Volume XXII, Number 1 Monday, January 5, 2015

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

Why You Want the Insider's Perspective of Lab News

TODAY I WOULD LIKE TO SHARE A QUOTE WITH YOU and offer some thoughts about how it relates to the profession of laboratory medicine that you practice every day.

> *News is what someone wants suppressed. Everything else is advertising. The power is to set the agenda. What we print and what we don't print matter a lot.*
>
> *—Katharine Graham (1917-2001), Publisher of the Washington Post*

Our editorial team was discussing this quote as we assembled this issue of THE DARK REPORT. It features two primary stories. First is the effort by **UnitedHealthcare**, **BeaconLBS** (and its owner, **Laboratory Corporation of America**), to require all physicians and all laboratories serving UHC patients in Florida to comply with a specific system of lab test pre-notification and pre-authorization. We report on more dissatisfaction by physicians about the intent and function of UHC's laboratory benefits management program.

Second is a series of stories about the lab industry's bad players and how they manage not only to survive, but to profit handsomely. This is due to lax enforcement of anti-kickback and medical necessity laws by federal and state prosecutors.

As you read through this issue, ask yourself the question, "Is this news that someone would prefer to be suppressed?" If so, why would they want it suppressed?

More importantly, does the insider's perspective we provide you on these major lab industry stories help you understand why today's events in the lab marketplace are what cause tomorrow's developments? For example, what will clinical practice look like if UnitedHealthcare were to implement the BeaconLBS program with doctors in your community—and your lab had to decide whether it wanted to sign a contract to be in the UHC lab network managed by one of your lab's biggest competitors in order to retain access to those of UHC's 34 million beneficiaries who live in your city?

As Graham stated, "What we print and what we don't print matter a lot." Our responsibility is to provide you with the essential business intelligence you need to understand unfolding events in healthcare and the lab testing marketplace. On this point, we invite your comments. TDR

Lab Industry To Confront Major Issues during 2015

Topping the list are FDA regulation of LDTs and PAMA's market price reporting requirements

CEO SUMMARY: Will 2015 turn out to be a watershed year for the clinical laboratory industry? Not only are two federal agencies pushing forward with initiatives that will touch nearly every medical lab in the United States in the next 12 months, but other equally powerful trends continue to negatively influence the prices labs are paid for their testing services. All these factors make it essential for lab administrators and pathologist business leaders to work proactively to maintain their lab's financial stability.

EVEN BEFORE THE ARRIVAL OF 2015, astute pathologists and lab administrators recognized that this new year will confront the profession of laboratory medicine with multiple and serious challenges.

Topping the list are two issues with the potential to have broad impact on clinical labs both large and small across the nation. One issue is the FDA's proposed guidance to regulate laboratory-developed tests (LDTs).

The second issue is implementation of sections addressing clinical laboratory testing in the Protecting Access to Medicare Act (PAMA) enacted into law last winter. This will be the responsibility of the federal **Centers for Medicare & Medicare Services**. Much attention will be given to the market price reporting requirements that CMS creates under PAMA and publishes this year.

Starting in 2016, designated clinical labs must report market price data for each test and for each payer. Under PAMA as currently written, CMS is to use this market price data to establish prices for the Part B Clinical Laboratory Test Fee Schedule beginning in 2017.

Each of these two issues has the potential to be transformational in how it reshapes the existing clinical lab test offerings and the revenue collected by labs of all sizes and types. For this reason, throughout 2015, lab administrators and pathologists will be encouraged by their respective associations and specialty colleges to support efforts to lobby Congress and educate federal regulators about the

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 $14.10 per week in the US, $14.90 per week in Canada, $16.05 per week elsewhere (billed semi-annually).

positives and negatives of regulating these lab activities.

In addition to the LDT and PAMA issues, most clinical labs and pathology groups will need to deal with several other strong forces during 2015. Just as it has in recent years, predictions are that, during the coming year, government and private payers will continue to forcefully implement restrictive coverage guidelines for lab tests while also reducing the prices they pay labs for many types of lab tests.

Histology Lab Finances

Such actions have already undermined the financial stability of many anatomic pathology group practices. In particular, strong price cuts for certain high-volume technical component CPT codes have made it uneconomical for most smaller pathology groups to operate a histology laboratory.

This is one reason why some smaller pathology groups have commenced negotiations to find an acquirer, seek merger with a stronger pathology group in the region, or even to approach hospital administrators to explore the option of becoming employees of the hospital.

It is a similar story for clinical laboratories. Along with reductions to lab test fee schedules, private health insurers are establishing narrow networks as a way to exclude higher-cost labs. Consequently, in many communities across the United States, local laboratories and hospital lab outreach programs are losing their managed care contracts and thus have less access to patients.

Three Market Forces

This trend will continue throughout 2015, fueled by three market forces. First, health plans organized under the health exchanges of the Affordable Care Act will continue to narrow their networks as a way to keep premiums as low as possible.

Second, payers are expected to continue enrolling Medicare beneficiaries into Medicare Advantage plans. This moves the individual out of the Medicare Part B fee-for-service program and into a private Medicare plan which probably has contracted deeply-discounted lab test prices from one or both of the national labs.

Third, some states are putting more energy into moving their Medicaid beneficiaries into managed care plans. This also reduces the proportion of patients that can be served by community labs and hospital lab outreach programs.

Collectively, these trends are why it is becoming harder for local labs to access the volume of patients and specimen referrals needed to generate the level of cash flow necessary to maintain the financial integrity of their lab organizations.

Another challenge labs face during 2015 is the health system's steady evolution away from fee-for-service reimbursement. During the past 24 months, the Medicare program has taken its first steps to implement bundled payments (similar to inpatient DRGs) for certain outpatient services. CMS officials have stated their goal is to increase the use of bundled payments for outpatient services.

