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From the Desk of R. Lewis Dark...

THE DARK REPORT

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

Restricted information, see page 3

COMMENTARY & OPINION by...

R. Lewis Dark
Founder & Publisher

Where Are Pathologists When You Need Them?

WHAT'S WRONG WITH THIS PICTURE? National health insurer has exclusive national contract with a single billion-dollar lab company. Billion-dollar lab company creates a business division to manage how physicians order lab tests.

This lab test order system requires physicians to follow the lab test order algorithms established by the national health insurer (and its national contract lab provider), even for routine tests with ordering guidelines already established from such credible bodies as the CDC. This system also restricts (or "guides") these physicians to refer only to "approved labs" and these labs are vetted by the business unit of the national lab and—once in this provider network—these labs will be paid by the business division of their national lab competitor. *(See pages 6 to 11.)*

All of this refers to **UnitedHealthcare** (UHC) and its exclusive national lab provider **Laboratory Corporation of America**, along with LabCorp's **BeaconLBS** subsidiary. UHC is now implementing its laboratory benefit management program pilot in Florida. And to say that physicians in the Sunshine State are unhappy about this development would be an understatement. One Florida physician association wrote a letter to UHC asking that "UHC suspend this test program as a requirement for Florida providers immediately and indefinitely."

As you will read in this issue, Florida physicians question not just the requirement that they order tests through the BeaconLBS system, which some call "burdensome and time-consuming." They also object to the requirement that they obtain a pre-notification number before ordering any of 79 designated tests, many of which are frequently ordered and have well-established clinical guidelines.

This causes me to wonder where pathologists in Florida (and nationally) are on this issue of appropriate lab test utilization. Shouldn't pathology associations be issuing statements that support the role of local laboratories and local pathologists in providing the consultative support that helps local physicians select the right test at the right time for their patients?

Yet, to my knowledge, no pathology or clinical laboratory association has spoken publicly about the obvious ethical and financial issues associated with the attempt by two public stock companies—an insurer and a lab—to have Florida physicians order lab tests under restrictions designed by these companies, while limiting their choice of local labs in a way that competing labs complain is arbitrary and anti-competitive. What might change if patients and the press in Florida were informed about these developments because of press releases and interviews issued by pathologists? TDR

Public Comment Started On FDA LDT Regulations

Pathologists and lab executives have 60 days to comment on draft guidance for regulating LDTs

CEO SUMMARY: On October 3, the FDA published draft guidelines to regulate laboratory-developed tests (LDTs). Pathologists and lab executives now have 120 days to comment on the guidelines. Several prominent national lab associations have expressed concerns about this additional bureaucratic oversight of LDTs. The FDA said that this new layer of regulation will be phased in over 10 years. Per the draft guidance, no LDTs will be granted "grandfathered" status.

REGULATION OF LABORATORY-DEVELOPED TESTS (LDTs) is now one step closer to becoming reality. In recent weeks, the **Food and Drug Administration** took the actions required for it to begin regulating LDTs.

On September 30, the FDA posted two draft documents for LDTs on its website. Days later, on October 3, 2014, the FDA published notices of these two draft documents in the *Federal Register*.

The publication of the draft rules also started a 120-day period for public comment that will end on February 2, 2015. Pathologists, lab directors, and other interested parties have until that date to submit their comments to the FDA.

On its website, the FDA has provided documents with the draft guidance and information on how to submit comments about the draft guidance. (Use this link: *http://tinyurl.com/l8tjuzt*.)

By moving forward with its intention to regulate LDTs, the FDA has stirred considerable controversy within the clinical laboratory testing industry. There are two sectors of the lab industry that will be affected by such regulation.

The first sector involves the overwhelming majority of clinical laboratories that daily perform LDTs that have been in use for decades. These tests have wide acceptance and there are few questions about their accuracy and clinical utility.

The second sector involves those laboratories—ranging from academic center labs and companies offering proprietary LDTs—that have developed a laboratory test and currently offer it to physicians and consumers under the existing LDT exemption.

In the first case, clinical labs offering LDTs that were developed years ago are concerned about having to meet burdensome regulations. In its draft rule, the FDA addresses this issue with a category of LDTs that it calls "low risk."

In the second case, academic center labs, national reference and esoteric labs, and companies with proprietary tests have legitimate concerns about the time, cost, and clinical documentation that will be required by the FDA as part of its proposed process to assess and regulate LDTs that it defines as "moderate risk" or "high risk."

Draft Guidance for Labs

In the draft guidance notices, FDA defined LDTs as "a type of *in vitro* diagnostic test that is designed, manufactured and used within a single laboratory" and that is intended for clinical use.

The framework for LDT regulation is found in the draft document titled, *Draft Guidance for Industry, Food and Drug Administration Staff, and Clinical Laboratories: Framework for Oversight of Laboratory Developed Tests (LDTs).*

The second draft document addresses guidance concerning notification. It is titled: *Draft Guidance for Industry, Food and Drug Administration Staff, and Clinical Laboratories: FDA Notification and Medical Device Reporting for Laboratory Developed Tests (LDTs).*

In the draft guidance, the FDA described how clinical laboratories will notify the agency about the LDTs they manufacture and how labs will use the FDA's medical device reporting requirements.

Low, Medium, & High Risk

In an article for the website *Lexology*, lawyers for the law firm **Jones Day** explained that the FDA proposes applying its risk-based system for regulating medical devices to most LDTs based on whether they are low risk (Class I), moderate risk (Class II), or high risk (Class III).

Any LDTs that the FDA has previously cleared or approved will retain their existing device classifications, wrote Jones Day lawyers Laurie A. Clarke, Colleen M. Heisey, and Brigid C. DeCoursey. "However, FDA's draft framework for regulating LDTs has effectively expanded the system by creating categories of LDTs that would be regulated first because they present the highest risk or be subject to minimal regulation to ensure availability or because they present the lowest level of risk," they added.

The FDA will not immediately implement the entire draft framework. Instead, the FDA outlined multiple steps for applying these regulations. Additionally, the FDA stated that three categories of LDTs will be subject to minimal regulation. They are: LDTs for rare diseases, traditional LDTs, and LDTs for unmet needs.

