Volume XXIV, Number 15 Monday, October 30, 2017

From the Desk of R. Lewis Dark...

THE DARK REPORT

RELIABLE BUSINESS INTELLIGENCE, EXCLUSIVELY FOR MEDICAL LAB CEOs / COOs / CFOs / PATHOLOGISTs

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COMMENTARY & OPINION by...

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Founder & Publisher

To Add Value, Focus on Patient Care

FOR THE PAST SEVERAL YEARS, and particularly since Congress passed the Patient Access to Medicare Act in 2014, clinical labs have focused on controlling costs, as they should. After all, PAMA calls for steep cuts in what the federal **Centers for Medicare and Medicaid Services** will pay clinical labs beginning Jan. 1, 2018. *(See TDRs, Oct. 9 and Sept. 18, 2017.)*

While cost control needs to be a high priority in every lab, speakers from some of the nation's most advanced and forward-looking clinical laboratories reminded us last week at the 11th annual *Lab Quality Confab* that patient care needs to remain our first priority. *(See pages 3-6.)*

In a presentation about the quality improvement journey **ARUP Laboratories** has been on, Bonnie Messinger, CPHQ, said, "It's all about patient care." Messinger, a Six Sigma Black Belt and Process Improvement Manager at ARUP, co-presented with David J. Layton, MSOM, Lean Expert, Improvement Engineering and Operations Leader with ARUP. Now two years into using the laboratory value pyramid as a road map to move two divisions toward the goal of best-in-class performance, the speakers shared the lessons learned, including the need to focus on delivering value to patients.

Gary W. Procop, MD, Medical Director, Enterprise Laboratory Stewardship Committee at the **Cleveland Clinic**, had a similar and more nuanced, message. "If you do the right thing, good things will follow, including cost savings," he said. "Chasing savings is just chasing savings. Improving patient care is sustaining."

This message was mirrored by Denise Uettwiller-Geiger, PhD, DLM(ASCP), Clinical Chemist and Director of Clinical Trials, at **John T. Mather Memorial Hospital**. In her presentation, she explained how her lab teams worked to cut costs wherever possible to free up resources to create real-time knowledge for better patient outcomes and to ensure patient safety with patient-centric approaches to care.

It is no coincidence that one theme at this year's *Lab Quality Confab* was to remind attendees that cost-cutting alone was a losing strategy. Instead, speakers from innovative labs emphasized a dual strategy: smart cost-cutting and projects to add value in ways that improve patient outcomes. Only by executing both strategies effectively will labs survive healthcare's ongoing transition to value-based provider payments. TDR

Labs Begin Applying Lean to Cut Costs, Add Value

At Lab Quality Confab 2017, lab directors outline steps on the journey from volume to value

CEO SUMMARY: In more than 40 presentations by 55 speakers, two big themes dominated the 11th annual Lab Quality Confab in New Orleans last week. One theme is the urgent need to cut clinical laboratory costs. The second theme is the need for both clinical labs and anatomic pathology groups to deliver more value to stakeholders. To measure such value, the most innovative labs are working to improve patient outcomes and reduce the overall cost per healthcare encounter.

SMART COST-CUTTING that supports added value was one significant theme at this year's *Lab Quality Confab* in New Orleans last week.

The need for labs to cut costs has greater urgency because of the Medicare Part B clinical laboratory test price cuts scheduled to become effective Jan. 1. Speakers at *Lab Quality Confab* shared how their labs are responding to this development and a second important trend.

That second trend involves healthcare's transition from volume to value. These speakers acknowledged the need for clinical laboratories to develop enriched lab testing services that deliver more value because they help physicians improve patient outcomes while also reducing the overall cost of each patient's encounter with the healthcare system.

Lacking a clear vision from payers, many of the nation's most forward-looking clinical labs have begun to define value by adopting their own versions of the laboratory value pyramid, which THE DARK REPORT has covered in detail. *(See TDRs, Sept. 22 and Nov. 24, 2014, Feb. 17 and March 30, 2015.)*

In general session presentations, three lab leaders discussed the innovative ways their lab organizations are adding value. Two labs are specifically using the laboratory value pyramid as a road map to guide their lab teams on this added-value journey. In all three presentations, the speakers noted that focusing on costs alone is not sustainable. Instead, they recommended improving processes.

One way to add value is to help physicians improve their utilization of lab tests.

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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.)

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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).

This is the focus of a team at the **Cleveland Clinic** laboratory. Leading that effort is Gary W. Procop, MD, Medical Director and Co-Chair of Cleveland Clinic's Enterprise Laboratory Stewardship Committee.

Improving Patient Care

"Have faith," advised Procop. "If you do the right thing, good things will follow, including cost savings." He also challenged attendees to focus on long-term goals such as ensuring that any gains continue into the future. "Long-term maintenance is essential," Procop said. "Chasing savings is just chasing savings. Improving patient care is sustaining."

In her presentation, Denise Uettwiller-Geiger, PhD, Clinical Chemist and Director of Clinical Trials at **John T. Mather Memorial Hospital** in Port Jefferson, N.Y., outlined how her lab uses the laboratory value pyramid as a blueprint for its journey from volume to value.

Similarly, David Layton, a Lean Expert and Improvement Engineering and Operations Leader at ARUP, and Bonnie Messinger, a Six Sigma Black Belt, Process Improvement Manager, explained how teams at **ARUP Laboratories** in Salt Lake City use the laboratory value pyramid to achieve an enterprise-wide Lean transformation with the goal of achieving best in class.

Lab Test Order Management

Although Procop did not specifically mention the laboratory value pyramid, his remarks were clearly focused on moving from volume to value. In his presentation, he explained how the lab at Cleveland Clinic built on its initial foray into lab-test utilization management to deliver added value in a second-generation effort.