Bundled Payments

Under bundled payment arrangements, labs must negotiate their share of the payment with the hospitals, health systems, physicians, and other providers that had a role in treating a Medicare patient. It is expected that private health insurers will begin adopting Medicare bundling guidelines for their own beneficiaries.

On the lab compliance front, 2015 is the year that CLIA labs will have the option to adopt individual quality control plans (IQCPs). By year's end, effective January 1, 2016, Equivalent Quality Control (EQC) will no longer be an acceptable option to meet CLIA quality control requirements. That will leave labs with the choice to use either CLIA QC regulatory requirements as currently written, or implement IQCP where appropriate.

This partial list of issues and market forces demonstrates why 2015 is expected to be a challenging year for all labs. TDR

Legal Update

'Nanotainer' vs. 'Microtainer': Theranos Sues Becton Dickinson

Legal fight commences after BD opposes the trademark application filed by Theranos

BY FILING A LAWSUIT IN FEDERAL COURT against **Becton Dickinson**, **Theranos**, the ulta-secretive lab testing company based in Palo Alto, California, has once again put itself in the headlines.

In papers it filed in the United States District Court for the Northern District of California, Theranos is asking the court to rule that its use of the trademark "nanotainer" does not infringe the "microtainer" trademark used by Becton Dickinson. The lawsuit was filed on November 3, 2014.

For decades, pathologists and laboratory professionals have worked with the line of blood collection products marketed under the "microtainer" name by Becton Dickinson of Franklin Lakes, New Jersey. BD says it originally registered that trademark in 1976.

Barring an out-of-court settlement by the two parties, it will be up to the federal judge to determine whether Theranos' use of nanotainer represents an infringement of BD's microtainer trademark.

Trademark Application Filed

It was in 2012 when Theranos applied for a trademark for the term nanotainer. In March, 2014, BD filed an objection to the Theranos trademark application. Becton Dickinson claimed that the name was too similar to its microtainer trademark. It also sent a series of letters to Theranos about this matter.

In response to these actions by BD, Theranos decided to file its lawsuit in federal court last month. What may add an extra element of interest to this case for pathologists and lab administrators is that one of the two law firms representing Theranos is **Boies, Schiller & Flexner, LLP**, of Armonk, New York.

High-Profile Attorney

Readers with good memories will recall the *Bush vs. Gore* case during the 2000 presidential election. When the Supreme Court heard oral arguments, it was David Boies who argued on Al Gore's behalf. Boies has been involved in some of the nation's high-profile legal cases over the past two decades. His law firm has represented Theranos for a number of years.

The other legal counsel for Theranos is **Fenwick & West LLP** of San Francisco, California. Representing BD is **Epstein Becker & Green LLP**, of San Francisco, California.

What will likely be a key issue in this case is the "tainer" part of the BD trademark. BD also holds the trademark for "vacutainer" and each year billions of these specimen collection devices are manufactured and used globally. A similar type of lawsuit was filed years ago by "**Toys R Us**" to protect its trademark from firms that tried to use such names as "Lamps R Us" and similar. Toys R Us prevailed in that case and Lamps R Us is now called Lamps Plus. TDR

Florida Docs Seek to Cut Ties with UnitedHealthcare

➤BeaconLBS program leads physicians to say UHC patients may need to go elsewhere for care

➤➤CEO SUMMARY: Physicians in Florida continue to express significant concerns about UnitedHealthcare's pilot program requiring pre-notification for 80 clinical laboratory tests, including many routine tests, and pre-authorization for two genetic tests. The program is so onerous that some physicians have said they want to get out of their United contracts. Moreover, during a recent webinar to show Florida physicians how the BeaconLBS system works, officials from BeaconLBS could not get the system to function!

BATTLE LINES ARE HARDENING in Florida over **UnitedHealthcare's** laboratory benefit management program. On one side are a growing number of physicians with legitimate concerns about the effect of the program on patient care and daily operations.

On the other side are executives of UnitedHealthcare (UHC) and **BeaconLBS**. The BeaconLBS lab benefit management program requires Florida physicians to obtain pre-notification or pre-authorization via the BeaconLBS website for a list of 82 medical laboratory tests. At some unspecifed date in the future, failure to comply means that UHC may not pay medical laboratories that perform these tests and, in-network labs would be unable to bill patients for the cost of those tests. BeaconLBS is a wholly-owned business division of **Laboratory Corporation of America**.

In the closing weeks of December, THE DARK REPORT learned that the concerns about UnitedHealthcare's new test-ordering pilot program is now at the point at which some physicians are declaring their intent to get out of their UHC contracts, according to Jeff Scott, General Counsel for the **Florida Medical Association**. Physicians say the UHC program is onerous, time-consuming, and not worth the hassle, he said.

UHC's laboratory benefit management program has been criticized since its inception. If enough physicians declare their intention to drop out of their UHC contracts, then patients may need to seek new physicians, which could lead to enough complaints to force UHC to postpone, revise, or scrap the program.

➤Program Deployed As A Pilot

Currently, the program is being introduced only for those patients in UHC's commercial HMO network, which contracts with employers and individuals. If employers hear enough complaints from their employees in commercial HMOs, the employers could demand that UHC make changes in the program to address physicians' complaints.

When UHC contracted with BeaconLBS to install the system, it planned to have the program begin on September 1. Then UHC required physi-

cians to use the program starting October 1 but said their use of the program would have no effect on claims payment. The effect on claims payment was scheduled to begin January 1, 2015, but in late December, UHC postponed using the program to make claims payment determinations. No new date was set. *(See story about UnitedHealthcare on page 12.)*

Members of the Florida Medical Association have significant concerns. "Physicians repeatedly tell UHC that the BeaconLBS system is difficult to use and it requires them to spend more time ordering tests, time for which they will not be paid," stated Scott. "Our members are not at all pleased with the pilot project. And that's putting it mildly.