As described in the draft guidelines, any laboratory that wanted to submit an LDT for approval would need to work through three steps of a five-step process. According to the Jones Day attorneys, in the first step toward approval, most laboratories would need to report adverse events associated with use of the LDT.

Descriptive Information

In the second step, clinical laboratories would need to submit descriptive information about their LDTs. In the third step, the FDA would classify each type of LDT based on any submitted adverse events and descriptive information. For this classification, the FDA will rely on comments from an advisory committee that the FDA will establish.

In the fourth step, the FDA will create priority lists for Class III and Class II devices based on their comparative levels of risk. And in a fifth and final step, clinical labs that have LDTs would be required to comply with the premarket and postmarket requirements that FDA has specified for these devices, the Jones Day lawyers explained.

The FDA would begin regulating the highest-risk LDTs and then rate other LDTs based on the level of risk. After regulating the highest-risk LDTs, it would rate the other LDTs in Class III, then the LDTs in Class II, and then those in Class I, the lawyers wrote.

Labs Must Notify FDA

Pathologists and lab administrators should be aware that their labs will need to notify the FDA about LDTs they manufacture. This will be true for both existing and new LDTs.

The FDA has proposed that laboratories identify and describe their LDTs within six months of publication of the final framework and guidance. To meet this requirement, laboratories must submit notification before the initial clinical use of any LDT introduced at least six months after publication of the final framework and when any LDT's intended use is changed significantly.

In a notice to their clients, attorneys Jane Pine Wood and Rick Cooper of the law firm **McDonald Hopkins** explained that members of the clinical laboratory industry have contrasting views about the FDA's plan to subject many LDTs to a new layer of regulatory requirements over the next 10 years. Some view the draft guidance documents as an essential step to improve patient safety. Others view regulation as a hindrance that will stifle diagnostic innovation and test improvement, they wrote.

FDA Determined To Act

"Despite that fundamental disagreement on the policy's substance, there does seem to be consensus among informed observers that the FDA is determined to take action, that legislative intervention to block the agency faces long odds, and that the agency's final guidance will create a regulatory challenge for labs unrivaled by anything out of Washington since CLIA '88," emphasized Cooper and Wood. TDR

—Joseph Burns

More Federal Regulation Of Labs Is Unwelcome

ACROSS THE CLINICAL LAB INDUSTRY, there is opposition to the FDA's stated intent to regulate laboratory-developed tests (LDTs).

This opposition was first voiced years ago, following statements by FDA officials that the agency intended to regulate LDTs. Several national laboratory associations have expressed their concerns about this new layer of government regulation over clinical laboratories. Among them are the **Association for Molecular Pathology** (AMP) and the **American Clinical Laboratory Association** (ACLA).

"We are deeply concerned by the FDA's intent to add another layer of unnecessary regulatory oversight on laboratory-developed tests already subject to strict and thorough regulation," said Alan Mertz, President of the ACLA. "Laboratories have been regulated for decades by the Centers for Medicare and Medicaid Services (CMS) under the Clinical Laboratory Improvement Amendments (CLIA) and by state law. There simply is no need for an additional layer of duplicative regulation that initiates more questions yet provides few answers."

In a press release issued following the FDA's notice to Congress on July 30 that it would regulate LDTs, AMP President Elaine Lyon, Ph.D., stated, "The CLIA program, in combination with laboratory accreditation programs and professional certification, provides the level of rigor, as well as the flexibility necessary, for ensuring high-quality laboratory testing in the U.S. Over-regulation or inappropriate regulation has the potential to negatively impact patient care and limit the availability of medically necessary laboratory developed procedures."

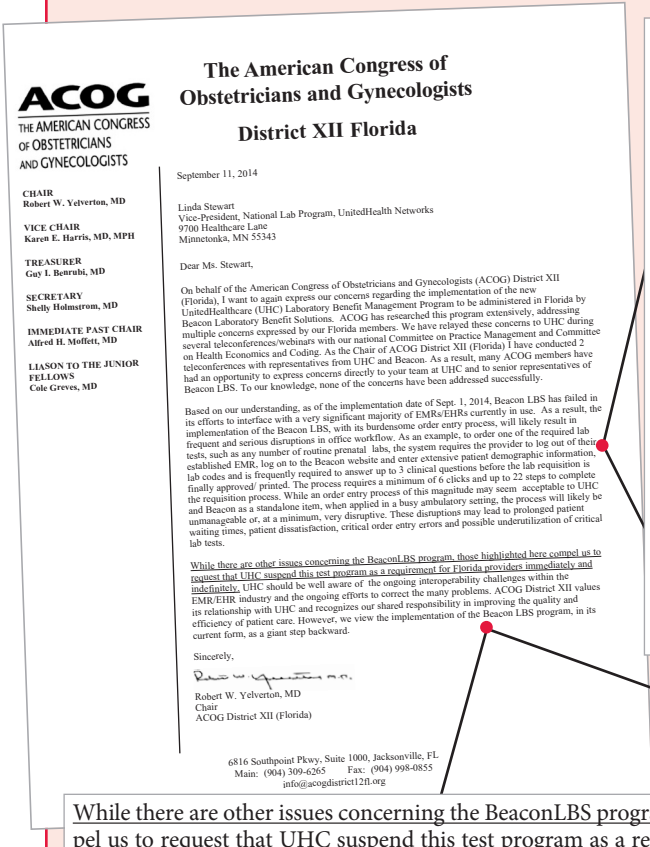
These quotes illustrate why the clinical lab industry has concerns about the FDA's plan to regulate LDTs. It would not be a surprise if some in the lab industry were to lobby Congress for regulatory relief on this issue.

American Congress of Obstetricians and Gynecologists Sends Letter to UnitedHealthcare about Its Concerns with BeaconLBS

JUST WEEKS BEFORE THE OCTOBER 1 IMPLEMENTATION of its laboratory benefit management program, officials at UnitedHealthcare (UHC) received a letter sent by the Florida District of the American Congress of Obstetricians and Gynecologists (ACOG).

On behalf of its member physicians, ACOG requested that "UHC suspend this test program as a requirement for Florida providers immediately and indefinitely." The letter identified serious concerns that its members have about important aspects of the laboratory benefit management program and the BeaconLBS system that physicians are to use to obtain pre-notification or pre-authorization for certain medical laboratory tests.