At Mather Memorial, Uettwiller-Geiger introduced a series of steps to manage how tests are ordered. "Patient outcomes improve when the correct test is ordered," she said. The key questions for Mather's physicians to consider when ordering tests are these:

- Is the test meaningful?
- Does the test enhance decisions?
- Is this an appropriate order?
- Is the test highly useful?
- Will the test change how patients are managed?

"The goal is to improve patient outcomes while reducing the cost per episode of care," she added. "The lab can spend a bit more money but contribute to millions in cost savings."

For the Mather lab, Uettwiller-Geiger aimed to maintain and improve quality levels to free up time and resources, to leverage intelligence, to drive decisions, to create real-time knowledge for better patient outcomes, and to ensure patient safety with patient-centric care.

Improving Patient Outcomes

One part of the plan involved answering a series of questions:

- How can lab resources, skills, core competency, automation, and technology support the organization's strategic plan, vision, and priorities?
- How will automation and technology fulfill our mission and vision moving forward?
- What advantages can be created by implementing the newest automation and technology?
- Will automation and technology strengthen the hospital and the laboratory's overall competitive position?

To answer these questions, the lab sought to improve turnaround time by identifying the biggest barriers to productivity, by streamlining processes, eliminating duplicate tests, and creating a culture that was proactive rather than reactive.

As an example, Uettwiller-Geiger explained how the lab improved TAT for lactate tests and a basic metabolic panel ordered by the emergency department. For both tests, the percentage of such results that exceeded allowable turnaround times

ARUP Laboratories Team Describes How It Customized Lab Value Pyramid to Its Own Needs

IN THEIR JOINT PRESENTATION, David J. Layton, MSOM, and Bonnie Messinger, CPHQ, of ARUP Laboratories in Salt Lake City, explained how the lab customized the laboratory value pyramid to suit its culture.

The laboratory value pyramid has four levels, they explained. On level one, the goal is to achieve normalcy and predictability. Level two is to establish and meet standards of value; on level three, deliver value that exceeds expectations, and on level four, use benchmarks to achieve best in class.

Layton and Messinger described how one of the nine lab divisions within ARUP adapted the pyramid so that on level one, the lab is focused on Lean Kaizen; on level two, it has achieved manager-led Lean (meaning some labs are on Lean level two), on three, it has employee-empowered Lean, and on four it is a Lean enterprise. The goal is to achieve what Layton and Messinger called "best in class" enterprise status.

Perhaps most enlightening about their presentation was the idea that it's a mistake for labs to begin by focusing on costs. Instead, ARUP found that the best-in-class method for process improvement involves starting with eliminating waste. Doing so makes the work easier to accomplish. Then "easier" leads to better quality, "better quality" leads to faster TAT, and "faster TAT" leads to cheaper, they said.

To describe ARUP's efforts to be the best among clinical labs, Layton and Messinger said the lab needed to educate and train the staff to be best in class. The first stage in a four-stage training program is the preparation and the assessment of challenges. In this stage, called the set up, it's important to ensure that all staff are empowered to participate in all process-improvement projects. To assess lab employees' willingness to participate, Layton and Messinger offered 10 statements to get a snapshot of workplace sentiment:

1. I believe I have an impact in the lab's overall mission and strategic direction.
2. I feel comfortable communicating with my direct supervisor.
3. I feel comfortable communicating with my peers.
4. When problems or mistakes occur, communications received are constructive.
5. When I provide feedback or raise concerns, it is responded to appropriately.
6. Our work practices result in consistent, high quality products or services.
7. I have adequate opportunities to acquire new, valued skills in the workplace.
8. I have adequate opportunities for advancement.
9. I am proud to be part of my team.
10. I feel valued at work.

The second of the four stages is the training itself. In stage three, the staff works on projects, the first of which are called "quick wins." These are small projects that can be accomplished quickly and that produce fast results. The last part of the projects stage involves sharing how the projects were done and what results they produced. The fourth stage is sustainability, they said.

Sustainability includes what Layton and Messinger called the five bridges to excellence, as follows:

1. The ability to manage change.
2. A structure that supports and drives execution.
3. Employees are involved in decisions and empowered to execute.
4. Alignment between leader behavior and vision or values.
5. Coordination and cooperation; then harmonization.

declined sharply from 2012 to 2015, she said. In 2012, more tests were delivered within 30 minutes, which was the goal, while in 2013 through 2015, more than 74% of basic metabolic panel results were delivered within a half hour. For the lactate tests, more than 80% of results were delivered within 30 minutes, she said.

Uettwiller-Geiger's detailed presentation included examples of how the lab saved $88,044 by improving urine specimen processing, reducing hospital-acquired infections, and adopting the Choosing Wisely campaign.

Procop also outlined the savings his lab test utilization management program achieved in the initial phase *(see TDR, June 1, 2015)* and in a second-generation effort. In the first phase, the Cleveland Clinic's lab test utilization program established what he called a soft-stop warning in the EHR to alert the physician when he or she was about to order a duplicate test.

Soft Stop Shifts to Hard Stop

"Later the soft-stop warning in the EHR became a hard stop, meaning the physician could not order a test until he or she called client services to request a waiver," explained Procop.

Few clinicians called client services to place a duplicate order, he said, and when they did, the lab could educate those physicians about how to limit certain testing. In the first phase to improve the utilization of lab tests, the lab hired a genetic counselor and implemented lab test ordering alerts for physicians in hospitals outside of the main campus.

In the second phase, Procop introduced more stringent requirements for expensive tests. With this effort, the lab averted 158 test orders and saved $224,435. Over four years—from 2013 through 2016—these policies helped the lab avert 514 expensive tests and save $787,834.