'Very Much Against It'

"The physicians we've talked to are very much against it," emphasized Scott. "For some, this system is a reason to get out of the contractual relationships they have with UnitedHealthcare.

"The level of frustration is significant and that's why they are looking for any reason they can find not to participate in this program," added Scott. "These physicians also don't like the fact that they are limited to one lab or the cumbersome nature of the BeaconLBS system."

In response to complaints from physicians, recently UHC held a webinar to demonstrate how the system would work. During the webinar, however, even officials from BeaconLBS couldn't get it to work, noted Michael A. Wasylik, M.D., an orthopedic surgeon in Tampa and chairman of the FMA's Medical Services Committee.

"We've been getting inundated with complaints about this from physicians," said Wasylik. "Doctors are very concerned about this because we already have to spend an extra hour a day just on electronic medical record systems. Now this makes our job that much more difficult. We are not against electronic transmission. But this is something that was set up poorly. It's just too cumbersome.

"When we complained to UHC, they said, 'It's not as bad as you think it is,'" he noted. "Then, they offered to set up a webinar but during the webinar, they couldn't get it to work. You could hear the UHC people in the background, saying 'Oh my word.'"

Scott said the failure to connect during the webinar was significant. "When the demonstration of the BeaconLBS system failed, it cemented the opinions for a lot of physicians," he stated. "It persuaded them this is not something they want to participate in.

"We have used every avenue and any contact we have with UnitedHealthcare to tell them how much we don't like this program," said Scott. "Officials from UHC and BeaconLBS have said they would pass along the physicians' concerns."

When asked about physicians' complaints, UnitedHealthcare referred questions to BeaconLBS. As of press time, BeaconLBS had not responded to requests for comment from THE DARK REPORT.

Physicians Are Concerned

The Florida Medical Association is not alone in its public statements about its members' concerns over UHC's lab test pilot program. Physicians representing family physicians and obstetricians and gynecologists also have sent letters criticizing the BeaconLBS system. In December, the **Florida Society of Pathologists** sent a letter asking UHC to suspend implementation of the pilot program. *(See pages 8-11 in this issue.)*

In its letter to the UHC, the **American Congress of Obstetricians and Gynecologists** (ACOG) District XII (Florida) asked UHC to discontinue the program immediately and indefinitely. *(See TDR, November 3, 2014.)* TDR

—Joseph Burns

Contact Jeff Scott at JScott@FLmedical.org or 850-224-6496; Michael L. Wayslik, M.D., at 813-877-9413.

FL Pathologists Critical of UnitedHealth, BeaconLBS

➤Pathologists share concerns, ask insurer to defer implementation of lab test program

➤➤CEO SUMMARY: In a letter to UnitedHealthcare, the Florida Society of Pathologists says UHC's pilot laboratory management program will have a negative effect on patient care by delaying access to care and timely diagnoses of disease. Signed by more than 120 members of the society, the letter lays out inconsistencies in the requirements of UHC's pilot program that Florida physicians must follow to obtain pre-notification or pre-authorization for more than 80 clinical laboratory tests.

ANOTHER FLORIDA MEDICAL ASSOCIATION HAS COMPLAINED TO **UnitedHealthcare** about the **BeaconLBS** laboratory management program.

In a letter sent December 19, more than 120 members of the **Florida Society of Pathologists** expressed numerous clinical concerns about the program, calling it ill-conceived and saying it will impair physicians' ability to practice medicine. They also said it would have a negative effect on clinical quality, patients' access to care, and timely diagnosis for United Healthcare enrollees.

Brett Cantrell, M.D., President of the Florida Society of Pathologists, said FSP members are reluctant to participate in UHC's laboratory benefit management program, which is managed by BeaconLBS.

"Pathologists believe the implementation of the pilot program as it exists now could have a negative effect on patient care, particularly if—as expected—many pathology groups are unable to meet UHC's second-opinion requirements for some clinical lab tests," added Cantrell.

"Pathologists also are concerned that they may not get paid if physicians do not comply with the pre-notification or pre-authorization requirements UHC has implemented for 82 or so clinical lab tests," he said. "Currently, claims denials under the pilot program have not been fully implemented.

"In particular, the members of the Florida Society of Pathologists are concerned about how the BeaconLBS system will affect the workflow in their offices, their clinical decision-making, and patient care," said Cantrell. The letter was addressed to Richard A. Justman, M.D., National Medical Director, and Linda Stewart, Vice President, National Lab Program.

➤Concerns About Patient Care

In the letter, the FSP said its members were concerned about UHC's laboratory benefit management program, including:

- How it could affect patients' access to care and could delay some diagnoses;
- How the program requires unnecessary certification by subspecialists for certain tests;

- How secondary review requirements infringe on the practice of medicine; and,
- How the program imposes an additional administrative burden on pathologists.

Florida pathologists are not alone in their criticism of the UHC and BeaconLBS program. "Pathologists across the country are watching how UHC has introduced the BeaconLBS program and have expressed concern about it as well," declared Jonathan L. Myles, M.D., Chair of the Economic Affairs Committee of the **College of American Pathologists**.

UHC has contracted with BeaconLBS, a subsidiary of **Laboratory Corporation of America**, to install the system and manage parts of the pilot program.

Pathologists Seek Revisions

The Florida Society of Pathologists asked UnitedHealthcare not to fully implement the pilot program and to make the system less onerous. "The entire pre-notification and pre-authorization end of this program is an order of magnitude more intrusive than anything to which physicians are accustomed," said Cantrell. "It's certainly understandable to require pre-authorization for a molecular test such as BRCA, but UHC actually is going in the other direction by asking for pre-notification for routine testing.

"We asked them not to fully implement the program and to retool it. I don't think the current program is workable," added Cantrell. "We recognize that UnitedHealthcare, providers, and pathologists can't go on with business as usual in healthcare. We all have to adjust to the new medical paradigm. But this is an ill-conceived program that UHC needs to modify and then come back to us with something more workable.