ACOG's members are concerned that use of the BeaconLBS system "may lead to prolonged patient waiting times and patient dissatisfaction," along with other serious issues.



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The American Congress of Obstetricians and Gynecologists

District XII Florida

September 11, 2014

Linda Stewart
Vice-President, National Lab Program, UnitedHealth Networks
9700 Healthcare Lane
Minnetonka, MN 55343

Dear Ms. Stewart,

On behalf of the American Congress of Obstetricians and Gynecologists (ACOG) District XII (Florida), I want to again express our concerns regarding the implementation of the new UnitedHealthcare (UHC) Laboratory Benefit Management Program to be administered in Florida by Beacon Laboratory Benefit Solutions. ACOG has researched this program extensively, addressing multiple concerns expressed by our Florida members. We have relayed these concerns to UHC during several teleconferences/webinars with our national Committee on Practice Management and Committee on Health Economics and Coding. As the Chair of ACOG District XII (Florida) I have conducted 2 teleconferences with representatives from UHC and Beacon. As a result, many ACOG members have had an opportunity to express concerns directly to your team at UHC and to senior representatives of Beacon LBS. To our knowledge, none of the concerns have been addressed successfully.

Based on our understanding, as of the implementation date of Sept. 1, 2014, Beacon LBS has failed in its efforts to interface with a very significant majority of EMRs/EHRs currently in use. As a result, the implementation of the Beacon LBS, with its burdensome order entry process, will likely result in frequent and serious disruptions in office workflow. As an example, to order one of the required lab tests, such as any number of routine prenatal labs, the system requires the provider to log out of their established EMR, log on to the Beacon website and enter extensive patient demographic information, lab codes and is frequently required to answer up to 3 clinical questions before the lab requisition is finally approved/ printed. The process requires a minimum of 6 clicks and up to 22 steps to complete the requisition process. While an order entry process of this magnitude may seem acceptable to UHC and Beacon as a standalone item, when applied in a busy ambulatory setting, the process will likely be unmanageable or, at a minimum, very disruptive. These disruptions may lead to prolonged patient waiting times, patient dissatisfaction, critical order entry errors and possible underutilization of critical lab tests.

While there are other issues concerning the BeaconLBS program, those highlighted here compel us to request that UHC suspend this test program as a requirement for Florida providers immediately and indefinitely. UHC should be well aware of the ongoing interoperability challenges within the EMR/EHR industry and the ongoing efforts to correct the many problems. ACOG District XII values its relationship with UHC and recognizes our shared responsibility in improving the quality and efficiency of patient care. However, we view the implementation of the Beacon LBS program, in its current form, as a giant step backward.

Sincerely,

Robert W. Yelverton, MD
Chair
ACOG District XII (Florida)

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Florida Ob-Gyns Call for UHC To End BeaconLBS

In letter, ACOG Florida says UHC should suspend program immediately, indefinitely

CEO SUMMARY: In Florida, obstetricians and gynecologists are complaining about the burdensome nature of the new lab test management system introduced by UnitedHealthcare. In addition to calling for an end to the program, some ob-gyns plan not to use the system, a process that could lead UHC to deny payment to clinical labs. In a letter to UHC, Florida Ob-Gyns expressed their concerns that use of the BeaconLBS system "may lead to prolonged patient waiting times and patient dissatisfaction."

OBSTETRICIANS AND GYNECOLOGISTS in Florida are calling on **UnitedHealthcare** to discontinue its new laboratory benefit management service immediately.

If the lab program, accessed through **Beacon Laboratory Benefit Solutions** in Florida, is not ended, there is concern that physicians in Florida may not use the service because it is onerous, burdensome, and disruptive to workflow, stated Robert W. Yelverton, M.D., Chair of District XII (Florida) for the **American Congress of Obstetricians and Gynecologists**.

In a letter sent September 11 to Linda Stewart, Vice President of UHC's national lab program *(see letter in sidebar on page 6)*, Yelverton outlined the research ACOG members have done and the concerns they have about how UHC's laboratory benefit management program will disrupt physicians' office workflow and affect patient care. ACOG members have expressed those concerns to UHC, he said, but the health insurer has failed to address their concerns. BeaconLBS is a subsidiary of **Laboratory Corporation of America**.

"While there are other issues concerning the BeaconLBS program, those highlighted here compel us to request that UHC suspend this test program as a requirement for Florida providers immediately and indefinitely," Yelverton wrote. "ACOG District XII values its relationship with UHC and recognizes our shared responsibility in improving the quality and efficiency of patient care. However, we view the implementation of the BeaconLBS program, in its current form, as a giant step backward."

Labs Might Not Get Paid

On October 1, UHC made the program available to physicians in Florida but it rescheduled the date when it would stop paying clinical labs for running tests each time physicians fail to follow the steps required in the BeaconLBS program. In September, UHC said it would move the date back for when it starts to base payment decisions on whether physicians comply with the requirements in BeaconLBS until January 1. *(See TDR, September 2, 2014.)*

The system so disrupts workflow that some physicians may not use the

BeaconLBS, Yelverton said. By not using the system, physicians suspect that UHC or BeaconLBS may not pay clinical labs for the tests they order. Instead, the labs may bill UHC's patients, a step physicians suspect will cause patients to complain to UHC. UHC forbids in-network labs from balance-billing patients, however.

"BeaconLBS is much more than a headache for physicians," Yelverton commented. "It's a migraine," he said.

Ob-gyns are the second physician specialty to complain about the burdens of the new BeaconLBS system. In August, some members of the **Florida Association of Family Physicians** said they will discontinue their association with UHC rather than use the BeaconLBS system to order lab tests. *(See TDR, August 15, 2014.)*

On January 1, United will require physicians serving its members in commercial HMOs in Florida to use the BeaconLBS system for ordering any of about 81 clinical laboratory tests. For two of those tests (BRCA1 and BRCA2), BeaconLBS requires physicians to get prior approval before it will approve the test for payment. For the remaining 79 tests, physicians must use the BeaconLBS system to notify it in advance that they are ordering one or more of these tests.

Should a physician fail to get prior approval or give BeaconLBS what UHC calls "advance notification," neither Beacon nor United will pay the clinical lab that runs that test.