"A strategic phased approach to lab test utilization builds trust and future support," noted Procop. "In addition, improvements in test utilization can address each issue that the **Institute of Medicine** highlighted in its landmark reports on healthcare quality." Adopting the principles of the IOM's reports is one way to implement the laboratory value pyramid.

Patient-Centered Ordering

In his conclusion, Procop said the lab-test utilization program at Cleveland Clinic ensures that test ordering is:

- Safe, because interventions facilitate running the right test at the right time;
- Effective, because the lab can demonstrate its results;
- Patient-centered, because it involves implementing best-practice guidelines;
- Timely, because interventions are done at the point of order entry;
- Efficient, because it helps to avoid unnecessary testing; and,
- Equitable, because interventions are activated for all.

Safe, effective, patient-centered, timely, efficient, and equitable are all tenants of the IOM's reports, noted Procop. These are also consistent with the goals of the Choosing Wisely campaign, which is recognized by most medical specialty associations and encourages physicians to improve utilization of diagnostic tests.

More International Attendees

About 300 lab professionals attended this year's *Lab Quality Confab*, including attendees from Portugal, Switzerland, Russia, Canada, Curaçao, Tanzania, and Saudi Arabia. **TDR**

—Joseph Burns

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LabCorp, Quest Open PSCs in Retail Stores

Despite failures of retail-based PSCs in years past, patients today appreciate such access

CEO SUMMARY: In the past year, both national laboratory companies have increased the number of patient service centers they operate in retail pharmacies and grocery stores. But these PSCs are not serving direct access testing (DAT) customers. Rather, early evidence indicates that patients are finding it more convenient to go to their nearby grocery stores or pharmacies to have specimens collected in PSCs than to drive to a lab's PSCs on a hospital campus.

With little publicity or fanfare, the nation's two largest lab companies have been opening patient service centers (PSCs) in grocery stores and retail pharmacies. Using retail stores for specimen collection is a response to changing patient and consumer habits.

The national labs are discovering that locating PSCs in grocery or drug stores can be a consumer-friendly feature. Early market experience shows that many patients prefer to have their lab specimens collected at grocery and drug stores near where they live and work. Also, because these locations often have coffee or snack bars, patients who fasted overnight can get something to eat and drink after having their specimens drawn.

Putting PSCs in neighborhood grocery stores and pharmacies offers patients other benefits. It means they don't need to spend additional time driving to hospital campuses where labs traditionally locate their patient service centers. It also means patients do not have to fight to find—and pay for—parking spaces and waste time getting to PSCs in medical office buildings on hospital campuses.

In the past year, both **Quest Diagnostics** and **Laboratory Corporation of America** have expanded the number of PSCs they operate in retail stores in specific regions of the United States. In June, for example, Quest announced it would open 15 PSCs in **Walmart** stores in Florida and Texas this year. That same week, LabCorp announced a deal with **Walgreens Boots Alliance** to develop PSCs in Walgreens stores.

99 PSCs in Grocery Stores

Quest Diagnostics is making a push to work with grocery stores. On its website, Quest lists 99 PSCs located in grocery stores in 10 states.

The grocery chains hosting Quest PSCs include **Randalls**, **Safeway**, **Tom Thumb**, and **Vons**. **Albertsons** will soon host some Quest PSCs. All of these grocery chains are owned by a single corporation. Within each grocery store, Quest puts its patient service center near the in-store pharmacy.

In announcing the deal with Walmart, Quest said the co-branded sites would provide laboratory testing services. Over

time, Quest said the two companies planned to include other basic healthcare services. The announcement did not say what those other basic healthcare services would include and a Quest spokesman would not elaborate.

More PSCs in Retail Stores

Last summer, Walgreens and LabCorp opened five PSCs in Denver and one in Morrisville, N.C., Bruce Japsen reported for *Forbes*. By year-end, LabCorp plans to open a seventh PSC in Deerfield, Ill. "LabCorp already has about 1,750 existing patient service centers and, depending on how the Walgreens partnership grows, it could tap into a drugstore chain with more than 8,000 stores," Japsen wrote.

PSCs in pharmacies have a checkered past. From 1999 to 2003, each of the two national lab companies arranged to put PSCs in retail pharmacies. During that time, executives from the lab companies and the pharmacy chains said direct access testing (DAT) was poised to grow.

Typically, these collaborations were intended as marketing tests. The two parties would put PSCs in a handful of retail pharmacies in specific cities or regions. After it was determined that few consumers wanted to visit pharmacies to order laboratory tests, these marketing experiments ended.

Payer Access Requirements

Another reason national lab companies have put PSCs into retail pharmacies is to meet the requirements of health insurers as part of managed care contracts. When a lab company wanted an exclusive contract to shut out other labs as in-network providers with that insurer, the lab would need to demonstrate that it had patient access in certain communities or regions.

To do so, it could put PSCs in retail pharmacies. LabCorp executed this strategy in New York after it won a 10-year exclusive national contract with **UnitedHealthcare** in 2007. It signed a deal with **Duane Reade** to put PSCs in retail pharmacies to guarantee patient access for UHC patients.

The current interest in using retail grocery stores and pharmacies as sites for PSCs is motivated by different reasons than to serve consumers with DAT or to meet patient access requirements of managed care contracts. In part, the current interest in putting PSCs into retail stores is a consequence of all the marketing that **Theranos** did in Phoenix in 2014 and 2015 to promote its consumer lab testing service that were based in Walgreens pharmacies in that area.

How Theranos Helped SQL

In those years, Theranos spent heavily to blitz the population of Phoenix and surrounding suburbs with its message that consumers could order their own lab tests by simply going to a participating Walgreens pharmacy. Theranos advertisements were everywhere.

