

Payment for clinical laboratory tests make up two of the stories on 2016's top 10 list. During the year, THE DARK REPORT identified several molecular and genetic testing companies that had revamped the prices of their proprietary tests. These lab companies decided that they would be more successful if they priced their genetic tests so that patients could afford them. In some cases, these genetic testing labs stopped billing any payer for any test. Instead, they are billing patients and collecting a high percentage of these bills. *(See page 6.)*

'Not' On Top 10 Story List

It is helpful to call attention to some major healthcare trends that have been on past top 10 story lists, but do not appear on this year's list. One such story is EHR implementation by hospitals and physicians. This is a mature trend and, in fact, EHR adoption and use is about to be incorporated into Medicare's physician incentive/penalty programs under the Medicare Access and CHIP Reauthorization Act (MACRA).

The other story that is not on this year's list is the integration of healthcare through such care models as ACOs and medical homes. This process continues, but other stories during 2016 had greater precedence for the clinical lab industry and thus made the top 10 list. TDR

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2016 1 CMS Publishes PAMA Final Rule, Prepares for Medicare Lab Fee Cuts

ALL THE PIECES ARE IN PLACE for the federal **Centers for Medicare & Medicaid Services** to begin accepting private payer lab test market price data from certain labs, starting on January 1, 2017, as mandated under the Protecting Access to Medicare Act (PAMA).

CMS will use this data to establish a new Part B clinical laboratory fee schedule that takes effect on January 1, 2018. CMS has said that the new fees will cut Medicare spending on lab tests by as much as $400 million during 2018.

THE DARK REPORT and others have predicted that implementation of the final rule—as currently written—has the potential to be the most financially-disruptive event to hit the clinical laboratory industry in 40 years. *(See TDRs, Nov. 7 and Nov. 28, 2016.)*

Moreover, lab executives and consultants who have compared the final rule to the PAMA statute believe that CMS is not following the language of the law nor the intent of Congress. At stake are fee cuts that CMS and OIG say will total $5.4 billion over the next 10 years. This amount is double the fee cuts that were predicted when Congress passed PAMA in 2014.

The next move is up to the clinical laboratory industry. Avenues of redress would be to file a lawsuit against **Health & Human Services**, file an administrative appeal, or get the new Congress to amend the PAMA statute.

2016 2 Theranos Implodes during 2016: Sanctions, Investigations, Lawsuits

IT WAS A BUSINESS REVERSAL of stunning proportions for the once high-flying **Theranos, Inc.**, of Palo Alto, Calif. In February, news outlets reported that a CLIA inspection of the Theranos lab facility in Newark, Calif., had identified serious deficiencies with the potential to cause "patient harm."

Next came revelations in April in *The Wall Street Journal* that Theranos was under investigation by the **Department of Justice** and the **Securities & Exchange Commission**. That was followed by the decision of the **Centers for Medicare & Medicaid Services** in July to impose the toughest CLIA sanctions against Theranos, including a two-year ban on Theranos CEO Elizabeth Holmes owning or operating a clinical laboratory.

At the **American Association of Clinical Chemistry** meeting in August, Holmes was to make a much-ballyhooed presentation about the Theranos technology and scientific data. Instead, she showed a new instrument and some assay validation data that use conventional methods and venous blood. The lab scientists in the audience and nearly all the major media outlets that were present panned her presentation. *(See TDR, August 15, 2016.)*

In the months that followed, Theranos announced that it was laying off hundreds of employees and closing its clinical laboratory operations in California and Arizona. It also said it would concentrate on developing instruments and assays that use its diagnostic technologies.

2016 3 FDA Announces Delay in Issuing Guidance for Lab-Developed Tests

OH WHAT A DIFFERENCE ONE NATIONAL ELECTION CAN MAKE! Following the Republican sweep of the presidency and both houses of Congress, the **Food and Drug** Administration made an unexpected decision.

FDA officials began to quietly tell selected stakeholders that it would delay finalizing its draft guidance for laboratory-developed tests (LDTs). This was welcome news for the clinical laboratory profession.

On November 18, *Genomeweb.com* reported that the FDA had sent it a statement, saying, among other things, that it realizes "just how important it is that we continue to work with stakeholders, our new Administration, and Congress to get our approach right [on LDT regulation]."

Apparently, FDA officials recognized that the new Congress and new administration would probably have different ideas on how the FDA should execute its regulatory responsibilities. Thus, attempting to push forward with its draft guidance for LDTs as currently written might run counter to the views of incoming legislators and the president.

Many in the clinical lab industry who have legitimate concerns about the role of the FDA in regulating LDTs welcomed this news. There has been much criticism of the language in the draft LDT guidance. *(See TDR, October 17, 2016.)*

Because the FDA has put a hold on further development of its draft LDT guidance, the lab industry now has the opportunity to educate the new Congress about this issue and work more closely with FDA officials to craft a regulatory scheme that works best for all parties.