Expert in EHRs, Order Entry

A former chief medical officer for one of the largest ob-gyn groups in Florida, Yelverton is an expert in electronic health record (EHR) systems and computerized physician order entry. In retirement, as Chair of ACOG's District XII (Florida), he does not see patients.

For several months, Yelverton has talked with ob-gyns who tried to learn the BeaconLBS system. He has explained their frustrations and their concerns about disruptions in patient care to officials from UHC and BeaconLBS. Also, he has had representatives from UHC and BeaconLBS explain the steps needed to order lab tests with the BeaconLBS system. As a result, he is thoroughly familiar with how it works, he said.

Impact On Patients

"Our main concern with BeaconLBS is the functionality of the system and how it affects our patients," he noted. "The order entry process is very burdensome because it takes us out of our EMR system that we use to order tests and get results bidirectionally. You have to do the BeaconLBS system separately, and that's not the way it goes when a physician's office works with any other payer or any other lab.

"To order one of the 81 lab tests, you have to get out of your EMR system and enter the online Beacon system," stated Yelverton. "Then, it takes what we estimate to be a minimum of six clicks to order a test. But then, if you have to register a new patient, you may need as many as 22 steps to enroll that patient and order the tests on the BeaconLBS list of lab tests.

"That's our major objection," continued Yelverton. "But also, BeaconLBS has not developed interfaces with any of the major EHR systems and even when it does, it's not clear the interfaces will resolve the workflow problems the BeaconLBS system creates.

"From talking with BeaconLBS representatives on numerous occasions, the way I understand it is the interface activity will be capable only of taking the patient's name and demographic information," he noted. "If that's the case, then the [EHR] interfaces they're developing will not relieve the burdensome nature of the system."

Last month, in a letter UHC wrote to providers, it said it had developed interfaces with two EHR systems: **Emdeon** and **Liaison Technologies**. The letter also

Florida Doctors Question Requirement by BeaconLBS to Obtain Pre-Notification for Common Routine Tests

WHY ARE PHYSICIANS REQUIRED to get approval for routine screening tests? That's a question that puzzles obstetricians and gynecologists, stated Robert W. Yelverton, M.D., Chair of the American Congress of Obstetricians and Gynecologists District XII (Florida).

Starting January 1, UnitedHealthcare (UHC) plans to require physicians to pre-notify it or to obtain pre-authorization each time they order any of 81 clinical laboratory tests as a requirement of the UHC laboratory benefit management program. The list includes many tests that are: a) important and routine; and, b) recommended for a substantial number of the patients an ob-gyn would see every day, Yelverton said.

"If a test is routine and if the federal **Centers for Disease Control and Prevention** recommends such tests, why is advance notification required by UHC?" asked Yelverton. Perhaps notification is required to limit overutilization or to deny payment, he suggested.

"For example, UHC now requires a physician to get approval from BeaconLBS to order the routine screening test for diabetes—yet every pregnant patient has to have that test as part of routine prenatal care," he said. "That's just one of several prenatal tests that physicians in a busy office regularly order and now we are required to give advance notification to UHC every time that we order these tests.

Using Beacon For Each Pap

"This is also true of the Pap test," continued Yelverton. "The physician must go through the BeaconLBS process for each Pap test ordered, and ob-gyns order Pap tests on every patient at least once every three years.

"To require an ob-gyn to go through the advance notification for every Pap test makes no sense at all," he stated. "We must now do the same for all prenatal lab tests. This includes such routine basic tests as blood type and Rhesus (Rh) test. Getting approval for every Pap test and every prenatal test simply doesn't make sense."

To this point, however, UHC has not provided responses to requests asking why routine lab tests are subject to pre-notification. Nor has UHC provided data that would demonstrate how much inappropriate utilization actually happens when physicians order any of the 81 tests listed by UHC that require pre-notification or pre-authorization.

"UHC is just one payer and that one payer is implementing a burdensome system that takes us out of our normal workflow and impacts patients," noted Yelverton. "Don't forget, over the past few years, physicians have worked extremely hard to make that workflow as seamless as possible for the women we serve.

Expert In EHR Systems

"During the day, as an ob-gyn works through each patient, he or she wants to stay on time and keep up with entering data into the electronic health record," explained Yelverton. "Ob-gyns don't want anything to interrupt that workflow."

In the Tampa Bay area, UHC has about 22% of the managed care market, he said. "This means that, in Tampa, a physician could see his or her workflow disrupted on about every fifth patient requiring lab tests," noted Yelverton. "UHC patients will have a completely different workflow from every other patient.

"UnitedHealthcare says it aims to improve efficiency and quality. But this new lab test ordering process is not improving our efficiency. Whether it improves quality is doubtful," Yelverton concluded.

UnitedHealthcare provided responses to questions asked by THE DARK REPORT. These responses are published on page 11.

noted that BeaconLBS said it plans to integrate soon with two other EHRs, **Aprima** and **eClinicalWorks**.

Few Interfaces With EHRs

"Those two systems, Emdeon and Liaison, are minor players and may represent only about 5% percent of the physicians in Florida," he added. "The fact that they haven't worked out these interfaces yet tells me a lot about the low level of software capability that BeaconLBS has. How the interfaces work is a major concern to physicians.

"If UHC and BeaconLBS do not support a thorough bidirectional interface, that may mean physicians will need to continually step out of their EHR systems and go to the BeaconLBS website to enter the required information for a lab test order," noted Yelverton. "Physicians with a bilateral interface, such as exists with the LabCorp test order system, may not have to enter that lab test order twice.

"At the same time, the requirement will remain for physicians to complete the prior authorization and advance notifications processes for those 81 or so tests that require that information," he added. "As many as three questions must be answered to get the BeaconLBS system to approve the lab test order in some situations.

Answering Clinical Questions

"The BeaconLBS people have said the ordering process is not burdensome and that we could train our staff to answer these clinical questions," stated Yelverton. "But when a physician looks at the questions the system asks in an attempt to justify the lab test order, these are not the kinds of questions that a medical assistant can answer with any clinical accuracy.

"The physician must stop what he or she is doing to answer those questions in order to obtain the prior notification or prior authorization," said Yelverton. "That's for each of those 81 tests, and, frankly, some of the tests listed by UHC are fairly common laboratory tests, such as the prenatal tests." TDR

—Joseph Burns

Contact Robert Yelverton, M.D., at ACOG District XII (Florida) at 904-309-6265.