"In addition to pre-notification and pre-authorization, physicians are concerned about the need for second-opinion pre-certification because many pathology groups will be unable to meet this requirement," explained Cantrell.

Pathologsts' Letter to United Outlines Concerns

IN A LETTER SENT RECENTLY TO OFFICIALS at UnitedHealthcare, members of the Florida Society of Pathologists expressed deep concern about United's pilot Beacon Laboratory Benefit Solutions program. Among the concerns the pathologists cited in the letter were the following:

- The volume of tests for which notification via BeaconLBS must be provided to meet pilot requirements (in excess of 80 tests, some of which are commonly performed cytology) is onerous and the program's requirements will have a significant effect on the daily workflow of ordering physicians and laboratories.
- The secondary pathology review requirement to be performed by pathologists with subspecialty certification is overly broad and does not reflect current widespread accepted practice, the letter said.
- The secondary review requirement infringes on the practice of medicine.
- There is a potential for delays in ordering tests and providing test results. These delays could affect patients' access to care.
- There is an additional administrative burden to comply with program requirements.

"The Florida Society of Pathologists estimates that about 40% of all pathology practices will have trouble meeting the requirements as UHC specifies in this pilot program," Myles said. "For these groups, their size and composition of subspecialists—in terms of the professionals in the practice—will mean they don't have the staff to meet the requirements set forth by UnitedHealthcare."

Cantrell is Medical Director for **Consolidated Laboratory Services** at **St. Vincent's HealthCare** in Jacksonville, Florida. His pathology group may not qualify for the BeaconLBS program, he said.

"In my six-man group, for example, we have a dermatopathologist, but we don't have a second dermpath available for subspecialty review," commented Cantrell. "If this part of the UHC program remains, our pathology group would need an arrangement to share subspecialty review for dermatopathology. That would cost money, and UHC has not said who would pay for that.

Why Few Labs Have Applied

"A large percentage of pathology groups in Florida cannot qualify for this requirement," he continued. "However, even those groups that can qualify are reluctant to sign up. That is why very few labs have applied to participate in the BeaconLBS system."

In particular, Myles said, the second-opinion requirements could negatively affect patient care.

"Many pathology practices may not be the appropriate size to meet the UHC requirements," he said. "If there are not enough practices to meet the requirements, it could delay diagnoses. That would lead to concerns about how the program could affect patient care.

"And who would bear the cost for that secondary review?" asked Myles. "That's unclear."

Second Opinion Is Required

The BeaconLBS system requires pathologists to have a second pathologist review the pathologic diagnosis for certain types of specimens. Morever, the subspecialist pathologists who review these tests must have specific certifications. The College of American Pathologists earlier asked UHC to reconsider these requirements but to date UHC has left them in place.

Cantrell has heard from UHC officials that it is implementing the BeaconLBS system because clinical lab test costs are rising sharply.

"Of course, the aim of the BeaconLBS program is not just to control costs," Cantrell said. "It's also about quality. We don't stand in the way of improving quality, but we don't agree on the direction UHC and BeaconLBS are taking with this pilot program.

"In particular, the Florida Society of Pathologists disagrees with the fundamental concept of the need for subspecialty review," he said. "The **American Board of Pathology** has gone on record that subspecialty review is an inappropriate use of subspecialty certification. That's not the intent of subspecialty certification.

"Pathologists want to practice medicine and feel strongly that the subspecialty review requirement is deeply intrusive. I'm a board-certified anatomic pathologist," emphasized Myles. "In my professional practice of medicine, there are times when it is my responsibility to seek another opinion. However UnitedHealthcare is determining for me when second opinions are necessary—irrespective of my assessment for that need."

Asking To See Clinical Data

Pathologists, like other physicians practicing in Florida, are asking legitimate questions about why UHC's laboratory benefits management program has requirements that infringe on long-standing and widely-accepted clinical protocols, be it in primary care, ob-gyn, or pathology, for example.

In particular, those physicians who have voiced these concerns have asked UnitedHealthcare to provide specific information and clinical data that support UHC's statements that the requirements of the BeaconLBS system for lab test pre-notification or pre-authorization are needed to resolve an unacceptable situation in either patient care or unnecessary healthcare costs, or both. To date, UHC is not believed to have provided such information to physicians as an answer to these concerns. TDDR

—Joseph Burns

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Pathologists Still Seeking Answers to Questions About UnitedHealthcare and BeaconLBS Program

PATHOLOGISTS HAVE A LONG LIST of questions for UnitedHealthcare about the reasoning behind requiring pre-notification and pre-authorization for 82 clinical laboratory tests, said Jonathan L. Myles, M.D., a pathologist and Chair of the Economic Affairs Committee for the College of American Pathologists.

"What problem is UnitedHealthcare (UHC) trying to solve with this pilot program?" he asked. "Also, why is UHC requiring secondary review for some specimens but not for others? Who will perform these secondary reviews? Why is a health insurer intervening into a pathologist's scope of practice by requiring secondary reviews irrespective of the pathologist's medical assessment of the case, and why doesn't the UHC pilot program address the issue of false negative test results?

"UnitedHealthcare has not said what the real problem is," noted Myles. "Pathologists need to know that before we can have a successful resolution to the issues and before there can be a successful program to mitigate any of UHC's concerns.

"What is also unclear is why UHC wants a subspecialist-pathologist to review some cases when these cases are referred from one type of practitioner, yet it doesn't require a subspecialist to confirm a primary diagnosis on other types of cases," added Myles.

Lack Of Consistency

"In the UnitedHealthcare pilot program, for example, when a lab receives a skin case referred by a dermatologist, both the primary and secondary review needs to be done by a dermatopathologist," he noted. "But if a skin case is referred from a physician who is not a dermatologist, any surgical pathologist can read that case, at least initially. So there is a lack of consistency in the UHC requirements—depending on what type of professional did the biopsy and referred the tissue.