2016 4 Genetic Testing Labs Find Success In Use of Consumer-friendly Prices

TODAY, A SMALL NUMBER OF GENETIC TESTING LAB COMPANIES set their genetic tests at price points considered reasonable and attractive to consumers. In some cases, these labs have ceased to bill any health insurers. Instead, they send 100% of their bills directly to their patients.

During 2016, THE DARK REPORT identified several laboratory companies offering genetic tests that adopted this approach to pricing their tests. They generally report good response by patients and their physicians. More significantly, these lab companies say they enjoy increased revenues, along with decreased costs associated with coding, billing, and adjudicating rejected claims for their genetic tests. *(See TDRs, May 2 and July 5, 2016.)*

This is a significant development in the clinical lab marketplace. Until now, the popular wisdom said that a genetic testing lab with a proprietary test should put a high price on the assay because most payers would reimburse much less for the test—if the payer sent any money to the lab at all.

But the difficulty of getting payers to reimburse for these test claims is what motivated these labs to decide to adopt a much lower, patient-friendly price for their tests. In so doing, patients were now willing to pay directly for those tests because they saw value in the genetic test at that lower price.

2016 5 Payers Get Tougher with Audits, Guidelines Due to Lab Fraud/Abuse

FRAUD AND ABUSE WITHIN THE CLINICAL LABORATORY INDUSTRY continues to be a serious problem. As a consequence, payers are tightening down on practices they consider to be illegal or unethical.

One trend reported by THE DARK REPORT is how more payers are auditing labs to determine if these labs are collecting the full amount due from patients. Another trend is for health insurers to simply refuse to pay claims coming from labs that are out of network.

THE DARK REPORT has provided extensive intelligence briefings about cases of lab fraud and abuse that have become public. One high-profile case involving cardiology testing is the ongoing federal whistleblower lawsuit that named, as defendants, **Health Diagnostic Laboratories** (HDL), **Singulex**, and **Berkeley HeartLab**. Separately, **Aetna** and **Cigna** each sued HDL to recover tens of millions of dollars in claims paid to HDL that are alleged to be fraudulent or medically unnecessary. The other sector of the lab industry that has become associated with a high rate of fraud and abuse includes labs providing toxicology and pain management testing services.

The extent of this illegal activity is deemed to be significant enough that both government and private payers are implementing restrictive coverage guidelines for many types of tests as one way to limit fraudulent claims. Unfortunately, this action punishes all labs—even those labs that are making extra efforts to fully comply with all federal and state laws. *(See TDR, May 23, 2106.)*

2016 6 More Hospitals, Labs Implement ISO's Quality Management System

ADOPTION OF THE QUALITY MANAGEMENT SYSTEM (QMS) built into ISO 9001 and ISO 15189 still happens at the rate of one hospital and one lab at a time. Yet, in recent years, that has been enough to create a critical mass of hospitals and labs that consider QMS to be essential to their ongoing clinical and financial success.

One benefit of implementing this QMS is that hospitals certified to ISO 9001 and labs accredited to ISO 15189 find it much easier to sustain efforts to improve quality, cut waste, and boost staff productivity.

Hospitals and health systems interested in adopting ISO 9001 are most frequently using the services of **DNV Healthcare**, of Cincinnati. DNV has hospital deeming authority from CMS since 2008. Today, more than 500 hospitals in the United States use DNV for both Medicare conditions of participation and ISO 9001 certification.

For clinical labs, along with CLIA accreditation, the **College of American Pathologists** offers CAP 15189 and the **American Association of Laboratory Accreditation** (A2LA) offers ISO 15189. Between the two organizations, they have accredited 46 labs in the United States. *(see TDRs, Feb. 29 and Sept. 26, 2016.)*

The important element of this story is that the momentum continues to build. Time and the experience of hospitals and labs are proving the value of a quality management system.

2016 7 | Safeway Uses Reference Pricing to Drive Down Lab Test Costs by 32%

REFERENCE PRICING IS A NEW TOOL for helping employers and health insurers drive down healthcare costs. For that reason, labs and pathology groups can expect to see more use of reference pricing in the years to come.

What should be considered a sentinel event for this trend is the publication of a study in *JAMA Internal Medicine* last July that documented the results of a pilot reference pricing project initiated by **Safeway**, the grocery store chain, that involved clinical lab tests.

Reference pricing is designed to reduce the variability in the cost of a healthcare service, such as a lab test. In its pilot project, Safeway set the reference price for lab tests at 60% of the median. If the patient selected a lab with a higher price, the patient paid for that test. If the patient selected a lab with a price at or less than the 60th percentile, he or she could apply the full benefits of their health plan.

The results should catch the full attention of all lab executives and pathologists. In the 24-month study involving 15,000 employees, Safeway and these patients paid 32% less for lab tests! Further, the number of patients using higher-priced labs dropped from 45.6% to just 15.6% during that same time. *(See TDR, September 6, 2016.)*

At a time when employers and health insurers are scrambling to cut costs, reference pricing is a powerful tool that can help them quickly achieve that goal.