Are Labs and Pathologists 'Asleep at the Switch?'

IT SEEMS THAT ANYONE WHO UNDERSTANDS medical practice and clinical laboratory testing has legitimate questions about the design and impact of the laboratory benefit management program introduced in Florida last month by UnitedHealthcare.

Several times in recent months, THE DARK REPORT has presented information about the concerns, questions, and objections raised by physicians and their specialty medical associations in Florida concerning aspects of the UHC and BeaconLBs lab program. On one hand, these physicians have legitimate gripes about the disruption to well-established workflow they must endure to meet the pre-notification and pre-authorization requirements of UHC—not to mention the poor design of the BeaconLBS system.

On the other hand, these physicians have equally legitimate questions about the true need for an insurer to question their clinical decisions about which test to order for their patients—particularly since many of the tests on the UHC list are common, have well-established clinical guidelines, and are essential in practicing evidence-based medicine.

So where are pathologists and their specialty colleges and associations in aiding their clinical colleagues in this matter? Pathologists are the experts in appropriate utilization of lab tests. Thus, it would seem that their lab associations would at least make some well-timed and public statements in support of the concerns that Florida physicians have about the requirements of the BeaconLBS program. After all, pathologists and physicians do share the common goal of improving patient outcomes by the proper utilization of the right test at the right time.

Managed Care Update

UnitedHealth Answers Queries about Function of BeaconLBS

As of January 1, physicians in Florida are required to obtain pre-notification of selected laboratory tests

ANSWERS TO QUESTIONS SUBMITTED to **UnitedHealthcare** about the insurer's laboratory benefit management program now coming into operation in Florida were provided by the company's public communication officer. These answers are reproduced below:

Q: *Will BeaconLBS process the claims that come through the BeaconLBS system or will UHC process those claims once they are approved by BeaconLBS?*

A: UnitedHealthcare will send the in scope claims to BeaconLBS to apply any edits for Labs Of Choice, then UnitedHealthcare will apply benefit claim adjudication. BeaconLBS does not process the claims. They make any appropriate edits, then UnitedHealthcare finishes processing the claims.

Q: *Will BeaconLBS pay the claims or will UHC pay the claims?*

A: UnitedHealthcare will process all claims and provide remittance advice to all providers. For payment, UHC will pay UnitedHealthcare network and non-network providers. BeaconLBS will pay its Laboratory of Choice providers. Beacon processes payments for Labs of Choice, and we process payments for all others.

Q: *Does "claims impact" mean doctors might not get paid?*

A: As of January 1, 2015, claims are subject to denial based upon the Lab Benefit Management policies and protocols. The ordering physician claims are not subject to denial. The additional time we are offering providers is so they can become familiar with the process and does not mean they will not get paid.

Q: *Doctors have communicated with their medical associations about getting compensated for the additional time required to use the BeaconLBS system for ordering lab tests. Is there any plan by UHC to pay doctors for the time needed to use the system?*

A: The provider will not be reimbursed for time spent using the BeaconLBS. BeaconLBS is working with those offices that have not started using Physician Decision support to understand and resolve issues, including increasing integration with EMRs by January 1, 2015.

Q: *Some physicians have publicly stated that they plan to stop working with UnitedHealthcare because they find the BeaconLBS system to be time-consuming and onerous. Has UHC or BeaconLBS heard from any physicians who say they want to drop UHC? And does anyone at UHC want to comment on this development or on the complaints we heard that doctors find BeaconLBS to be time-consuming and onerous?*

A: UnitedHealthcare continues to work with any physicians who have questions or concerns about the program.

Clients and regular readers of THE DARK REPORT who have questions or information about UnitedHealthcare's laboratory benefit management program are invited to contact our editor in confidence. TDR

Cigna Sues HDL, Alleges Unlawful Fee Scheme

➤Lawsuit accuses Health Diagnostic Laboratory of defrauding Cigna of as much as $84 million

➤➤CEO SUMMARY: In court papers, Cigna alleged that HDL misrepresented patients' responsibilities by promising not to collect co-payments, co-insurance, or deductibles. Also, HDL promised not to seek reimbursement from patients for any portion of its bills that the health insurer did not cover, the court documents show. HDL misleadingly billed the health insurer at exorbitant rates, the complaint said. HDL also urged physicians and other providers to order unnecessary tests, the court papers show.

IN RICHMOND, VIRGINIA, a troubled **Health Diagnostic Laboratory** was just hit with an $84 million lawsuit by **Cigna** for alleged schemes to defraud the health insurer.

The lawsuit was filed in the U.S. District Court in Connecticut by **Connecticut General Life Insurance Company** and its affiliated health insurer, **Cigna Health and Life Insurance Company**. This action is the second in as many months involving HDL. In September, *The Wall Street Journal* reported that federal officials were investigating HDL for violations of the anti-kickback law.

➤Out-of-Network Rates

In its complaint against HDL, Cigna explained how HDL developed the fee-forgiving scheme. HDL was not in the Cigna network, which would mean that when a patient used any out-of-network lab, the patient normally would bear a portion of the cost of the lab testing. Such costs would come in the form of co-payment, co-insurance or deductibles, which Cigna used as a disincentive to patients to use out-of-network providers.

In its court filing, Cigna alleges that HDL undermined this disincentive through its fraudulent fee-forgiving scheme by misrepresenting patients' responsibilities. HDL did this by promising physicians and patients that it would not try to collect co-payments, co-insurance, or deductibles, the court documents show. HDL also promised not to seek reimbursement for any other portion of its bill that the plan did not cover, the documents show.

"HDL then misleadingly bills the plans themselves at exorbitant and unjustified 'phantom' rates—rates that misrepresent what HDL actually intended to collect," the complaint said.

The Cigna lawsuit included several examples to illustrate HDL's scheme. Court records show that, for one patient, HDL submitted a bill for $2,979 to Cigna. Based on this bill, the patient should have paid $649.40, but HDL charged the patient nothing.

