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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

Prediction of ICD-10 as Negative for Labs Comes True

IMPLEMENTATION OF ICD-10 DIAGNOSIS CODES in the United States happened on Oct. 1, 2015. At that time, a national laboratory association predicted that use of ICD-10 codes would cause Medicare Administrative Contractors (MACs) to pay labs less often and with lower reimbursement.

THE DARK REPORT agreed with this prediction and published the warnings of the **American Clinical Laboratory Association** in our June 22, 2015, issue. Now, that prediction has come true, in a slightly different way. Many health plans today use the richer data generated by use of the ICD-10 codes to deny lab test claims.

As you will read on pages 3-5, lab billing experts report that most payers are using the increased information about an individual patient's condition to then demand clinical labs and pathology groups provide more documentation of medical necessity. These health insurers will then deny payments and some payers—including **Humana**—go one step further and demand repayment.

Other than coverage by THE DARK REPORT, there has been little news in the lab industry about how lab revenue has been negatively affected by adoption and use of ICD-10 diagnosis codes. That is one point we want to make today. Clients and regular readers of THE DARK REPORT had an early warning about how use of ICD-10 codes was predicted to shrink lab test revenues and increase payer requests for documentation of medical necessity for ever-larger numbers of lab tests.

That's a positive outcome your lab gained from using THE DARK REPORT as a reliable source of business and management intelligence. It puts your lab's executive team ahead of the marketplace and gives you the knowledge you need to protect revenues that sustain your lab's high quality mix of lab tests and services.

Also in this issue are two other stories about significant developments. One is the steady growth of laboratory benefit management (LBM) companies because they interpose themselves between the health plans they represent and the physicians who order tests and the labs that perform those tests. *(See pages 6-9.)*

The other significant story is the progress of separate lawsuits by uninsured consumers who are suing **Quest Diagnostics** and **Laboratory Corporation of America** claiming they were grossly overcharged for clinical lab tests. *(See pages 10-18.)* Should the plaintiffs prevail in these cases, there may be legal rulings that change how all labs quote prices to uninsured consumers in advance, and possibly even limit what prices they can charge cash-paying patients for lab tests. TDR

ICD-10 Gives Payers More Data About Lab Claims

Detailed procedure codes give health plans more reasons to question claims, deny coverage

CEO SUMMARY: Evidence shows that adoption of ICD-10 diagnosis codes in 2015 made it possible for health insurers to track clinical laboratory testing more closely, ask more questions about those tests, and deny coverage. Increased detail about each patient's condition has led to increased demands for medical-necessity documentation and to denied payments of as much as 20% of all testing, one expert said. In some cases, insurers pay claims, ask questions, and then demand repayment.

Since October 2015, the United States' adoption of ICD-10 diagnosis codes has disrupted laboratory test billing and collections, leading to rejected claims and increased demands from health insurers for medical-necessity documentation.

In the four years since the adoption of ICD-10 CPT codes, there has been little discussion or news reporting about the disruption that these diagnosis codes have caused for clinical laboratories and pathology groups. Some lab billing experts have said using the new codes has been challenging for labs because many payers are requiring labs to submit more data to support the test claims they submit for payment. Late in 2015, THE DARK REPORT predicted this outcome.

ICD-10 is designed to provide more clinical detail on each patient's diagnosis to help health networks, hospitals, physicians, and health insurers deliver better care. When compared with ICD-9, ICD-10 codes have 19 times as many procedure codes and nearly five times as many diagnosis codes—a total of 71,932 codes in 2019. *(See TDRs, June 22 and Dec. 28, 2015.)*

This new level of detail may be useful on paper for tracking disease and patients' outcomes, but since 2016 and continuing to this day, the detail insurers have from ICD-10 codes has created new challenges for clinical laboratories and anatomic pathology groups.

Armed with more data on patients' disease states, health insurers have required clinical laboratories to provide more information on the tests physicians prescribe, said Kyle Fetter, Executive Vice President and General Manager of Diagnostic

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Services for **XIFIN**, a revenue cycle management company for clinical labs.