"Another issue pathologists have with the pilot program is that it focuses on secondary review of malignancies but doesn't mention any consideration of potential false negatives," continued Myles. "We are curious about why there is no discussion about false negatives.

"Identifying false negatives is important because those would be diagnoses that would be missed," he observed. "If they are missed, then ultimately, downstream costs might be increased, not to mention how missing a false negative would affect the patient's outcome.

Secondary Review Rules

"Yet another clinical concern is the question about who will perform the secondary reviews," stated Myles. "Routinely, physician-pathologists decide which cases require second opinions and it is within a pathologist's professional judgment if a case needs a consult from another pathologist before it's signed out or interpreted.

"In fact, the diagnoses we make as pathologists are within the scope of our licensure and within the scope of services that the **American Board of Pathology** has deemed us capable of doing," he emphasized. "That is a major clinical concern for us.

"The entire UHC pilot program is provocative because it raises all these questions that need to be answered," stated Myles. "Moreover, it is not just pathologists in Florida who are concerned about this pilot program. Pathologists across the country are equally concerned.

"Additionally, the BeaconLBS system also creates an administrative burden on physicians who order any of the 80 or more clinical laboratory tests and on pathologists who must ensure that ordering physicians have taken all the necessary steps for pre-notification and pre-authorization," concluded Myles. "If ordering physicians do not complete the necessary steps, then pathologists may not get paid."

BeaconLBS Update

In Florida, UnitedHealth Delays BeaconLBS Claims Decisions

LAST WEEK, ONE PART OF THE Beacon Laboratory Benefit Solutions pilot program in Florida was postponed. A UnitedHealthcare spokesperson provided additional information about this decision.

"We have lifted the January 1 claims impact deadline in order to give providers additional time to become further familiar with all aspects of the pilot program and allow for the continued exchange of constructive feedback," stated UHC's Elizabeth Calzadilla-Fiallo, Director, Public Relations for Florida and the Gulf States Region.

"Constructive provider feedback has been instrumental in our refinement of this important program that seeks to improve upon our overall delivery of healthcare to our members," she added. "We've been having conversations with a variety of specialty groups, including the **College of American Pathologists**, the **American Academy of Dermatology Association**, and the **American Congress of Obstetricians and Gynecologists**."

"The pilot program was implemented officially on October 1, and a great majority of those physicians and pathologists in the UHC network who were required to participate have started using this new process," Calzadilla-Fiallo explained.

"Now only the claims impact date has been changed," she emphasized. "Please note that the claims impact date should not be confused with the pilot program implementation date. The claims impact date has now been pushed back for a second time with no definitive deadline being set. However, we will give all appropriate parties a 30-day notice before initiating the claims impact portion of the program," she said.

"We have removed the January 1 deadline in response to some of the feedback we received from physicians and pathologists," she added.

In response to questions from THE DARK REPORT about what steps clinical labs could take to get paid if physicians ordering lab tests fail to use the BeaconLBS system, she said: "If an in-network lab completes a test for a UnitedHealthcare member that is among the 80 tests requiring advance notification—but notification was not filed—the lab has an opportunity within 10 days after the date of service to request that the physician secure notification prior to submitting the claim."

Out-Of-Network Labs

If the ordering physician does not notify UHC about the lab test, in-network labs would not be allowed to bill UHC patients. But out-of-network labs could bill the patient, she said. "Contracted, in-network labs cannot balance bill UnitedHealthcare members. In general, as part of participating in an insurer's network, physicians, hospitals, labs, ancillary providers, etc. cannot balance bill patients because they've agreed in advance to specific reimbursement rates and administrative guidelines," she explained.

"However, if the care provider does not have a contract with the insurer, the insurer cannot prevent them from balance billing the patient," said Calzadilla-Fiallo. "That's why a key goal of the lab management program is to encourage greater use of in-network labs, so our members can maximize their in-network benefits coverage." TDR

Contact Elizabeth Calzadilla-Fiallo at Elizabeth.Calzadilla-Fiallo@uhc.com.

Legal Update

Health Diagnostic Lab Pushes Back on Federal Fraud Probe, Cigna Suit

HEALTH DIAGNOSTIC LABORATORY of Richmond, Virginia, is mounting its own offensive against the dual blows it suffered recently: a federal fraud investigation and a lawsuit by **Cigna**, a health insurer in Bloomfield, Connecticut.

In September, *The Wall Street Journal* reported that federal officials were investigating HDL and four other labs for violations of the anti-kickback law. All of the labs denied the charges. *(See TDR, September 22, 2014.)* In October, **Cigna Health and Life Insurance Company** filed a legal complaint with the U.S. District Court in Connecticut, saying HDL used a scheme to forgive fees owed by patients for lab tests to take $84 million from Cigna unlawfully. *(See TDR, November 3, 2014.)*

In an apparent effort to build a defense against the fraud investigation and the Cigna lawsuit, HDL issued a press release on December 8 about an analysis of claims data of 7,396 patients. One group of patients had "comprehensive laboratory testing and personalized lifestyle consulting from HDL" and one group of patients did not.

The study determined that HDL patients had a 41% decrease in incidence of heart attacks and lower occurrence of diabetes complications than a similar group of patients who did not have the testing and counseling.

HDL paid **Optum**, a health services division of **UnitedHealthcare**, and researchers at the **University of Richmond** to conduct the study, although HDL did not say how much it paid, the *Richmond Times-Dispatch* reported. The study was promoted in a press release but was not published in a peer-reviewed medical journal.

Steve Thompson, the lead author of the study, said improvements in outcomes emerged in a relatively short time of 12 to 42 months and overall medical costs for the patients declined even though laboratory costs rose. Thompson is an associate professor of management at the Robins School of Business at the University of Richmond.