Such fee forgiving is a form of medical billing fraud, according to a fraud alert from the Office of Inspector General of

In Court Documents, Health Insurer Describes A "Fraudulent Fee-Forgiving Scheme" by HDL

IN A LEGAL COMPLAINT FILED OCTOBER 15, Cigna, a health insurer, alleged that Health Diagnostic Laboratory had "a business model designed to game the healthcare system by submitting grossly inflated, phantom 'charges' to Cigna that do not reflect the actual amount HDL bills patients. The outline of HDL's scheme is simple."

HDL represented to its patients that they would not need to pay anything for clinical laboratory tests that HDL performs on their behalf, the court documents showed.

"HDL misrepresents to members of Cigna-administered plans that they may receive services from HDL without incurring any financial obligation, and that Cigna will be responsible for the cost of services delivered under these conditions. After luring plan members in this way, HDL submits charges to Cigna at astronomical rates, which are much higher than the 'normal charge' HDL actually intends to accept as payment in full. Cigna then relies on the representations in HDL's bills, by paying more for HDL's services than it is obligated to pay under the relevant plans," the complaint explained.

In addition, HDL does not typically join major managed care networks, choosing instead to remain out-of-network.

"HDL entices members to use its out-of-network services by expressly promising (i) not to collect any part of the members' cost-sharing responsibility, and (ii) not to seek to recover any other portion of its 'charges' for which it fails to obtain reimbursement from the plan," the complaint said.

Included in the complaint is a brochure from HDL that explained to patients that they will not need to pay for lab testing. The brochure says the following:

"
- HDL, Inc. will accept the amount your insurance company allows for each diagnostic.
- In other words, your 'out-of-pocket' cost is ZERO for initial and follow-up testing.
- HDL, Inc. takes all the risk if your insurance company does not pay for the ordered diagnostics."

the federal **Department of Health and Human Services** and advisory opinions from the **American Medical Association**, the complaint said.

Deceive Health Benefit Plans

"The effect of HDL's scheme is to deceive health benefit plans into paying far more for services than the plans are obligated to pay. But misleading plan members is also essential to the scheme. By convincing patients that HDL offers services at little or no cost (when, in fact, HDL was artificially increasing the cost of healthcare to Cigna and its clients), HDL increases the volume of its business and, at the same time, increases the harm to Cigna and the plans it serves," the court documents said.

As a result of a special investigation of HDL, Cigna confirmed the billing practices were fraudulent and then reduced or denied claim payments that HDL submitted, the complaint explained.

In addition to the fee-forgiving scheme, Cigna alleged that HDL suggested that physicians order medically unnecessary tests. HDL encouraged physicians and other healthcare providers to order tests, regardless of whether the provider believed the tests were needed to diagnose or treat the patient, the complaint said.

"HDL assures the providers that the patient will not complain if the patient's plan does not cover these tests because, pursuant to the fee-forgiving practices described above, HDL never bills its patients anything for the services at issue," the document showed.

Many of HDL's business practices described in the Cigna lawsuit are familiar

to lab executives who have competed against HDL in the years since its founding in 2008. These executives believed that the fees of as much as $20 per patient that HDL was paying to physicians for processing specimens were inducements and violations of federal and state antikickback laws. But in the absence of effective federal or state enforcement of these laws, laboratory companies competing against HDL had no way to counter such business practices.

High-Flying Lab Performer

HDL was the high-flying laboratory performer in Richmond and got plenty of attention for its phenomenal revenue growth. As reported by *The Wall Street Journal* in September, HDL's revenue in 2013 topped $383 million.

Little is known about what caused federal prosecutors to launch their investigation of Health Diagnostic Labs and a handful of similar labs. In that federal case, HDL and four other labs (**Atherotech Diagnostics Inc.** in Birmingham, Alabama; **Berkeley HeartLab Inc.**, in Los Angeles, California; **Boston Heart Diagnostics Corp.** in Framingham, Massachusetts; and **Singulex Inc.**, in Alameda, California) allegedly were being investigated for paying physicians to refer patient's blood samples to the labs, the *Journal* reported. *(See TDR, September 22, 2014.)*

Feds Investigating Kickbacks

Federal investigators were looking into whether money HDL and the other labs paid to doctors for patients' blood samples were kickbacks designed to induce physicians to order tests from these labs, the newspaper said. All of the labs denied the allegations and said they were cooperating with the investigators, according to the *Journal*.

Following news of the federal investigation, HDL President and CEO Tonya Mallory resigned September 23 from both positions. The company said she was stepping down for personal reasons. Mallory would remain on the board of directors and advise the new President and CEO, Joseph P. McConnell, Ph.D., a co-founder of HDL, who succeeded her in both roles.

McConnell had been HDL's Chief Laboratory Officer. Before co-founding HDL, McConnell was the director of cardiovascular laboratory medicine and chair of the clinical chemistry fellowship program at the **Mayo Clinic** in Rochester, Minnesota.

There is another aspect to this case that will be closely watched throughout the lab industry. In both the Cigna lawsuit against HDL and the federal investigation into HDL's business practices, clinical lab professionals wonder whether the physicians who accepted the various forms of alleged illegal remuneration will also face investigation and prosecution.

After all, a lab that offers illegal payments and bribes can only go forward if enough doctors are willing to accept these payments. It takes both parties to make the scheme work. Yet, too often, federal and state prosecutors will only pursue the laboratory and will not bring charges against individual doctors who accepted payments in exchange for lab test referrals.

Federal Prosecution

One important exception to this situation was last year's federal prosecution of **Biodiagnostic Laboratory Services** of Parsipanny, New Jersey. Not only did the owners and many managers of the lab plead guilty to criminal charges, but at least 19 physicians also pled guilty for their role in the scheme.

Thus, many in the clinical laboratory profession approve of the federal investigation of HDL and the decision by a private payer like Cigna to file a lawsuit against Health Diagnostic Laboratory. Step one is bringing these actions against the offenders. Step two is to win these cases and establish a useful precedent. TDR

—Joseph Burns

Dark Index

LabCorp, Quest Diagnostics Report Improved Q-3 Revenue

Both lab companies attributed increased sales and greater specimen volume to acquisitions

THIRD QUARTER EARNINGS at each of the nation's two biggest public lab companies showed improved growth in revenue and specimen volume, as compared to recent years.