"Many times, those requests for more information lead to demands for more data on medical-necessity or to payment denials, or both," he added. Health insurers have narrowed coverage by at least 20% for lab testing under ICD-10 when compared with those patients who would have been covered under ICD-9 codes, he estimated.

Specific Coverage Policies

"Not only do we see health insurers denying claims for testing more frequently, but they also use more specific coverage policies under ICD-10 as the basis for more requests for medical necessity documentation," observed Fetter. The problem for labs trying to provide the supporting documentation is that physicians must provide patients' medical records and often fail to do so. When requests for documentation go unfilled, insurers can deny the claims.

"Requests for documentation often lead insurers to seek refunds from labs if the original tests have been paid, but the insurer later finds reasons to claw-back the paid amount, either in full or in part," Fetter commented.

"Since ICD-10 was implemented in 2015, we've seen a narrowing of coverage for many routine clinical lab tests and for many molecular tests that both specialty labs and anatomic pathologists do for patients," he explained. The reduction in coverage for many lab tests started in 2016 and has continued since then, he added.

"All major health insurers are narrowing their coverage of a growing number of lab tests and they're using the increased procedure and diagnosis information they have from the ICD-10 codes to their advantage," he said.

Those insurers are **Aetna, Anthem Blue Cross and Blue Shield, Cigna, Humana, and UnitedHealthcare**. Among these five health insurers, Humana has been aggressive in requiring clinical laboratories to repay amounts it's paid for these tests, Fetter added.

"The narrowing of coverage results directly from the higher specificity that insurers have with ICD-10 codes," he explained. "The insurers use this increased information to challenge payments they've already made. They do so by saying to labs, 'Well, this test was never meant for this patient. Instead it's meant for only a smaller subset of patients. Once they challenge a lab test, they request medical-necessity documentation on the patient's condition.

"The labs then need to request medical-necessity information from the ordering physicians and often the physicians don't respond to such requests," he commented. "The physicians are too busy or don't have the staff to respond to medical-necessity requests." After labs get a number of denials or requests for more medical information, they often need to begin educating those physicians who have ordered tests incorrectly.

Why Labs Don't Get Paid

"In these educational efforts, the labs tell the doctors that ultimately, the physicians are responsible for ordering the tests, but there are guidelines that health plans and Medicare have put in place and, if physicians don't follow those guidelines when ordering, labs don't get paid," he said.

"Since 2016, the increased attention that health plans place on labs using ICD-10 has been building each year," Fetter said. "In 2019, for example, we're seeing coverage narrow significantly for even routine clinical laboratory testing, compared with what payers allowed in the past. We also see narrower coverage for certain tests for infectious disease and many molecular tests.

"The molecular tests involve different areas of pathology such as molecular-based cytogenetics testing, next-generation sequencing, and proteomics, among others," he added. "In that area, we see narrowing coverage where we didn't see such narrow coverage before.

"For example, let's say that, in the past, a physician would send a specimen out to a pathologist for a review of what the physician thought was a malignant neoplasm of the lung," Fetter said. "Today, health insurers have much more specific information with ICD-10 and they can ask for more detail on that specimen. Insurers use that detail to establish additional coverage criteria.

"Additional coverage criteria could mean a patient needs to have failed on another diagnostic test or a procedure in the last number of weeks or months," he added. "What ends up happening is that the insurer pays for the test because the ICD-10 CPT code matches the test request.

"But then the insurer uses retrospective requests on these cases to see if the underlying clinical information supports the clinical indications for coverage," he said. "If the physician submits that information, it may show that the patient didn't qualify for the test. In many cases, this is more of an issue with how the physician documents the test order, rather than the patient not meeting the criteria for coverage.

"Based on this review, the health insurer will seek to recoup what it paid for the test," he noted. Also, if the physician fails to provide the documentation, the insurer will seek recoupment."

About 20% of all tests are being denied coverage under ICD-10, even though health insurers paid for those tests when labs used ICD-9 codes, Fetter commented. "The changes in how payers reimburse labs mean that labs should think about holding a reserve of about 20% or so, in case health insurers decide to recoup what they pay."