Patients HDL diagnosed with cardiovascular and cardiometabolic diseases or risk factors for disease and who had counseling from HDL had fewer adverse events and better health outcomes at no additional cost when compared with a comparable group of patients who had similar diseases or risk factors but did not have HDL's counseling, the study showed. The cost of care for each HDL patient was $950 per month versus $957 per month for patients who did not have HDL testing and management.

Response To Cigna Lawsuit

HDL also pushed back against the Cigna suit. On December 10, it asked the court to dismiss the action. HDL said Cigna filed the suit under the federal Employee Retirement Income Security Act of 1974 (ERISA). It challenged that claim saying Cigna wanted to enforce its own cost-containment strategies which are not mandated under ERISA, HDL said. "In reality, this suit is motivated by Cigna's personal desire to limit out-of-network providers of healthcare services, such as HDL, that Cigna refused to allow to operate in-network," HDL said.

"Moreover, Cigna is not suing to obtain any remedies permitted by ERISA. Cigna seeks money for itself or other 'Cigna entities' and not for the ERISA plans that it purports to represent," HDL claimed. TDR

—Joseph Burns

Lab Compliance Update

Why 'Bad Actors' Continue To Operate in Lab Industry

OVER THE PAST TWO DECADES, pathologists and lab managers have regularly watched certain new lab companies burst on the scene and generate startling growth in revenue and profits by offering proprietary tests—often unsupported by published clinical studies that demonstrate the utility of these tests.

Too often, these newcomers use aggressive sales and business tactics that to some of lab industry professionals would appear to be clear violations of federal and state laws governing inducement and medical necessity for lab tests. Yet, their game continues year after year because of the lack of timely, vigorous, and tough enforcement by U.S attorneys and state attorneys general against these types of lab companies.

Excessive Overuse Charged

Such enforcement failure is extremely frustrating to the vast majority of clinical laboratory professionals. It also has consequences that are equally corrosive to a nation founded on the rule of law. In the absence of swift and tough enforcement by federal and state prosecutors, the offending labs continue to operate for many years, increasing their revenue and net profits generated from the creative ways they induce referrals from physicians willing to conduct business on those terms.

At the same time, other individuals see that, by using the identical sales tactics, they can also make big profits. So they create new lab companies and enter the market. They use these same tactics with little apparent fear of civil or criminal prosecution.

Over these same two decades, both state and federal prosecutors have generally been slow to act against each new crop of offending lab companies. And even in situations in which such labs found themselves to be targets of state or federal investigations, they continued their business practices for months or years before any final resolution of their cases, thus earning more profit.

Another reason why the owners of such aggressively-operated lab companies have little fear of government prosecutors is that often the final settlement will be for only a small proportion of the total revenue and profit. The government seems willing to resolve these types of cases by accepting just a portion of the total amount of profits that could be attributed to the offending lab company's use of certain sales and marketing practices.

Similarly, the owners and executives of these types of lab companies have watched how the government is reluctant to pursue criminal charges in such investigations. Thus, the owners of these labs believe they face little chance of a criminal indictment and jail time.

Add up these factors, and it is not a surprise that there are constantly new groups of bad actors among the lab companies active in the marketplace.

There is irony in this situation. The majority of laboratory professionals want to comply with the law fully. But the lack of vigorous and effective prosecution against this handful of lab companies by the federal officials charged with enforcing anti-kickback and medical necessity laws is what seems to encourage each new crop of bad players to regularly emerge and game the system for years at a time. TDR

Current Federal Investigation Proved To Be No Bar To Profitable Sale of Laboratory Company

WILL LAST MONTH'S SALE of **BostonHeart Diagnostics** turn out to be an example of a lab company that allegedly used sales and business practices that violated certain federal and state laws to generate amazing rates of growth in revenue and profits, after which its owners were able to cash out their investment without fear of criminal indictments or an expensive civil settlement with the federal government?

BostonHeart Diagnostics of Framingham, Massachusetts, was one of five lab companies identified as being under federal investigation in a story published by *The Wall Street Journal* on September 8. The *WSJ* said that federal prosecutors were investigating allegations that some of the five lab companies: a) induced physicians to refer patients to them using several illegal methods that generated payments to the physicians; b) induced physicians to order medically-unnecessary tests; and, c) did not require patients to pay any money for these lab tests.

Officials of BostonHeart Diagnostics and the other four lab companies denied all allegations and noted that they had stopped the practice and were cooperating with federal investigators.

What is noteworthy about the BostonHeart story and has caught the attention of executives at labs that compete against BostonHeart is the lab company's recent sale to **Eurofins Scientific**, a European company. Announced on December 8, the sale confirmed the fast growth of the company, according to a press release.

The press release stated that BostonHeart was on track to earn revenue of $95 million in 2014, a CAGR of 75% since 2011. Purchase price was $200 million, of which $140 million was paid up front and another $60 million in contingency payments could be paid over time. This represents a purchase price that is 1.4 to 2 times annual revenue, a strong price in this market environment.

Executives at competing labs are questioning whether this sale is an example of how lax enforcement action by federal regulators and federal prosecutors allows a lab company to make big profits, even as competitors believe the lab was using allegedly illegal sales and business practices.

These executives note that **Bain Capital Ventures**, the former owner, is reaping a substantial profit from its ownership of BostonHeart, which was founded in 2007. Moreover, BostonHeart's buyers apparently do not fear the eventual outcome of the federal investigation. In the press release about its acquisition, Eurofins Scientific acknowledged the federal investigation and said that "after due diligence, Eurofins is confident in the accretive value of this transaction for its stockholders."

Rumors About The Case

The prevailing rumor on the street is that federal prosecutors are negotiating settlements with some or all of the labs under investigation and a resolution to the case may be announced at any time. The conventional wisdom among executives at competing labs is that the resulting settlements are not likely to include criminal charges against the lab owners and operators, nor will the resulting civil settlement recoup the majority of money paid by government health programs for the claims being challenged.