Sonora Quest Laboratories leveraged that heightened consumer awareness. It cut a deal with Safeway to put PSCs into two Safeway stores in 2015. That deal was expanded into six more Safeway grocery stories last year. *(See TDRs, Dec. 7, 2015, and Oct. 17, 2016.)* Executives at Sonora Quest Laboratories told THE DARK REPORT that, after opening the first two PSCs in Safeway stores, within weeks the combination of appointments and patient walk-ins filled those PSCs to capacity.

As an interesting side note, the Sonora Quest PSCs began to hand out beepers during peak demand periods. Doing so allowed patients to shop in the grocery store until the PSC staff was ready to draw the specimen. One Sonora Quest manager noted that another benefit of locating PSCs in the Safeway grocery stores was the increased compliance of patients with physicians' recommendations for lab testing.

Hospital lab outreach programs and independent labs should consider

Health Insurers' Need for Patient Access Often Motivated Quest, LabCorp to Open Retail PSCs

TO WIN EXCLUSIVE MANAGED CARE CONTRACTS while meeting payers' demands for patient access, the two national lab companies used the strategy of opening patient service centers (PSCs) in retail pharmacies.

A lab executive who has observed the strategies of **Quest Diagnostics** and **Laboratory Corporation of America** for many years said the need to meet payers' demands for PSCs was one important factor in why the public lab companies wanted to put PSCs in retail pharmacies.

The More PSCs, The Better

"Health insurers believe that the more PSC stations your lab has, the more value it has as a lab provider because of better patient access to lab tests," he explained. "One of the first questions any payer looking to contract with a lab company asks is, 'How many PSCs do you have?'

"Remember that LabCorp and Quest want to capture greater market share through exclusive managed care contracts," the lab executive explained. "During contract negotiations, they may seek to pad their PSC numbers so that when payers ask that question, they can give a big number.

"Beyond the incremental cost of opening and running retail PSCs, these outlets don't hurt them and may, on occasion, actually give them an advantage with payers," he noted.

"Health insurers care about the image they project when they are able to tell patients that their lab test specimens can be collected at any of numerous PSCs," he continued. "However, the reality is that less than 30% of lab specimens from office-based physicians come through a lab's standalone patient service centers."

The willingness to fulfill payers' needs may be one reason so many patient service centers located in retail stores have failed in the past 10 years, the executive added. "There are several memorable examples of retail pharmacies failing as PSCs," he said. "The most recent failure was **Theranos**, but that failure was based on a different problem.

"Go back 10 years to 2007 when UnitedHealthcare gave LabCorp an exclusive 10-year contract as a national lab provider while excluding Quest from its lab network," he added. At the time, Quest dominated the market in New York with a huge number of PSCs in the area. UHC was concerned that LabCorp would be unable to handle the demand for PSCs in New York and required LabCorp to open dozens of PSCs in a short period of time.

"Knowing that it did not have the time or resources to meet UHC's requirements, LabCorp cut a deal with **Duane Reade** to put PSCs in retail pharmacies throughout the city. That effort, however, proved unsuccessful and disappointing.

Meeting Payer Requirements

"One reason was that Duane Reade's pharmacies were older and often located in unfriendly locations," he said. "But LabCorp's primary intention was not to serve patients so much as to meet UHC's requirements for adequate numbers of PSCs.

"LabCorp's strategy worked," stated the lab executive. "UnitedHealth was satisfied with the number and location of these PSCs. Then, over the next several years, LabCorp opened enough PSCs in medical office buildings and other locations so that it could shut down the PSCs in the Duane Reade stores."

approaching retail pharmacies and grocery stories in their communities and experiment with opening patient service centers in these settings. It may prove to be a useful way to attract new patients. TDR

—Joseph Burns

CEO SUMMARY: Management companies using a new generation of potentially fraudulent schemes are targeting hospitals and health systems for arrangements that use questionable means to increase lab test volume and revenue. The management companies often use the term "hospital outpatient department (HOPD) billing model" to describe these arrangements. The scammers want the hospitals, as in-network providers, to bill for lab tests performed at their labs. Most often, these labs perform toxicology, pharmacogenomics, pain management, genetic, and specialty cardiology testing.

Federal, state laws implicated in HOPD and MSO arrangements

Lab Scheme Recruits Hospitals To Bill as In-Network Providers

MOSTLY UNNOTICED, new and complex billing scams are spreading through the clinical lab industry and costing the Medicare program and private health insurers billions of dollars. Until now, this trend has not been reported widely either in the general or lab industry media.

In this latest generation of abuse, scammers are targeting hospitals and health systems that typically are in-network for the largest health insurers. Management companies engaged in these activities seek agreements with hospitals and health systems so that their associated physicians can refer lab tests to these facilities and then the hospitals and health systems can bill payers as in-network providers for toxicology, pain management, pharmacogenomics, molecular diagnostics, genetic, and specialty cardiology testing. The hospitals or health systems then will split the revenue with the management companies.

Healthcare attorneys familiar with these arrangements say they are the newest variation on pass-through billing schemes, long-recognized as possibly fraudulent under federal and state laws.

Using sophisticated arrangements, the management companies make it difficult for Medicare and private health insurers to recognize that these increased outpatient lab test claims may involve medically-unnecessary or clinically-worthless lab tests.

In an investigation into these schemes, THE DARK REPORT has learned that the management companies promoting this pass-through billing scheme have several commonalities. First, they are designed to defraud private health insurers and the Medicare program, and second, they involve sending inflated bills to patients to increase lab revenue. Third, many of the patients give blood or other specimens for lab tests that are not needed or have little or no clinical utility. Then, the patients are billed several hundreds to thousands of dollars for these tests.