Although, to date, Fetter has seen evidence only that Humana has been seeking to recoup funds for denied tests, other insurers may do so as well, Fetter added. TDR

—Joseph Burns

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Labs Can Respond to Insurers' Demands

FOR CLINICAL LABORATORIES FACING INCREASED CLAIM REJECTIONS, the best way to respond is to fight back aggressively, said **XIFIN's** Kyle Fetter.

Labs could fight back by monitoring payments and denials closely and by providing as much information to support medical necessity for testing as possible, suggested Fetter and other consultants. Also, labs need to continue to invest in systems to monitor payments, he said.

Ann Lambrix, Vice President of Client Services at **Vachette Pathology**, agreed that labs need more data on every test for every patient. "The problem for labs is that much of the diagnosis information needed to support a lab test must come from the ordering physician," she said. "Consequently, labs are hindered by a lack of complete documentation to support the diagnosis code and so they don't always have the most accurate information on the patient.

"It is essential for all ordering physicians to provide that information to labs because, when labs get denials, those denials are based on someone else's information," she added.

For rejected claims, labs need to decide how much to invest in fighting each rejection, she said. "If the rejected claim is for a $6 test, that's a much easier decision to make than if the rejected claim is for a $600 test," noted Lambrix.

"If the ordering physician is not providing the necessary information from the patient's history, for example, then the lab won't know how to submit that bill correctly," she said.

"Therefore, that lab test claim may go unpaid. Then, the lab needs to decide how much effort to invest in getting the ordering physician to provide more accurate diagnosis information. But too often, labs just don't have the staff to do that because of the large volume of lab test claims."

Lab Benefit Managers Want to Help Health Plans

➤Five LBMs expect steady growth as health insurers seek help managing laboratory test costs and quality

➤➤CEO SUMMARY: Laboratory benefit management companies that offer a range of services to health insurers are gaining influence over clinical lab testing in important ways. On behalf of health insurers, LBMs will select labs for a payer's network, then manage that network. They also manage claims and lab-test utilization, often reviewing medical necessity. A primary goal of LBMs is to help payers control the cost of lab testing, which is one reason why two payers operate their own LBMs.

LABORATORY BENEFIT MANAGEMENT (LBM) COMPANIES are growing in influence, complicating the ability of clinical laboratories to get paid for the tests they perform for their client physicians. As health plans take steps to manage outpatient laboratory testing more closely, their growing use of LBMs gives these intermediaries increased influence over such testing.

That influence affects testing in two ways. First, LBMs develop lab networks for health insurers, allowing them to include preferred labs and exclude others. Second, LBMs determine coverage requirements and the payment rates for clinical, genetic, and molecular testing.

➤Not Much Data about LBMs

Quantifying the effect LBMs have on clinical and genetic lab testing is difficult because there is not much data from independent sources on the reach and scale of LBMs. Therefore, it is too soon to determine if these benefit managers have a positive or a negative effect on outreach testing.

There is little doubt, however, that LBMs' position between health plans and physicians will continue to grow as the complexity and cost of laboratory testing rises. Health plan executives are seeking to control utilization of outpatient testing, particularly given that the number of expensive and complex tests, such as genetic and molecular assays, has risen sharply in recent years.

Among the companies known to be offering LBM and prior-authorization management (PAM) services are the following:

- **AIM Specialty Health**
- **Avalon Healthcare Services**
- **BeaconLBS**
- **eviCore Lab Management**; and
- **Kentmere Healthcare Consulting**.

The following example of this new go-between in the lab testing business shows why lab directors and pathology groups should be concerned about LBMs' and PAMs' increasing level of influence between physicians and health plans.

In August, Bruce Quinn, MD, PhD, founder of **Bruce Quinn Associates** and an expert in lab testing and payment policy for Medicare and commercial payers, wrote about how news reports on the growth of LBMs had a dramatic effect on the stock price of **Myriad Genetics**.

After Myriad's stock price rose in June and July, it dropped in August following news reports about reduced revenue, Quinn explained on his blog, *Discoveries in Health Policy*. One reason for the drop was related to FDA action on Myriad's GeneSight test, and the other was linked to LBMs. "Reduced revenue was attributed in part to the rising activity of lab benefit managers [which increases the denial rate on claims payers receive]," Quinn wrote.