As a final note, under Bain's ownership, another lab company it owned was involved in a major federal court case. Bain acquired **Damon Clinical Laboratories** in 1989. It sold that lab company to **Corning Corp.** in 1993. In 1996, Damon settled a federal case by admitting that, from 1988 to 1993, it had submitted false claims to Medicare and other federal programs. Damon paid a criminal fine of $35.3 million plus $83.7 million in restitution to federal health programs.

Phlebotomist Describes Questionable Lab Practices

Source told to use the same 10 diagnosis codes on every test requisition going to one lab company

CEO SUMMARY: While working in the office of a physician who was a client of Health Diagnostic Laboratory, a phlebotomist says he was instructed to write the same 10 diagnoses on every test requisition a doctor sent to HDL, a lab company in Richmond, Virginia. HDL is under federal investigation, according to published reports. The same 10 diagnoses were recorded for every patient even though some of these tests were appropriate only for women, the source said.

BY NOW, MOST CLINICAL LAB EXECUTIVES know that federal prosecutors are investigating five lab companies that provide lab tests to heart patients. This story was front-page news in *The Wall Street Journal* on September 8, 2014.

The lab companies identified by the *WSJ* as subjects of the investigation were:

- **Health Diagnostic Laboratory** in Richmond, Virginia.
- **Atherotech Diagnostics Inc.** in Birmingham, Alabama.
- **Berkeley HeartLab Inc.**, in Los Angeles, California.
- **BostonHeart Diagnostics Corp.** in Framingham, Massachusetts.
- **Singulex Inc.**, in Alameda, California.

Each of the labs denied the allegations and each said it was cooperating with the investigators, the *Journal* reported. *(See TDR, September 22, 2014.)*

In their coverage of the federal probe, *WSJ* reporters John Carreyrou and Tom McGinty described some of the alleged business practices that federal prosecutors were investigating. One example was an arrangement in which a lab company would pay a referring physician as much as $20 for processing and handling lab specimens. *(See sidebar on page 18.)*

But *The Wall Street Journal* story did not identify additional schemes that allegedly violate federal Medicare laws and that one or more of these labs used. THE DARK REPORT has been in communication with a former worker for one of the labs under investigation who has provided information about these and other alleged illegal business practices.

Phlebotomist In Doc's Office

This individual was employed by a temporary services company believed to be reimbursed by one of the lab companies under investigation. He is a phlebotomist who worked within the office of a physician who was a client of Health Diagnostic Laboratory (HDL). The phlebotomist asked that his name be withheld.

What this individual described is a business practice that will astonish experienced pathologists and lab professionals for its brazenness. Also amazing is another fact.

During the several years that this practice is alleged to have been operative, no Medicare or Medicaid official appears to have identified a pattern of identically-coded lab test claims for hundreds or thousands of patients that would easily be recognized as potential fraud and abuse and, no official initiated some type of audit or compliance action in response to such knowledge.

This questionable practice involved recording identical ICD-9 codes on every lab test request form. The phlebotomist says he was instructed by managers to record the same 10 diagnoses for every patient on every requisition for clinical laboratory testing. Statistically, it's highly unlikely—if not impossible—that every patient, male or female, would have these identical diagnoses.

Same 10 Codes Each Claim

"I was a short-term contingent worker covering for a phlebotomist who was absent. I worked in a practice that uses HDL heavily," the phlebotomist said. "I was instructed to write the same 10 billing codes on the lab test request form for every patient who was having the HDL baseline lab test panel done, and to write down a smaller number of codes for patients who were there to provide specimens for follow-up testing. *(See sidebar at right.)*

"These patients were walk-ins for a blood draw," noted the phlebotomist. "They saw no provider, and I generated the lab test requisition. When I questioned managers about the legality of having a phlebotomist provide the billing codes, I was told that everyone who came to the practice was there for the same reason and so it was appropriate to order the same tests for every patient.

"Every patient had exactly the same diagnoses and yet the doctors weren't writing the diagnoses on the lab test requisitions," he stated. "I was instructed to write them even though it was illegal for me as a phlebotomist to determine any patient's diagnosis for entry on a lab test requisition.

Phlebotomist Told to Give Every Patient Same 10 Codes

ONE PHLEBOTOMIST WORKING in an office with a physician who contracted with Health Diagnostic Laboratory was told to use these same 10 ICD-9 codes on test requisitions for every patient, regardless of whether the patient was male or female. A source told THE DARK REPORT the codes were:

627.2/.4	Menopause
627.2	Symptomatic menopausal or female climacteric states
627.4	Symptomatic states associated with artificial menopause
256.39	Suboptimal testosterone
244.9	Thyroid dysfunction
V17.49	Family history of other cardiovascular diseases
780.79	Vitamin B deficiency
259.9	Unspecified endocrine disorder
796.4	Other abnormal clinical findings
272.0	Pure hypercholesterolemia

Essentially, this meant the doctor was putting the identical diagnoses codes on the lab test orders for each of his patients."

This phlebotomist was also asked to engage in additional activity that would be a red flag for any knowledgeable laboratory compliance officer. "As a worker placed by a third-party in the doctor's office, I was instructed to collect specimens not just for HDL, but also for BostonHeart Diagnostics and Singulex," he said. "Plus, I was instructed to use the same 10 ICD-9 codes on lab test requisitions that went to BostonHeart and Singulex."

Other Compliance Issues

These were not the only Medicare compliance issues associated with directions provided to this phlebotomist. He was also instructed to tell patients that they would never pay a dollar of their own money for these lab tests. "I found it equally unsettling when I was instructed to tell every patient

Doctors Were Paid $60 to $100 in "Process Fees" From Three or More Labs for a Single Patient

IN ITS NEWS STORY about the federal investigation of the business practices of four lab companies performing heart testing last September, *The Wall Street Journal* did not provide details about one major type of alleged fraud and abuse.