Laboratory Corporation of America was first to release its financial report for the quarter ending September 30, 2014. The company said that revenue totaled $1.55 billion, compared to $1.46 billion for Q3 in 2013. This was an increase of 6.1%. Specimen volume increased by 6.9% and was attributed to organic growth.

For the first nine months of 2014, LabCorp said its revenue was up 2.9% at $4.0 billion, compared to $4.37 billion during the first nine months of 2013. Specimen volume increased by 5%. LabCorp's revenue per requisition for Q3 declined by 0.7% and by 2% for the full nine months of 2014.

Days later, **Quest Diagnostics Incorporated** issued its Q3 earnings report. It said Q3 revenue totaled $1.9 billion, an increase of 6.5% over the Q3 in 2013, mostly due to acquisitions. Specimen volume grew by 7.1% for Q3.

Quest Reports Revenue

For the first nine months of 2014, Quest Diagnostics reported revenue of $5.6 billion. This was an increase of 3.0% compared to the prior year. In its Q3 earnings press release, the company did not provide data on specimen volume and price changes for the full nine months of 2014.

During the respective conference calls with financial analysts, executives at both lab companies discussed issues of importance to all laboratories. One subject that came up early in both conference calls was regulation of laboratory-developed tests (LDTs) by the **Food and Drug Administration**.

LabCorp CEO Dave King responded to an analyst's question by saying, "My perspective on FDA regulation of LDTs is quite clear and I've been pretty vocal about it. Diagnostic testing is not a device, it's a medical service.

No Authority To Regulate

"The FDA, in our view, does not have the authority to regulate LDTs as medical devices," he continued. "They don't have the statutory authority to do that because medical tests are not devices.

"...the [FDA's] attempt to make this kind of regulatory change through a guidance document—which on its face says that it's not binding on the FDA and only reflects their current views—and yet... this document lays out a 10-year regulatory plan with registration requirements and penalties for those who don't register," explained King. "To me, this just incomprehensible.

"My perspective is this is one of the biggest land grab attempts in the history of regulation," he emphasized. "And from my perspective, we intend to vigorously oppose it.

"...Furthermore, there's been no study of the economic impact on our industry, on patients or on the practice of medicine related to this because FDA has not fol-

lowed the proper administrative procedure for doing what it's trying to do," said King. "So I think you can tell that I feel very, very strongly about this, and my perspective is that we, as an industry, need to oppose this attempt at regulation as strongly as we possibly can."

Also Opposed To FDA's Plan

The CEO of Quest Diagnostics, Dennis Rusckowski, was equally emphatic about opposition to the FDA's plans to regulate LDTs. On this point, Rusckowski stated "We continue to work closely with our trade association [ACLA] on another important issue. And that is to oppose the FDA's proposal to regulate laboratory-developed tests, referred to as LDTs. We strongly believe that unnecessary and duplicative regulation could delay patient access to life saving treatments and compromise America's leadership in diagnostic discovery."

During both conference calls, the executives at each lab company emphasized the success of their respective cost-cutting initiatives. In particular, Quest CEO Rusckowski told analysts that his company was delivering on its goal of reducing annual costs by $500 million. He projected that the lab company would deliver $700 million of savings by the end of 2014 and would announce a plan to achieve $1 billion in annual savings at an upcoming investor conference.

Autonomous Robots

LabCorp called attention to the use of Propel robots to improve operational effeciency. These Propel robotic systems are in place in the company's Burlington and Tampa lab facilities. The next lab scheduled to get these robotic systems is in Dublin, Ohio.

Another subject of interest to all labs was discussed on each conference call. Both lab companies reported that they are participating in discussions with CMS on how the lab price market survey will be formulated and conducted. TDR

LabCorp Tells Analysts About BeaconLBS

BECAUSE OF ITS BUSINESS RELATIONSHIP WITH UnitedHealthcare (UHC), Laboratory Corporation of America has been able to position its **BeaconLBS** business as a lab test utilization management tool.

UHC's laboratory benefit management program is conducting a pilot program in Florida that incorporates BeaconLBS. *(See pages 7-11 in this issue.)* LabCorp CEO David King discussed BeaconLBS during the third quarter conference call. His comments are presented below:

As discussed on our last earnings call, we invested in BeaconLBS in 2011 because we understood that providers need assistance in selecting the right test for their patients and payers need help at appropriately managing the utilization of laboratory testing. After extensive market analysis and an enormous amount of hard work, we invented a tool that helps physicians choose the right test at the right time and helps payers improve quality of care and thoughtfully address concerns about unit cost and trend. UnitedHealthcare launched the innovative Laboratory Benefit Management Program with BeaconLBS in Florida on October 1, and we are pleased with the rollout thus far.

...I think it's too early to draw any conclusions about more lab tests or fewer lab tests from the population of users of BeaconLBS ...the point is, BeaconLBS is really less about overutilization/underutilization than it is about choosing the right test for the patient at the right time based on a Q&A that's presented to the physician. I don't think we're talking about dramatic decreases in volume of laboratory testing as a result of trying to manage cost and trend. I think what we're talking about is... better use of lab testing for diagnostics, better use of the tools to get at the disease state, and better use of lab testing in support of precision medicine and personalized care.

Alberta Picks Sonic Health For $3 Billion Lab Contract

Other respondents to the lab test RFP were DynaLifeDx, Quest Diagnostics, and Mayo Clinic

CEO SUMMARY: For more than a year, Alberta's C$3 billion RFP to develop an integrated laboratory testing service for Edmonton and surrounding regions has been the focus of intense interest. On October 17, health officials announced that Sonic Healthcare Limited was the preferred proponent. The two parties will now enter into negotiations to finalize an agreement. Several hurdles need to be overcome before a deal is signed and construction begins on a new medical lab facility in Edmonton.

At $3 BILLION, it's the world's biggest RFP for clinical lab testing services and, based on the October 17 announcement by the **Alberta Health Service** (AHS), **Sonic Healthcare Limited** will be in the driver's seat for the next step in the RFP process.

At stake is a 15-year lab testing contract that covers Edmonton and the central and northern regions of Alberta. It involves 27 million tests per year and will pay C$200 million per year to the winning lab company. The process was launched in late 2013. *(See TDR, September 30, 2013.)*

In April, Edmonton newspapers reported that three commercial laboratory companies had responded to the RFP, along with **Mayo Clinic**. The lab companies were **DynaLifeDx Laboratory Services**, **Quest Diagnostics Incorporated**, and Sonic Healthcare.