Offering a variety of services to health insurers, LBMs can have a negative effect on lab revenue. In addition to doing utilization, claims, and medical necessity reviews, LBMs also provide education for ordering physicians about which tests are appropriate for each patient case.

LBMs Manage Networks

LBMs also develop and manage networks of preferred labs and grant test-ordering privileges to certain physicians. In addition, LBMs write and implement prior authorization (PA) requirements, conduct PA reviews, and develop test formularies and coverage policies.

The top priority of LBMs is to contain inappropriate lab test ordering and costs. This priority is an obvious goal for all five of the nation's LBMs, but particularly for the two LBMs that health plans own:

- AIM Specialty Health, which **Anthem** acquired in 2007, and
- eviCore, which **Cigna** acquired last year when it merged with **Express Scripts,** a pharmacy benefit manager.

Laboratory Corporation of America owns a third LBM, BeaconLBS. The remaining two LBMs—Avalon and Kentmere—are independent companies. They focus on containing lab testing costs and on forming and managing lab networks for their health plan clients.

Both Avalon and Kentmere state publicly that their services can cut the cost of clinical lab testing. Last month, Avalon announced that when health plans apply its Medical Benefits Management Software to the high-volume, low-cost outpatient laboratory services that represent about 90% of the lab spending, payers can cut costs by 8% to 12%.

Similarly, on its website, Kentmere says health plans get a 20-to-1 return on their investment, meaning that for every dollar spent on Kentmere's LBM program, insurers can save $20 on lab testing. Last year,

Little Evidence LBMs Improve Patient Outcomes

IN A HEALTH POLICY JOURNAL BLOG POST LAST MONTH, researchers reported they could not find evidence showing the effect laboratory benefit managers (LBMs) have on clinical management or patient outcomes.

They reported that LBMs could present barriers to patient care due to mandatory laboratory prior-authorization requirements for all genetic tests and rules requiring ordering physicians to provide documentation of medical necessity that supports prior-authorization.

In addition, there may be conflicts of interest when a lab or payer owns an LBM, resulting in closed networks and monopolistic pricing, they wrote.

The *Health Affairs* blog post was published on Oct. 23 and titled, "The Emerging Use by Commercial Payers or Third-Party Lab Benefit Managers for Genetic Testing." The researchers were Kathryn A. Phillips, PhD, a health services researcher in the School of Pharmacy at the **University of California, San Francisco**, and Patricia A. Deverka, Director, Value Evidence and Outcomes at **Geisinger**, the health plan in Danville, Pa.

"With the emphasis on reducing inappropriate utilization, it is difficult to assess how LBMs are addressing the potential for underutilization of genetic testing other than through provider education," they wrote. "The unintended consequence is that genetic testing continues to be viewed as a commodity without the ability to demonstrate the value of testing on provider behavior and patient outcomes."

when **The Health Plan** of West Virginia announced that Kentmere would manage its lab benefits, Kentmere said it saves its clients 10% to 20% on clinical laboratory testing costs, "while still delivering the same level of service—or better." Kentmere also has a contract with **Horizon Blue Cross Blue Shield** of New Jersey.

One question that health plans may be less interested in asking is whether LBMs deliver any other value beyond cost cutting. *(See sidebar, "Little Evidence LBMs Improve Patient Outcomes," page 7.)*

Low Costs, High Quality

Kentmere promises savings on lab spending by forming networks of laboratories that meet its criteria for costs, access, and quality. Kentmere describes itself as more than an LBM and seeks to differentiate itself from companies that manage prior authorization and simply deny lab test requests as a way to manage utilization.

"To us, lab benefit managers are companies that take control of your laboratory network," stated Charles Cini, CPA, Kentmere's CFO and Chief Financial Analyst. "In addition to LBMs, there are prior-authorization companies that simply deny claims and say they're serving in a laboratory benefit manager's role.

"We are different from those companies, and health plans recognize that distinction because there is a big difference between managing laboratory benefits and simply doing prior-authorization," Cini explained. The difference between the two types of companies is important, he added, because companies that serve health plans by simply doing prior-authorization review are revising their offerings to add LBM services.