2016 8 | HDL's Bankruptcy Trustee Proves More Aggressive than Federal DOJ

MISCREANTS IN THE CLINICAL LAB INDUSTRY should take notice! You may not fear the federal **Department of Justice** and its relatively toothless enforcement of federal anti-kickback laws. But there's a new enforcer ready to get tough with lab fraudsters.

The precedent set this year happened in the bankruptcy case filed by **Health Diagnostic Laboratory, Inc.**, of Richmond, Va., that was originally filed in the summer of 2015. The bankruptcy trustee is using every legal tool at his disposal to collect as much money as possible from all parties associated with HDL's allegedly fraudulent practices.

Thus, in September, the bankruptcy trustee announced a $20 million settlement with **LeClairRyan**, the law firm that provided legal advice and legal opinions to HDL that the lab used to convince physicians that various forms of alleged payments were not in violation of federal and state laws. LeClairRyan denied guilt.

Also in September, the bankruptcy trustee announced a $600 million lawsuit that included 76 counts against 100 defendants, including HDL shareholders, officers, and sales consultants, among others. This followed a separate action in which the bankruptcy trustee engaged a law firm to send letters to hundreds of physicians who accepted alleged inducements from HDL demanding full repayment of those inducements. *(See TDR, Sept. 15, 2016.)*

This case is a stunning example of how an aggressive bankruptcy trustee can bring to account all the parties who participate in lab testing schemes that skirt the law.

2016 9 New Crop of Republicans in Capital Certain to Change Status Quo

IT WAS A FEDERAL ELECTION LIKE NO OTHER! Americans elected an unorthodox and unlikely candidate to be president. They also voted to allow Republicans to control both houses of Congress.

Thus, all bets are off on how the new administration and new Congress will deal with the problems of healthcare in this country—not to mention the Affordable Care Act. At this moment, no political pundit can say what will happen inside the beltway.

Most observers believe the Republicans will repeal Obamacare. One scenario has Congress voting to repeal the ACA, but setting the expiration date two or three years into the future. That would create a deadline that would force Republicans and Democrats to work together to craft a replacement bill and pass it before the expiration of the ACA.

When the new administration and Congress take office next month, it will present the clinical laboratory industry and anatomic pathology profession with an opportunity to educate lawmakers and HHS officials about the value of lab testing. The time may also be opportune for labs to make their case on a host of troublesome issues.

The list of such issues is long. Probably at the top of the list is the CMS final rule for PAMA market price reporting, which most labs would like amended. Another priority would be to improve the FDA's plan to regulate laboratory-developed tests.

2016 10 UnitedHealth Prepares to Launch LabCorp's BeaconLBS in Texas

IN OCTOBER, **UnitedHealthcare** quietly let it be known that it would introduce its controversial laboratory benefit management program in Texas, with Jan. 1, 2017, as a start date and March 1, 2017, as the date when claims impact will begin.

As was true in Florida, the program in Texas will be administered by **BeaconLBS**, a wholly-owned subsidiary of **Laboratory Corporation of America**. Also, as was true in Florida, UHC is pushing to implement this on a fast time line, thus leaving physicians and laboratories serving them with little time to understand the details of the program.

UHC is implementing the program for the 500,000 patients enrolled in fully-insured commercial plans in Texas. Based on the Florida experience, most labs in the Lone Star State will lose some or all of their access to these patients. *(See TDR, October 17 and pages 11-13.)*

Further, the **Texas Society of Pathologists** has sent letters to its members calling attention to the fact that any lab that agrees to be in the "laboratories of choice network"—UHC's network-within-a-network, must accept prices that are at or below the 25th percentile, as calculated by UnitedHealthcare.

UHC announced the introduction of this program in its October Network Bulletin. Thus, most physicians, pathologists, and labs are unaware of the requirements of the program and how they are to use the BeaconLBS system to obtain pre-notification or pre-authorization when ordering any of 79 tests. TDR

Compliance Update

PAMA Reporting Penalties Can Be Substantial for Labs

STARTING JAN. 1, 2017, there are substantial penalties for labs that fail to properly meet the complex lab test price marketing reporting requirements of the Protecting Access to Medicare Act of 2014. Labs that fail to do so face the potential of stiff, multi-million dollar fines.

"Under PAMA, clinical labs need to report full and accurate data in a timely manner," warned Jeffrey J. Sherrin, a health lawyer and President of **O'Connell & Aronowitz**, in Albany, N.Y. "Under the law, labs can be liable not only for the failure to report required information or the failure to timely report it, but also can be liable for misrepresentations or omissions in reporting the required data. Penalties are possible just because your lab may have mistakenly failed to report certain information or failed to report that information on time.

"The penalties can be severe," Sherrin added. "The statute and regulations put in place a maximum penalty of $10,000 a day for each failure to report or for each such misrepresentation or omission." Sherrin provides legal services to the **National Independent Laboratory Association** (NILA). He participated on THE DARK REPORT's recent webinar about PAMA.