DynaLifeDx holds the existing contract with AHS for lab testing in Edmonton. It is a joint venture between **Dynacare, Inc.** (a division of **Laboratory Corporation of America**) and **LifeLabs Medical Laboratory Services** of Toronto, Ontario.

Mayo Clinic's proposal to AHS was for a different management and consulting arrangement involving lab testing services. For that reason, AHS officials decided to defer any decision on Mayo's proposal until the established request-for-proposal process is completed.

Distinctive Aspects To RFP

There are several interesting aspects to this RFP for lab testing services. First, it is a rare example of a government health program willing to pursue full integration of clinical laboratory and anatomic pathology services in a large metropolitan area by contracting with a for-profit lab company.

Second, it is equally rare for any government health program to issue a sole-source lab testing contract for a period of 15 years. It is a sign that AHS sees value in selecting a compatible laboratory provider for the long term. Further, it is believed that the RFP includes an option for both parties to renew the contract for an additional period of years.

Third, this may be the first time that the world's three largest publicly-traded laboratory companies have gone head-to-head for such an exclusive, government-issued lab testing contract. Because of that fact, after the final decision about awarding the contract is made, there will be keen interest among investors to learn what factors swung the decision to Sonic versus DynaLifeDx (LabCorp) and Quest Diagnostics.

Unified Regional Lab Service

Fourth, THE DARK REPORT believes this is the most extensive effort to create a single, unified regional lab testing service by any government health program in the world. Population of the Edmonton metropolitan area is about 1.2 million and as many as 600,000 people live in the surrounding regions to be served by the proposed new lab testing service.

Should AHS and its selected lab partner successfully integrate lab testing services as planned, this may become a template for health systems in other countries to emulate. However, the scale of the challenge is not to be underestimated.

AHS officials have stated that the goal is to create a modern central laboratory in Edmonton that not only does the routine and reference testing for inpatient, outpatient, and ambulatory settings, but also supports the academic mission of the **Edmonton University Health Centre** and the **University of Alberta** in Edmonton, including medical training programs, research and development, clinical trials, and esoteric testing.

Bringing Tests To Alberta

AHS CEO Vicki Kaminski addressed exactly this point during a press conference. She was quoted by *CTV News* as saying, "We looked at things like cost and quality and the ability to do tests other than what's currently being done. We do send a number of tests outside of Alberta and we'd like to get those tests done back in Alberta."

Pathologists and lab administrators in the United States should take note of this statement. The use of reference and esoteric testing labs is much more extensive in the United States than in Canada. This is probably one reason why AHS wants to select a laboratory partner that is capable of expanding and managing the menu of new and future esoteric tests performed within Alberta that are needed to provide appropriate care to patients in the province.

AHS already operates an integrated lab testing service in southern Alberta. **Calgary Laboratory Services** is wholly-owned by AHS and serves the academic center, hospitals, and outreach providers in the city and surrounding regions. Thus, the lab testing business model proposed for Edmonton has been developed to be consistent with this experience and the lessons learned.

So why would AHS bring in an outside laboratory partner if it already has a working, integrated laboratory service in the southern region of the province? One reason could be to access the capital that outside parties could bring to this project.

Capital In Short Supply?

Assuming that the demand for capital within the AHS strips the available supply of money, it could be a wise strategy to engage outside parties to contribute the capital needed for the AHS to create a state-of-the-art lab and pathology testing service for almost 2 million people.

That could explain the 15-year term of the proposed agreement. It would allow the private lab company and any affiliated enterprises to fund the modern lab test infrastructure and earn an acceptable return on investment. Meanwhile, the physicians and people of Alberta get a top-flight, modern lab testing service that might just turn out to be the envy of people living in other provinces of Canada.

For all these reasons, Alberta's lab contract strategy may provide a road map that government health programs in other countries could decide to study and copy. TDR

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

In response to the Ebola outbreak, the **Food and Drug Administration** issued an emergency authorization for the use of two rapid tests to detect Ebola. The tests are manufactured by **BioFire Defense LLC**, a division of **BioMerieux**. The BioFire Defense FilmArray NGDS BT-E Assay is authorized for use by laboratories designated by the **Department of Defense**. The BioFire Defense FilmArray Biothreat-E exam, a PCR test, is authorized for use in hospitals and commercial laboratories that perform moderate complexity tests and high complexity tests.

MORE ON: *Ebola Test*

News reports say that these rapid tests can produce an answer in two hours. The BioFire test can analyze human samples from the bloodstream, respiratory system, or gastrointestinal tract. A BioFire executive told *Reuters* that "More than 300 U.S. hospitals have BioFire lab equipment... including **Emory Hospital** and **Bellevue Hospital**," two hospitals that have treated Ebola patients here in the United States.

QUEST DIAGNOSTICS OPENS NEW LAB IN MARLBOROUGH

On October 2, officials from **Quest Diagnostics Incorporated** officially opened the company's new lab facility in Marlborough, Massachusetts. This is a 200,000 square foot lab and is expected to employ 1,350 people when fully operational. Quest Diagnostics has said that it will consolidate lab testing from six different facilities into the Marlborough lab. **Siemens Diagnostics** and **Inpeco** were selected to provide laboratory automation. When the main automation line is fully installed, the companies say it will be 200 meters long. Quest Diagnostics will also employ as many as a "dozen physicians and medical faculty employed by... the U**niversity of Massachusetts Medical School** to provide scientific leadership for several facets of laboratory testing" at the Marlborough lab.

TRANSITIONS

• **Vermillion, Inc.,** of Austin, Texas, announced the appointment of Valerie Palmieri to the position of Chief Operating Officer. Previous executive positions for Palmieri include **LifeCycle Laboratories, LLC**, **DiagnoCure U.S.**, and **Dianon Systems**.

• **Devita Labs**, based in Deland, Florida, named Loren L. Holland, M.D., as Chief Laboratory Officer. Holland was formerly a medical director at Quest Diagnostics, **PathGroup**, and **University of Colorado Hospital**.

That's all the insider intelligence for this report. Look for the next briefing on Monday, November 24, 2014.