Fourth, under most of these schemes, many of the management companies use inducements, kickbacks, or bribes to get physicians to order a substantial number of tests that are unnecessary, clinically inappropriate for patients, or have no clinical utility.

History shows that plenty of doctors are willing to participate in fraudulent schemes involving lab tests. In fact, these scams cannot exist unless physicians order large numbers of useless laboratory tests.

These new forms of abuse involve three separate levels of activity that could be illegal. First, physicians must be willing to order outpatient lab tests that are unneeded or clinically useless. Without such orders, this type of fraud cannot exist.

Second, the lab management company submits its lab claims to private health insurers and Medicare. If payers do not reimburse the companies for these outpatient lab test claims, the fraudulent scheme fails and the management companies go out of business.

$21,500 Test Bill For Patient

Third, the management companies recognize that payers will deny a substantial portion of their lab test claims. To generate revenue, the management companies bill patients for amounts ranging from hundreds to many thousands of dollars. THE DARK REPORT has reviewed one patient's explanation of benefits that showed $21,500 for such lab testing.

To date, there is no evidence that the federal **Department of Justice** or state attorneys general have recognized these developments and started enforcement actions. Private insurers have filed several lawsuits accusing management companies, toxicology lab companies, and some hospitals of submitting fraudulent lab test claims. Some of these lawsuits were dismissed during pre-trial motions and others are ongoing.

In THE DARK REPORT'S investigation, we have found that these management companies use two arrangements to perpetuate this fraud on hospitals, health systems, clinical labs, and patients: management service organizations (MSOs) and hospital outpatient department (HOPD) billing models.

To be clear, THE DARK REPORT is not suggesting that every MSO or HOPD is committing fraud. But our investigation to date shows that these vehicles are increasingly being used in schemes that more than one payer has alleged are fraudulent, and that healthcare attorneys we have consulted believe may violate multiple state and federal laws.

The scammers may use MSOs to induce physicians to refer patient specimens to their participating laboratory companies, typically labs performing toxicology, pain management, pharmacogenomic, cardiology, and genetic tests.

Often, these MSOs are organized to allow physicians to refer to the MSO almost any type of medical service, such as radiology or imaging services, physical therapy, electrocardiograms, or lab tests.

In these arrangements, the MSOs send the patient referrals from participating physicians to their affiliated lab companies or other providers.

The MSOs also send money back to the referring physicians in a way that can trigger violations of federal and state laws.

Billing In-Network Rates

The management companies use HOPDs to lure hospitals and health systems into agreements for lab testing and billing and collections arrangements. The management companies enlist in-network hospitals or health systems to bill health insurers at in-network rates.

The management companies solicit lab administrators of hospitals and health systems about entering into HOPD agreements so that the hospital can bill health insurers for the management companies' lab tests. The management companies want hospitals and health systems to agree to the following:

- Accept lab specimens from the management companies' associated physicians.
- Accession these specimens and perform the routine tests, using their automated chemistry analyzers and other equipment while referring other lab specimens to the management companies.
- Bill for all lab tests using their provider numbers and in-network managed care contract rates, regardless of whether it was the hospital lab or the management company that performed the test.

Oversight of Sales Reps

Typically, the management company does the sales and marketing to referring physicians. That means the hospital or health system has little control or oversight into whether the management companies' sales representatives comply with state and federal laws, particularly the anti-kickback statute.

The HOPD agreements reviewed to date mention that these arrangements comply with state and federal laws and regulations. The management companies also offer legal opinions to the hospital and health system administrators that explain how the proposed agreements comply with existing law.

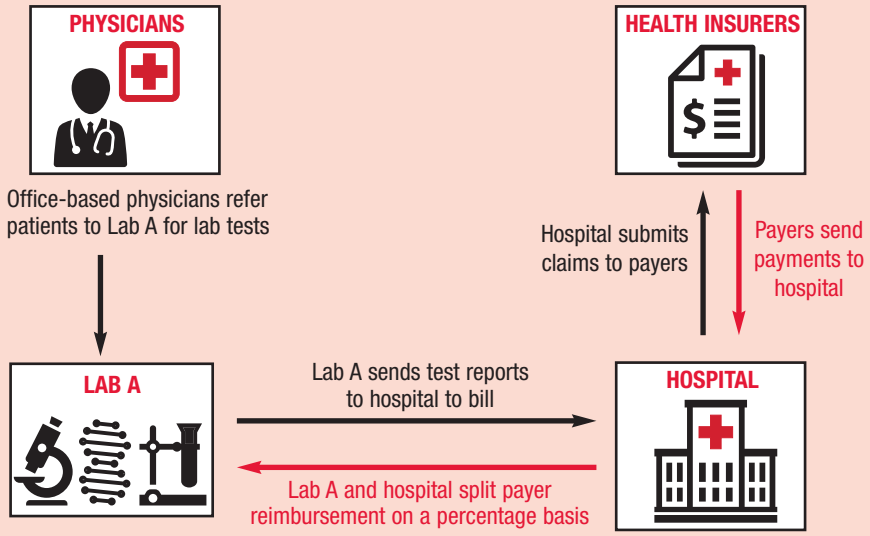
As part of its investigation into the use of these HOPDs and MSOs to defraud private and public payers, THE DARK REPORT interviewed attorneys who recognized that the HOPD scheme—which requires the hospital to submit claims to payers for lab tests the management company performs—is a variant of a fraud scheme known as pass-through billing.