"When enacting PAMA, Congress set up penalties that are similar to those established for pharmaceutical companies under the Medicaid drug rebate program," noted Sherrin. "Under the Medicaid drug rebate program, recent penalties for individual drug companies have ranged from $60,000 to $12.6 million. These penalties were assessed for violating the price reporting requirements.

"Here's how the Medicaid rebate program works: Manufacturers must submit quarterly pricing data to CMS so the agency can calculate what's called the unit rebate amount," explained Sherrin. "The reporting requirements in this drug rebate program are similar to the laboratories' requirements for reporting under PAMA.

Penalties Of $10,000 Per Day

"The Medicaid drug rebate program calls for penalties of $10,000 a day for each act or omission in the reporting," he said. "The statute also refers to the False Claims Act, which will apply to the calculation or imposition of civil monetary penalties.

"Under the Medicaid drug rebate program, HHS issued a special advisory bulletin to drug manufacturers in September 2010, stating that the OIG had learned of significant failures to report data in a timely fashion, and that CMS would implement a new enforcement initiative," observed Sherrin. "Since that special advisory, recent penalties of as much as $12.6 million were made against drug companies that did not follow the price reporting requirements." Sherrin provided two examples:

- On March 11, 2015, **Sandoz** settled with OIG for $12.6 million related to allegations that Sandoz misrepresented drug pricing data.
- On Aug. 31, 2016, **Glenmark Pharmaceuticals** settled with OIG for $2.9 million for failure to submit certified monthly and quarterly average manufacturer's price (AMP) data. TDR

—By Joe Burns

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UHC, LabCorp Play Hard Ball With Texas Lab Contracts

For BeaconLBS program, UnitedHealthcare requires all Texas labs to be in lowest 25th percentile for costs

CEO SUMMARY: In launching BeaconLBS in Texas, UnitedHealthcare included a new, more onerous twist than it used for BeaconLBS in Florida. To be a BeaconLBS in-network 'lab of choice,' a lab must be in the lowest quartile for lab test prices. Any lab above the 25th percentile would have to renegotiate its contract with UHC and agree to be paid less to be a lab of choice, sources in Texas said. In effect, labs will compete aggressively against each other to drive down lab test prices, sources added.

DETAILS ARE EMERGING about how **UnitedHealthcare** intends to implement its laboratory benefit management program in Texas after the new year. As was the case in Florida, UHC will use **BeaconLBS**, a subsidiary of **Laboratory Corporation of America**, to administer the program.

In meetings with providers from Texas, including pathologists, UnitedHealth has announced that, beginning on Jan. 1, 2017, it wants physicians to begin using the BeaconLBS system to obtain pre-notification or pre-authorization for the 79 clinical laboratory tests that are listed on the UHC website.

Enforcement Begins March 1

UnitedHealthcare also announced that on March 1, 2017, it will begin to enforce the requirement that lab test claims for these 79 tests must have a pre-notification or pre-authorization number from the physician, otherwise Texas laboratories in the UHC network, including laboratories in the "laboratory of choice" network, may not be paid.

UHC's laboratory benefit management program is required for the approximately 500,000 members in Texas who are in fully-insured commercial plans.

There is additional unwelcome news for anatomic pathologists and clinical laboratories in Texas. In a letter to members of the **Texas Society of Pathologists**, society President Kevin Homer, MD, explained several problems with the UHC program that are of concern to the society. The most significant of these concerns is that to be included on the BeaconLBS "lab of choice" list, a laboratory must accept fees in the lowest quartile of UHC's contracted labs. Any lab that has UHC rates above the 25th percentile cannot participate as a lab of choice.

Last month, representatives from the Texas Society of Pathologists participated in a meeting with officials from UHC, LabCorp, and BeaconLBS. Texas pathologists worry that UHC's laboratory benefit management program may be more onerous for clinical laboratories than it was when UHC and LabCorp started the BeaconLBS system in Florida in April.

(See TDRs, January 5 and February 17, 2015.)

As in Florida, BeaconLBS is establishing a sub-network of Texas laboratories, called laboratories of choice. On the UHC website, currently only 20 labs are shown as labs of choice; none are based in Texas and a large proportion are lab companies owned by LabCorp.

Difficult For Labs To Get Paid

In another similarity to the Florida program, the BeaconLBS system in Texas makes it difficult for laboratories to get paid each time a referring physician does not follow BeaconLBS' protocols. Also, pathologists in Texas are concerned that the BeaconLBS program may upset long-standing patient referral patterns that physicians have with clinical labs in the Lone Star State.

"The notion that an insurance company can create a network within a network—steering referrals within a network of contracted providers based on the reimbursement accepted by that provider—should alarm all of us," Homer wrote in a message to TSP in the society's November issue of its newsletter. "BeaconLBS threatens physicians' fundamental right of choice in the care of our patients, it unlinks cost from quality and steers patients to the lowest cost provider, and it provides a new mechanism by which insurance companies can deny payment of a 'clean claim.'