The *WSJ* did report that at least one lab targeted in the investigation—Health Diagnostic Laboratory—was being investigated for allegedly paying a $20 processing fee for each specimen to the referring physician. Most lab compliance officers would question this fee as an inducement and a violation of Medicare anti-kickback statutes.

In their defense, the labs under investigation state they were paying fair market value for the labor and resources used by a physician to process, package, and transmit the specimen. But no major publicly-traded lab company appears to share that legal opinion or is known to engage in this practice of paying physicians to process lab specimens.

Sources tell THE DARK REPORT that this scheme was conducted at a much larger scale. If the physician collected a specimen from a single patient and sent aliquots of that specimen to other labs, each lab would pay $20 to that doctor. More than one source has said that there were many examples in which a single patient had specimens sent to HDL, BostonHeart Diagnostics, and Singulex. Each lab would pay a separate $20 processing fee. This generated $60 per patient for a doctor willing to participate in this scheme.

Other lab industry sources tell THE DARK REPORT that they know of situations in which some physicians were collecting this $20 processing fee from as many as five labs for specimens from a single patient! This was generating $100 in processing fees per patient at that doctor's office.

The federal Office of the Inspector General issued a Special Fraud Alert on June 25 to address this practice. The lab companies under investigation say they no longer pay such processing fees. However, lab industry insiders say some offering heart testing have amended their arrangements to define physicians as independent paid contractors as a way to continue funneling some type of processing fee to participating physicians.

that if he or she got a bill from an insurance company, that patient should call a sales representative from one of the labs," explained the phlebotomist. "I was instructed to tell patients that they would not get a bill from an insurance company and if they did, this sales rep would take care of it.

"I was instructed to write on every bill: 'If you receive a bill, contact NAME DELETED (a sales rep assigned to this physician's account)' and I would include his phone number," he continued. "I was directed to say this to each patient, 'If you get a bill, you will not have to pay as long as you call this sales rep's number.' As far as I know, the patients never had to pay if a health insurance company sent them bills for these lab tests. At that time, I assumed this sales rep was representing the labs that were getting patient specimens from this doctor's office."

➤Pulling Aside The Curtain

It is not often that lab administrators and pathology get to read a more detailed explanation of alleged non-compliant sales and marketing schemes by an insider. Given the large volume of lab claims, it is also disappointing that, in such cases, federal and state prosecutors seem unable to hit offending labs—and their owners and executives—with tougher enforcement actions, including large financial penalties, loss of the Medicare license, and criminal charges that include prison time. It is for this reason that all forthcoming federal and state settlements will be closely watched by the lab industry. TDR

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

In Vermont, a multi-year effort to create a statewide single-payer health insurance program has failed. On December 17, Governor Peter Shumlin announced that the state would not go forward with its plans to create a health program called **Green Mountain Care**. "The bottom line is that... it became clear that the risk of economic shock is too high at this time to offer a plan," stated Shumlin at a press conference. "In my judgment, the potential economic disruption and risks would be too great to small businesses, working families, and the state's economy."

MORE ON: *Vermont*

Forbes writer Avik Ray noted that "The Shumlin administration, in its white-flag briefing last week, dropped a bombshell. In 2017, under pre-existing law, the state of Vermont expects to collect $1.7 billion in tax revenue. Green Mountain Care would have required an additional $2.6 billion in tax revenue: a 151% increase in state taxes. Fiscally, that's a train wreck."

FRENCH MED LABS FINED FOR FIXING LAB TEST PRICES

Last month, the **Ordre National des Pharmaciens** (ONP), the group in France that oversees pharmacies and clinical laboratories, lost a court review of an anti-trust and anti-competition case. The European Union's General Court upheld a commission's ruling that the association must pay a fine of about US$5.7 million. The ONP was accused of imposing minimum prices on the French market for clinical laboratory tests and hindering the development of groups of laboratories in that market during the period 2004 and 2007. Notably, the commission said that clinical lab test prices in France were often two to three times higher than in other EU member nations.

ADD TO: *Lab Prices*

Estimates are that the European market for clinical laboratory testing services is €25 billion, of which €4.4 billion relate to just the French market. In recent years, as many as 5,000 independent lab companies operated in France. Consolidation is reducing that number.

TRANSITIONS

• **Vermillion Inc.**, of Austin, Texas, announced the appointment of Valerie Palmieri to President and CEO. She had been hired as COO in October 2014. *(See TDR, November 3, 2014.)*

DARK Daily
Clinical Laboratory and Pathology News/Trends

DARK DAILY UPDATE

Have you caught the latest e-briefings from DARK Daily? If so, then you'd know about...

...the FDA's new requirement that providers using Class III (high-risk) medical devices must report adverse patient events involving such devices and include the number on the unique device identification (UDI) label of the device.

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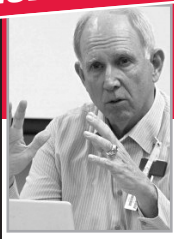
That's all the insider intelligence for this report. Look for the next briefing on Monday, January 26, 2015.

SPECIAL EVENT!



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Colonel Jeffrey D. McCausland (retired)
former Dean of Academics at the Army War College

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Now, more than ever, your lab or pathology group needs strong leaders. To take your skills to the next level, we've arranged two superb learning opportunities at this year's *Executive War College*. We've engaged **Colonel Jeffrey D. McCausland** (retired), former Dean of Academics at the U.S. Army War College. He's developed leaders in the military and business for more than four decades.

You'll hear Col. McCausland address the full *Executive War College* on Wednesday, May 6, on how to use the military's top ten leadership lessons to advance your lab (and help your career)!

The following day, on May 7, he and his team will lead a special six-hour **Executive Leadership Workshop** for those who pre-register. Three modules will address the priority issues facing lab executives today: Leadership in Four Directions; Organization Change and Culture; and, Leading in Crisis. Plan to send your brightest managers who have key roles in your lab's succession plan.

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