Five Types Of Federal Law

The attorneys identified five types of federal or state laws that these HOPD agreements could violate, including:

- The False Claims Act.
- The Anti-Kickback Statute (if the hospital or laboratory might be receiving referrals in return for remuneration

Current HOPD Scheme is Classic 'Pass-Through' Billing Arrangement Involving Hospital, Lab Firm



A New Form of Possible Lab Test Abuse: Hospital Outpatient Diagnostics (HOPD)

DIFFERENT FORMS OF HEALTHCARE FRAUD AND ABUSE involving "pass-through billing" arrangements have been around for decades. What is new today is the scheme that some scammers present as an HOPD agreement—hospital outpatient diagnostics—whereby the hospital bills for outreach lab tests performed by the lab management company's lab facility.

For a lab management company, the HOPD scheme is a way to have the hospital use its NPI number and its managed care contracts to bill for lab tests performed in its lab. Attorneys familiar with healthcare law point out that such HOPD schemes have the potential to violate a number of federal and state laws, as well as to be violations of the hospital's contracts with health insurers.

There is another important element to the HOPD scheme that is required for the lab management company to produce revenue. It must originate a substantial volume of lab test orders. To do this, many of the lab management companies are developing clever ways to induce the physicians to order lab tests. One way is the use of medical service organizations (MSOs). In some versions of the MSO, physicians hold ownership shares and are paid remuneration (such as profit-sharing, dividends, etc.) proportional to the volume of lab test specimens they referred to the MSO. This has the potential to violate anti-kickback and Stark referral laws.

that reflects the volume and value of referrals. There is no safe harbor if the hospital and the management company are doing a percentage split.)

- The Stark Law (if the hospital or laboratory is physician owned.)
- The shell lab rule.
- Laws in certain states that cover such activities as fee-splitting, anti-kickback, fraud and abuse, as well as anti-markup.

HOPD Agreements

Private health insurers have targeted HOPD agreements involving a hospital and a management company for civil actions in state courts. When a hospital has managed care contracts, several prohibitions may be part of these contracts. They include:

- Exclusivity of services by payer-credentialed healthcare entities.
- Anti-assignment language.
- Limitations on billing for referred services.

There are multiple ways that these HOPD arrangements involving management companies, hospitals, or health systems can violate federal and state laws. Similarly, the hospital's participation in these lab test outreach schemes can put its contracts with health insurers at risk for multiple reasons. One example is the lawsuit filed by **Blue Cross Blue Shield of Mississippi** against **Sharkey-Issaquena Community Hospital** and four toxicology lab companies. *(See sidebar, next page.)*

Rural, Smaller Hospitals

Another lawsuit that garnered national headlines and alleges fraud involving lab tests is **United Healthcare Services Inc.** and **UnitedHealthcare Insurance Company** vs. **Next Health LLC**, **United Toxicology LLC**, **Medicus Laboratories LLC**, **US Toxicology LLC**, **American Laboratories Group LLC**, Erik Bugen and Kirk Zajac.

Filed on Jan. 26, 2017, the insurer describes the fraud as involving $100 million. In court documents, UnitedHealth claims that, between 2011 and mid-2016, Next Health and subsidiaries submitted false claims and engaged in false and fraudulent conduct.

UnitedHealth alleges that, Next Health et al relied on kickbacks to generate test requests; Next Health et al performed unauthorized testing services; Next Health et al had standing orders for "custom" profiles and confirmation testing; Next Health et al billed for services performed by another provider; and, Next Health et al waived all patient responsibility.

Many Hospitals Approached

How common are these HOPD arrangements between management companies and hospitals? Many pathologists and lab administrators working in hospitals and health systems tell THE DARK REPORT that sales representatives have approached their institutions to pitch these schemes. Additional evidence of the prevalence of these schemes comes from recent lab conferences. When asked if hospitals have been approached about entering into an HOPD agreements, many hospital lab officials have raised their hands.

THE DARK REPORT predicts that these new forms of fraud involving laboratory testing will reach into the multiple billion-dollar range and could dwarf the $2 billion the federal government collected from labs in the 1990s as a result of its LabScam investigations. TDR

—Joseph Burns

WANTED: HOPD, MSO EXAMPLES

For its investigation into HOPDs and MSOs involving lab testing, THE DARK REPORT welcomes information, marketing presentations, legal opinions, and similar documents of such arrangements. Contact Robert Michel in confidence at 512-264-7103 or rmichel@darkreport.com.

Mississippi Blue's Lawsuit Describes Hospital Lab 'Pass-Through' Scheme with Toxicology Labs

ONE HEALTH INSURER THAT HAS SUED an alleged fraudulent HOPD arrangement is Blue Cross Blue Shield of Mississippi. In a case filed May 4 in the U.S. District Court for the Southern District of Mississippi, BCBS named as defendants a small community hospital and four toxicology laboratories, among others. *(See TDR, June 5, 2017.)*

At the time, TDR said the case could mark a turning point in payers' willingness to take legal action against entities that submit lab test claims based on potentially fraudulent business arrangements.

Hospital, Tox Labs Sued

In the lawsuit, BCBS named as defendants Sharkey-Issaquena Community Hospital, a 29-bed hospital in Rolling Fork, Miss., a town with a population of 2,500. The other defendants were: **Sun Clinical Laboratory, Mission Toxicology Management Company, Mission Toxicology, Mission Toxicology II,** and 10 unnamed "John Does."

In court documents, BCBS charged the hospital and the labs with breach of contract, fraud, civil conspiracy, negligent misrepresentation, and unjust enrichment. The lawsuit said that, "between February and May 2017, the hospital submitted to the insurer claims totaling in excess of $33.8 million. Of that, Blue Cross has paid out more than $9.8 million. Claims submitted, but which the plaintiff contends are misrepresented, thus not covered, amount to over $24 million.

The suit alleged that, "since February 2017, claims were submitted to Blue Cross for payment for laboratory services that: 1) purported to have been performed at and by the hospital; 2) were not ordered by a licensed health professional with appropriate staff privileges at the hospital; and, 3) were not performed at the hospital in Rolling Fork, Miss."