"For these reasons, it is becoming increasing clear that we must prevent or delay implementation of Beacon in Texas," Homer wrote.

He also called attention to a new, and more onerous twist that UHC and LabCorp have added to the list of criteria for what BeaconLBS calls its in-network labs of choice: These labs must be in the lowest quartile for lab test prices. In other words, in-network laboratories must be among the lowest-cost, highly efficient labs in Texas.

THE DARK REPORT interviewed a Texas pathologist who is familiar with the BeaconLBS proposal and who asked to remain anonymous. "One of our biggest concerns is that this system adds a whole new layer of bureaucracy to healthcare. While UHC says it is implementing the system to curb costs and to lower the total cost of care, the fact is that the BeaconLBS program will lower UHC's expenses and their cost of care, but will actually increase the total cost of care," the pathologist said. "It does this by requiring physicians and pathologists, when ordering lab tests, to do things they did not need to do before.

"I know from talking with pathologists and referring physicians in Florida that some of the larger physician groups had to hire new full-time employees just to handle the administrative burden of the BeaconLBS program," he added.

"So, in effect, BeaconLBS will be paying physicians and pathologists in Texas less but will be asking us to do more," the pathologist explained. "Basically, UHC and BeaconLBS are increasing the cost of care. What's strange about this program is that everything UHC claims BeaconLBS will achieve seems possible by simply using their network-contracting process.

Quality Standards For Labs

"UHC says it wants to steer lab tests to labs that meet certain quality standards. For example, labs must be inspected by the **College of American Pathologists** or by **The Joint Commission**, and pathologists must be board-certified in subspecialties or have provisions for secondary pathology review," he said. "UHC could require these quality standards of every contracted laboratory without using BeaconLBS.

"But, in addition, UHC officials said in-network labs also must meet certain efficiency standards, explained as accepting reimbursement in the bottom quartile of the network for their place of service," noted the pathologist.

"In other words, if you are an independent lab, you've got to be in the bottom 25% of reimbursements for independent labs," he said. "And, if you are a hospital lab, you've got to be in the bottom quartile for hospital labs; if you are a physician lab, you've got to be in the bottom quartile for physician labs.

"If lower cost is UHC's goal, why is BeaconLBS necessary?" the pathologist asked. "Laboratories are price takers. Couldn't UHC refuse to contract with labs at higher rates? If quality is UHC's goal, why is BeaconLBS necessary? Couldn't UHC refuse to contract with labs that do not meet its quality standards?

"It seems that the only real purpose for BeaconLBS is to create a barrier that makes it more difficult for physicians to order tests their patients need, and more difficult for pathologists to get paid for work they perform," he added.

Take It or Leave It Terms

"In simple terms, UnitedHealthcare, LabCorp, and BeaconLBS have established a network within their own network," he commented. "When you think about it, it's a brilliant strategy. UHC has enlisted laboratories to do their (UHC's, LabCorp's, BeaconLBS') work of driving down lab reimbursements.

"If my lab is in the 30th percentile for reimbursement and I want to be a lab of choice, then I have to go to UHC and renegotiate my contract," he continued, "and accept a lower rate.

"So, now my lab might be in the 25th percentile or lower, but what have I done?" he asked. "I've just kicked some other lab higher up the price percentile curve, which means that lab may no longer be a lab of choice.

"That's what I mean about how labs might cannibalize each other," he explained. "It will be a dive to the bottom for lab fees in Texas—at least that's what UHC, LabCorp, and BeaconLBS seem to want.

Texas Pathologists Comment On Issues with BeaconLBS

TO INFORM ITS MEMBERS ABOUT THE ISSUES associated with UnitedHealthcare's laboratory benefit management program that is coming to Texas on Jan. 1, 2017, the Texas Society of Pathologists posted two letters on its website.

In a letter to his colleagues, TSP president Kevin Homer, MD, wrote, "The TSP finds many facets of this program disturbing, not the least of which is the appearance of a significant conflict of interest. BeaconLBS is a wholly-owned subsidiary of LabCorp, and, not surprisingly, all LabCorp owned laboratories are 'labs of choice.' Although Beacon claims that program participation is open to all labs meeting its quality and cost standards, not many non-LabCorp labs make the preferred list."

Another issue is UHC's compliance mechanism. Homer wrote that, "If the referring physician fails to complete the on-line advance notification, the laboratory does not get paid for testing. Even if the testing is appropriate. Even if the laboratory has a contract with UHC to perform the testing. Even if the laboratory submits a 'clean claim' to UHC. Payment will be denied for an omission that is entirely out of the laboratory's control. UHC expects the laboratory to enforce compliance with Beacon by hounding referring physicians to complete the Beacon submission, but compliance may not really matter to UHC. Either the referring physician complies with the program and the test is sent to the lowest cost laboratory, or UHC denies payment [to the lab] for testing. UHC may not object to either outcome."

"Will it happen that way?" he asked. "Only time will tell. But in its effort to pay less for clinical lab tests, UnitedHealthcare is adding a whole new unnecessary layer of bureaucracy that only increases the total cost of care for everyone in Texas." TDR

—Joseph Burns

Phlebotomy Leases Raise Cost of Care in Australia

Some medical lab firms report that lease fees paid to physicians now make up 20% of total costs

CEO SUMMARY: In the United States, medical labs have long recognized that paying over-market rates to lease phlebotomy space in physicians' officers is an inducement and a violation of federal anti-kickback laws. In Australia, a law in 2010 that removed the cap on what labs could pay to lease phlebotomy space in physicians' offices caused huge increases in these lease payments. It is a real-world demonstration of how physicians will play labs against each other to maximize their lease fees.

In Australia, pathologists are giving a real-world demonstration of what happens when clinical laboratories have no restrictions on how much they can pay physicians for renting office space from doctors for phlebotomy draws.

In 2010, the Australian government lifted the restrictions on how much labs could pay to physicians for leasing office space in doctors' offices. Since then, the Australian government has seen healthcare costs rise sharply as labs seek to gain lab test referrals from physicians. Labs stand to gain referrals from physicians when they pay to lease space in doctors' offices to draw blood and take other patient specimens.

Naturally, with no cap on the market rate for these leases, and with no anti-kickback law comparable to that of the Medicare program here in the United States, physicians will play one medical lab against another to get the highest lease rate in exchange for referring lab tests. The problem for Australian labs in this situation is that they end up paying more to do clinical lab testing than they paid before the government lifted the restrictions.

Now, clinical laboratory directors and pathologists in Australia are complaining to the federal government that doctors are seeking such deals as a way to generate additional income after the government reduced what it pays physicians in a move to control national healthcare spending.

Labs Pay 20% of Revenue

Medical lab directors and pathologists say that they are now forced to pay as much as 20% of their labs' income to physicians to rent office space for phlebotomy and specimen collection.

Last month, newspapers reported that Australia's Prime Minister Malcolm Turnbull promised to help pathologists get lower-cost rents for blood-drawing centers in the clinics of general practitioners. In exchange, **Pathology Australia**, an medical lab trade group, agreed to stop campaigning against the government's plan to remove certain financial incentives for bulk billing.

The Australian newspaper reported that Turnbull's offer angered the **Royal Australian College of GPs** and the

Australian Medical Association (AMA). Michael Gannon, the president of the AMA, complained that two major publicly-traded companies dominate the pathology industry, whom he identified as **Sonic Healthcare** and **Primary Health Care**.

Docs: Limit Inducements

In a letter on the issue, Gannon wrote, "The proposed changes fundamentally alter the intent of the existing law, which is designed to prevent inducements to refer, so that it would instead regulate (collection center) rents by imposing a blunt cap on the commercial rents that GPs and other specialists can receive for co-located (collection centers)."

The number of blood drawing and specimen collection centers in physician offices had risen in recent years, reported *The Australian*, because the two pathology companies were competing for market share. In addition, physicians were struggling financially because the government had imposed a freeze on what the federal Medicare program pays to doctors. Therefore, doctors were interested in leasing office space to pathologists willing to rent blood-drawing specimen collection centers, according to Gannon.

In December, the Turnbull government had not yet unveiled a solution to the problem. In the meantime, pathologists were struggling financially, noted the *Brisbane Times*. "Pathologists claim they are being used as a piggy bank to fill the gap between rising doctor costs and the Medicare freeze," wrote reporter Amy Remeikis.

Meanwhile, the Turnbull government has promised to alter the definition of 'market value' for space pathologists rent in the GP clinics, the newspaper added. By altering the definition, the Turnbull government would effectively be mandating rent control to protect pathologists, the newspaper added.

The change in the definition was intended to be implemented in January. However, in December, the Turnbull government said it would delay implementation to allow continued discussions of the issue with pathologists and those physicians who rent space to pathologists. Meanwhile, many pathology groups complain that they are struggling financially and that—if many of them go out of business—only the two largest clinical laboratory companies would remain, the Brisbane newspaper reported.

Wayne Smit, MD, the managing partner and general pathologist of **Perth Pathology**, told the *Brisbane Times* that he had no choice but to sell his 10-year-old pathology business to a larger lab company. He also said that the reason he was selling the practice was because the cost to rent space in a physicians' offices had risen from 5% of the cost of running the lab to 20%.

"I would have preferred to remain independent and viable but this was simply not possible," Smit told the newspaper. "The collection center rents were deregulated in 2010 without consideration as to the longer-term implications for pathology provision."

Labs Forced to Close or Sell

Smit's West Australian practice is one of six private pathology companies that has sold to a larger entity or closed in the past two years, the newspaper reported. If a solution to the problem is not found quickly, Liesel Wett, CEO of Pathology Australia, predicted that patients would bear most of the share of any increased costs, the newspaper said.