According to the lawsuit, in January 1995, BCBS contracted with the hospital to provide "hospital services which are medically necessary when such services are ordered by a licensed physician or other licensed health professional who has appropriate staff privileges at [the] hospital." In the lawsuit, BCBS alleged that the physicians who submitted lab tests to the community hospital were not affiliated with the hospital.

At the core of this lawsuit is the allegation of "pass-through billing," whereby the hospital—although it did not perform the outreach lab tests that were run in laboratories of the other defendants—billed BCBS of Mississippi for all the lab tests.

Rural, Smaller Hospitals

In the court documents, Blue Cross described how its initial investigation revealed that, under the "arrangement" between the hospital and Sun and the Mission companies, orders for laboratory services were submitted to Sun Clinical Laboratory, Hermann Drive Surgical Hospital, Houston, TX, CLIA #45D2027576 and Mission Toxicology, 2145 NW Military Hwy #102, San Antonio, TX, CLIA #45D2071649.

The court documents further stated that the lab test results were submitted to the providers who ordered the tests on forms with Mission Toxicology or Sun Clinical Laboratory logos—but with the hospital's CLIA number and Mississippi address and with a Texas phone number.

Defendants have filed a motion to dismiss the BlueCross complaint and that motion is still being briefed.

As described in the lawsuit, this is one way that the lab management companies use the HOPD agreement so that the hospital's NPI number and managed care contracts are used to bill payers as an in-network provider for lab tests that were performed at the lab management company's facilities.

Regulatory Update

Some Labs Performing ADLTs May See Increased Medicare Fees

CMS published proposed ADLT prices, then released deidentified market price data file

MIXED IN THE BAD NEWS concerning the proposed Clinical Laboratory Fee Schedule for 2018, there is some good news regarding what the federal **Centers for Medicare and Medicaid Services** proposes to pay for certain advanced diagnostic tests.

After analyzing the proposed fee schedule, **Quorum Consulting** of San Francisco, reported, as other analysts have concluded, that CMS has proposed drastic cuts for many of the most common clinical laboratory tests. At the same time, CMS also has proposed that advanced diagnostic laboratory tests (ADLTs) would not face wholesale cuts in payment.

For example, payment for **Myriad Genetics'** Vectra DA test—an assay used for patients with autoimmune rheumatoid arthritis under HCPCS code 81490—got a proposed 42.34% increase in payment, from $590.61 this year to $840.65 next year, Quorum said.

In an article for *GenomeWeb*, Turna Ray reported that most ADLT codes would benefit. **Genomic Health's** Oncotype DX test for breast cancer recurrence would rise from $3,443 to $3,873, but payment for its colon cancer test would drop slightly from $3,126 to $3,116, Ray wrote.

While price increases are effective immediately, price cuts will be phased in at no more than 10% per year over the first three years, noted Bruce Quinn, MD, PhD, Principal with **Bruce Quinn Associates**. Another test for breast cancer recurrence, **Nanostring's** Prosigna, would initially drop from $3,443 to $3,099, Quinn added, although its ultimate median price under PAMA is only $900.

CMS proposed increases for two other ADLTs: **Veracyte's** Afirma Gene Expression Classifier would rise from $3,222 to $3,600, Ray reported. **CareDx's** AlloMap test would go from $2,841 to $3,240, she added.

After analyzing the market price data submitted by labs, CMS published the raw deidentified data file of 5 million lines that showed all the prices that labs reported. The data show wide ranges in prices from among labs that reported private payer market price data. "As an example, for BRCA sequencing (CPT code 81211), the new median price is $2,395, but the raw data shows dozens of payments were made at over $30,000," Ray wrote.

In the Protecting Access to Medicare Act of 2014, an ADLT is defined as a laboratory service that is offered and furnished by only the developing lab and also meets one of the following criteria:

- The test is an analysis of multiple biomarkers of DNA, RNA, or proteins combined in a unique algorithm to yield a single patient-specific result; or,
- The test is cleared or approved by the FDA: or,
- Meets other similar criteria established by CMS.

TDR

—Joseph Burns

Finally, Abbott Buys Alere to Become #1 in POCT

Abbott's purchase of Alere consolidates two big point-of-care businesses into one company

CEO SUMMARY: After nearly two years of legal battles, Abbott Laboratories' acquisition of Alere concluded on Oct. 3. Despite antitrust requirements to divest several of Alere's diagnostic businesses to Quidel and Siemens Healthineers, the merger makes Abbott the world's largest provider of point-of-care testing systems. Hospitals and clinical laboratories buying POC products from Abbott and Alere can expect changes as Abbott integrates the two businesses.

BIG CHANGES ARE COMING TO THE POINT-OF-CARE TESTING MARKET now that **Abbott Laboratories** is the new owner of Waltham, Mass.-based **Alere Inc.**

The acquisition was finalized on Oct. 3 and combined the number two and number three biggest companies in the point-of-care (POC) market. The merger now makes Abbott Laboratories the world's largest POC testing company, according to **Kalorama Information**.

This acquisition is the latest example of consolidation in the *in vitro* diagnostics industry. Laboratories and hospitals that purchase POC systems and consumables from the two companies can expect to see many changes over the next year or two as Abbott Laboratories integrates the two companies; realigns Alere's sales and service staffs with their counterparts at Abbott; and develops new marketing strategies for the combined POC systems, tests, and related products.

Abbott's purchase of Alere proved to be a complicated transaction. In February 2016, Abbott confirmed an agreement to acquire Alere for $5.8 billion. A month later, however, the federal **Department of Justice** subpoenaed documents from Alere regarding sales and distribution practices in foreign markets—including Africa, Asia, and Latin America.