"If this continues, we will end up with a duopoly, which would lead to increased prices and lower service standards," Wett commented. "If GPs are relying on rent from pathologists to be profitable, and this is sending pathology practices to the wall and out of business, then this is not sustainable." TDR

—Joseph Burns

HIPPA Update

Patient Privacy Breach at Quest Attracts National News Coverage

Episode is a reminder that HIPAA requires all labs to take steps after unauthorized disclosure of PHI

IT WAS NATIONAL NEWS RECENTLY when **Quest Diagnostics Incorporated** disclosed a security breach involving the protected health information (PHI) of 34,000 individual customers.

This episode is a reminder to clinical labs and pathology groups of the need to guard protected health information. In fact, as part of its compliance with federal law, it was Quest Diagnostics that contacted the media to report this breach of PHI.

Notifying Patients

When a patient's personal health information is made public, clinical laboratories have an extensive set of requirements to meet under the Health Insurance Portability and Accountability Act of 1993. HIPAA requires labs, called covered entities under the law, to disclose to the individuals involved that their personal health information (called PHI) was part of an unauthorized disclosure.

"In addition, covered entities and any business associates—meaning any other providers or vendors doing business with the covered entity—must also notify the secretary of the federal **Department of Health and Human Services** (HHS) if the personal data of more than 500 individuals is released," stated attorney Elizabeth Sullivan, a member of the national law firm **McDonald Hopkins**. "If data on more than 500 individuals is involved, then covered entities and business associates need to disclose the details of this failure of security to the media."

Sullivan did not comment on the incident involving the security breach at Quest Diagnostics. She simply spoke in general terms about what steps clinical labs and pathology groups need to follow when PHI is part of a breach, whether the data source was paper records, a stolen or misplaced laptop containing PHI, or a cyber attack on the lab's computer system.

PHI has great value to hackers. Security experts say that, for hackers, PHI has higher value than any other kind of personal or financial information, including credit card information. In 2014, **Reuters** reported that PHI was worth about $10 per record—or about 10 or 20 times the value of the credit card number of a U.S. citizen! That makes cyber crime against pathology groups, clinical labs, and all healthcare providers, a potentially lucrative enterprise.

Step 1: Analysis Required

"If a clinical laboratory or pathology group suspects that patient data is compromised, then the provider should conduct a thorough review of what happened," Sullivan said. "The first thing the lab should do is ensure that the cause of the incident is corrected as quickly as possible. After that, the laboratory must analyze the security incident to determine whether a breach has occurred and what level of notification is required."

Sullivan next offered an important piece of advice: how the lab describes the incident at this stage of the discovery and investigation makes a difference. "It is important to understand why every incident should not be referred to as a 'breach' immediately," she added. "A breach has a specific meaning under HIPAA. Further, not all breaches are reportable breaches.

"Although this is not a verbatim definition, a breach is an impermissible use or disclosure under the HIPAA privacy rule that compromises the security or privacy of PHI," stated Sullivan. "It is possible for a security incident or even a breach to fall short of a reportable breach under HIPAA."

Security Incidents

Two examples illustrate this point. "As one example, a security incident could be the result of an unauthorized disclosure of PHI between employees of a covered entity," explained Sullivan. "Or, a breach could be a loss of encrypted PHI that, despite it being lost, is encrypted and therefore no one can read or access the data. Before labeling an incident a 'breach,' the laboratory should perform an analysis.

"In the lab's analysis of such an incident, it must take into account the elements of personal data that were disclosed, the manner in which such information was disclosed, and whether the information was protected by encryption," she said. "Whether the incident involves names and addresses or more sensitive health information or Social Security numbers and financial information, it is considered PHI under HIPAA and warrants investigation.

"At this point in the analysis, it's best to work with a data privacy expert if the provider doesn't have a privacy officer," she commented. "This may be a law firm or a cyber security firm or some combination of both.

"If PHI is disclosed, the covered entity or business associate—along with its data privacy experts—collect information on what was disclosed, to whom the information was disclosed, whether the PHI was secured, and any other relevant details to determine if the incident in fact qualifies as a reportable breach. The entity also will need to determine how many people were affected," noted Sullivan.

"These issues must be examined to determine if the incident would be con-

Quest Diagnostics Reports 34,000 Records Were Hacked

IN AN ANNOUNCEMENT DEC. 12, Quest Diagnostics Incorporated said it was investigating an unauthorized third-party intrusion into an internet application on its network and that it had notified 34,000 individuals who were affected. The notifications were sent by mail and Quest Diagnostics established a toll-free phone number for patients who have questions about the incident.

On Nov. 26, an unauthorized third party accessed Quest Diagnostic's MyQuest by Care360 internet application and obtained the protected health information (PHI) of about 34,000 customers of the lab company. The third party accessed data that included the name, date of birth, lab results, and in some cases, telephone numbers, Quest said. "The information did not include Social Security numbers, credit card information, insurance or other financial information," the lab company added. Also, Quest said it had no indication that individuals' information had been misused.

In addition, Quest is working with a cybersecurity firm to assist in its investigation and to analyze the company's security systems.

In the days following this disclosure, at least one law firm trolled for patients that could be plaintiffs in a class action lawsuit against Quest. This development is a reminder to clinical labs and pathology groups about the legal risks following an unauthorized disclosure of PHI.

sidered a reportable breach under HIPAA," Sullivan added.

Notification Within 60 Days

"If the covered entity or a business associate of the covered entity determines that the incident is in fact a breach and that the PHI was not appropriately protected, then the law requires that the covered entity or business associate notify the individuals whose PHI was disclosed that a breach has occurred," she warned. "That notification must be made without unreasonable delay and in no event more than 60 days after discovery of the incident. While those 60 days might seem like a long time, the two months may be needed to give your lab the time to determine if it is a reportable breach.

"In addition to notifying affected individuals you must notify the Secretary of HHS, and if the breach affected 500 or more individuals you must also notify the media," she added.

"Labs should have written HIPAA policies and procedures about what to do when there is an unauthorized disclosure of PHI," Sullivan advised. "Once these are established, it's important to follow such policies and procedures.

"If the lab determines that the incident was not a breach or reportable breach, then your lab must document the reasons for that determination," she said. "And those records must be retained in the event of an audit.

Step 3: Send Notifications

"If your lab finds that there was a reportable breach, then you must notify the affected individuals within 60 days of the discovery of the breach," Sullivan said. "If the breach involves more than 500 individuals, then you also must notify the Secretary of HHS and the media within that same 60-day period. For all breaches involving more than 500 individuals, HHS publishes the information on its web site.

Insider Breaches More Common Than External Hacks, Attacks

IT MAY SURPRISE many lab administrators and pathologists to learn that the leading cause of a breach of patients' protected health information (PHI) comes from insiders, not from external attacks and hackers.

Protenus publishes *The Breach Barometer* report. For November 2016, it documented that 54.4% of healthcare data breaches were caused by insiders. Of these, 17 breaches were accidental breaches by healthcare employees and 14 were the result of malicious actions by employees with access to PHI. Hackers were responsible for nine of the breaches that month. Healthcare providers reported 40 of the month's breaches, and health plans reported 11 breaches.

"Laboratories and pathology groups should be aware that HIPAA breaches can result in investigations or audits and ultimately in fines for covered entities or business associates," she warned. "Under HIPAA, there is no private right of action to sue a covered entity or business associate for a HIPAA violation.

"But most states have privacy laws and if an individual is harmed through disclosure of personal information, then that individual or group of individuals may be able to seek recourse in the form of a lawsuit under other privacy laws," she added.

"It is critical that covered entities and business associates evaluate the safeguards they have in place to protect PHI and to implement improvements as needed," concluded Sullivan. "As more and more information is gathered, transmitted, and stored electronically, the importance of appropriate safeguards will only increase." TDR

—Joseph Burns

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INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Pathologists and lab managers interested in developing diagnostic management teams within their hospitals and health systems will be interested in an upcoming conference on that topic. Organized by Michael Laposata, MD, PhD, Chairman of the Department of Pathology at the **University of Texas Medical Branch, Galveston**, it will take place at the Galveston Island Convention Center on February 7-8, 2017. Laposata has gained national attention for his work in demonstrating how diagnostic management teams can contribute to improved patient outcomes while reducing the cost of care.

"BEST" LISTS INCLUDE FIRMS SERVING LABS

It is the end of the year and several publications are releasing their "best companies" lists. Included in these lists are several companies serving the clinical laboratory industry. In its list of the "Top 100 Innovative Companies," *Forbes* listed the following firms that serve laboratories: **Illumina** (ranked 24); **Sysmex Corporation** (ranked 28); **Cerner Corporation** (ranked 37); and, **Roper Industries**, parent company of **Sunquest Information Systems**, **Data Innovations**, and **Atlas Medical** (ranked 69).

MORE ON: *'Best Company' Rankings*

In December, *CIOReview* issued its list of the "50 Most Promising Healthcare Solution Providers for 2016." Companies were listed alphabetically and firms serving labs included **Change Healthcare**, **McKesson**, and **Visiun**.

TRANSITIONS

- Julie Khani will become President of the **American Clinical Laboratory Association** (ACLA), effective Jan. 1, 2017. She joined ACLA in 2013 as its Executive Vice President. Previously, Khani held positions with the **National Association of Chain Drug Stores** and **Ford Motor Company**.
- Alan Mertz, President of the American Clinical Laboratory Association, is retiring, effective Jan. 1, 2017. He will continue to serve ACLA in an advisory role. Prior to joining ACLA, Mertz spent almost 30 years in Congress working on the staffs of Senators and Representatives.
- **Theranos, Inc.,** announced that Gregory J. Tsongalis, PhD, was joining its Scientific and Medical Advisory Board. Tsongalis is Director, Clinical Genomics and Advanced Technology, at **Dartmouth Hitchcock Medical Center**.

That's all the insider intelligence for this report. Look for the next briefing on Monday, January 9, 2017.

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