Problems Delayed Merger

Abbott then wanted to terminate the acquisition agreement, but Alere's board of directors refused that request. In July 2016, Alere received another DOJ subpoena related to alleged illegal government billing and payments to doctors at **Alere Toxicology Services**—Alere's pain management laboratory in Austin, Texas. Alere also issued a permanent recall for its INRatio and INRatio2 Prothrombin Time and International Normalized Ratio Systems.

More bad news hit Alere when, in November 2016, **Arriva Medical**, a subsidiary of Alere, lost Medicare reimbursement privileges following allegations the company sought reimbursement for 211 dead people.

Following these accusations and recalls, Abbott sought to cancel the merger in a lawsuit triggering the material

adverse effect clause of its initial agreement in December 2016. According to *GenomeWeb*, the two companies reached an agreement—including a lower acquisition cost—in April 2017 and dismissed lawsuits against each other.

Bloomberg Gadfly reported on the DOJ subpoenas and criminal accusations involving Alere, reporting that Alere settled with the SEC regarding "improper revenue recognition practices at foreign subsidiaries." Separately, Arriva Medical continues to appeal its suspension of its Medicare billing privileges.

Still, Alere faced another challenge because both Abbott and Alere held significant shares of the POC market, leading the **Federal Trade Commission** to require divestment of two point-of-care testing devices before it would approve the acquisition.

In September, the FTC said, "According to a complaint filed by the FTC, the proposed acquisition would result in market concentration and likely harm competition in the U.S. for the sale of two types of devices: point-of-care blood gas testing systems (which measure blood pH, oxygen, carbon dioxide, and electrolyte levels) and point-of-care cardiac marker testing systems (which measure specific proteins in the blood to assess whether a patient is having a heart attack or experiencing congestive heart failure)."

Divesting POC Test Lines

To meet the FTC's divestiture requirements, Alere struck deals with **Quidel** and **Siemens Healthineers**. Quidel will acquire Alere's Triage BNP assay and Triage MeterPro cardiovascular and toxicology assets. Siemens Healthineers will acquire Alere's Epocal point-of-care blood gas testing and diagnostics system.

Some of the required divestitures were ordered because Abbott owned and sold similar technologies. *FierceBiotech* noted, "Epocal sells products including the handheld, wireless epoc blood analysis system. As Abbott sells the competing i-STAT, antitrust regulators are uncomfortable with the prospect of the company owning both businesses after it acquires Alere."

New Selling Opportunities

Among the reasons Abbott was interested in buying Alere is that the combined businesses would create new selling opportunities for Abbott. *Zacks Equity Research,* a web site, reported that the combined company will enable Abbott "to gain access to new channels and geographies, including entries into fast-growing outlets, such as doctors' offices, clinics, pharmacies, and at-home testing." Also, Alere's complementary portfolio of diagnostic products, comprising tests for infections such as HIV, tuberculosis, malaria and dengue, will be added to Abbott's portfolio, Zacks wrote. Significantly, Alere develops simple, rapid tests, including Alere i—the molecular test for flu and strep—to deliver reports in less than 15 minutes.

The shared business will allow Abbott to pursue testing in the areas of infectious disease, molecular, cardiometabolic, and toxicology, the web site reported. Also, the union of the two companies would allow Abbott Laboratories' platforms to include benchtop and rapid strep tests, Zacks concluded.

Now that Abbott owns Alere, the hospital and lab customers of Alere will likely see significant changes as Abbott integrates Alere's POC products with its own POC products.

Strategically, Abbott's acquisition of Alere continues what is now a trend of IVD consolidation that stretches across three decades. Since the early 1990s, the world's largest IVD manufacturers have regularly swooped down to buy any IVD company that had promising technology and was building market share at a steady pace. TDR

—Jon Stone

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

In a development that has implications for medical laboratories in developed nations, healthcare organizations in Africa have launched a "landmark electronic referral project" to digitally track workers who travel to South Africa to work in the mining industry. The project is being administered by **TIMS** (TB in the Mining Sector in South Africa). This digital medical referral service will track the workers as they return to their home countries and help ensure that they get consistent medical care for their TB and other diseases.

MORE ON: *TB in Africa*

About 500,000 workers from different countries work annually in South African mines. The incidence of tuberculosis among these workers is one of the highest in the world—almost 10 times higher than the level the WHO has established for a medical emergency. A miner with TB can infect as many as 10 to 15 people when he returns to his home community. TIMS hopes that its electronic referral service will help workers with infectious diseases, like TB, to continue accessing therapeutic drugs and medical care as they travel between their homes and their jobs in South Africa. The project organizers recognize the need for improvements to medical laboratories and medical resources in these regions to support the TIMS program.

NEOGENOMICS OPENS NEW LAB IN SWITZERLAND

Neogenomics, Inc., of Ft. Myers, Fla., said it has opened its first international lab facility near Geneva, Switzerland. The lab is intended to provide testing in support of clinical trials.

QUEST TO BUY CLEVELAND HEARTLAB

In a deal announced on Oct. 18, **Quest Diagnostics** agreed to purchase **Cleveland HeartLab**, a spin-off business of the **Cleveland Clinic**. Cleveland HeartLab performs propietary specialty cardiology tests using technology developed at the clinic. It was founded in 2009.

TRANSITIONS

• **Meridian Bioscience** of Cincinnati announced that John Kenny is its new CEO. Previously, Kenny held executive positions at **Siemens Healthcare**, **BD**, **Leica Microsystems**, **Quest Diagnostics**, **Bayer Diagnostics**, and **Abbott Diagnostics**.

That's all the insider intelligence for this report. Look for the next briefing on Monday, November 20, 2017.