"Companies that process claims have an unsustainable business model because all they do is try to reduce costs," he said. "But health plans need more than that to deliver quality healthcare. That's why some companies that do prior authorization have asked us to be a strategic partner with them through our LBM program.

"We would never do that because we have a completely different approach," Cini explained. "We're the only company in the LBM business that does more than just aim to reduce costs. Our primary focus is to control utilization, increase lab test quality, and improve service to health plans by redirecting business to in-network labs."

In most cases, Kentmere and other LBMs form lab networks on behalf of their health plan clients, or add or subtract labs as needed from payers' existing networks.

"When a health plan contracts with us, we do a complete medical policy review and claims analysis," Cini said. "In that analysis, we review everything that touches outpatient lab testing for our health plan clients. Then, we make recommendations—including which labs should be in their lab network based on fast turnaround time and quality service.

"For the laboratories that end up in the network, there may be less reimbursement, but they will get more utilization because our goal is to redirect business to them once they're in the network," he added. "This supports the goal of our health plan clients to ensure their members have better service, better access, and higher quality testing."

A Comprehensive Approach

At **Avalon**, Chief Growth Officer Barry Davis said his company has a similar approach and its first goal is to produce savings for its health plan clients. "For us, it all starts with science and policy development," he added. "We've analyzed data from more than 70 health plans and see 8% to 12% over-utilization of units on the high-volume, low-cost tests versus the science."

For its health plan clients, Avalon offers lab network management, genetic prior authorization, or its Medical Benefit Management Software (MBMS). It uses this software to apply evidence-based lab policies to high-volume, low-cost tests.

"We can either do it all for a health plan or supplement what that plan already does," he added. "Avalon has approxi-

LBM Companies Are New Lab Marketplace Factor

LABORATORY BENEFIT MANAGEMENT (LBM) COMPANIES serve health plans in ways that are similar to the role provided by pharmacy benefit management (PBM) companies. At least five LBMs are known to be operating today on behalf of health insurers.

One of the first companies to provide lab-test management services was **Kentmere Healthcare Consulting**, which was formed in 2000. Another was **DNA Direct**, a company in San Francisco that was founded in 2005. *(See TDR, August 18, 2008.)* **MedCo**, a pharmacy benefit manager, acquired DNA Direct.

In 2012, **CareCore National** acquired DNA Direct. CareCore was then renamed **eviCore Health Management** and the LBM was rebranded as eviCore Lab Management. In 2017, **Cigna** acquired eviCore, a utilization and prior-authorization management company that says it has taken on a large role among LBMs.

One significant development for the LBM industry was the launch of **Beacon Laboratory Benefit Solutions**, a subsidiary of **Laboratory Corporation of America** (LabCorp). In 2014, **UnitedHealthcare** (UHC) announced an agreement with Beacon to manage how physicians order lab tests for UnitedHealthcare's commercial members in Florida. With this program, BeaconLBS combined prior-authorization review and a network of approved laboratories, including many labs that were part of LabCorp. Recently, UHC indicated that it was ending Beacon's activities in Florida.

Two other LBM programs also have operated in this field. Neither one was a major player among LBMs, but both have a growing influence today. They are **AIM Specialty Health**, a division of **Anthem Blue Cross and Blue Shield**, and Kentmere Healthcare Consulting, an independent company in Wilmington, Del., that runs an LBM program.

In 2013, **Avalon Health Care Solutions**, another independent company, was formed and has had steady growth serving Blues plans and other insurers. In this role, Avalon administers lab networks and promotes broad networks to limit out-of-network leakage. "We've seen 15% to 25% out-of-network leakage in narrow networks leading to increased costs for patients and payors overall. The broad network ensures the labs agree to follow the health plans' lab policies," stated an Avalon spokesman.

mately 140 evidence-based lab policies," he continued. "Each was developed with our independent clinical advisory board. About half of those 140 policies are for genetic testing and the other half are for lower-cost, high-volume testing.

"Genetic testing is about 10% of all lab testing today," noted Davis. "But it's growing quickly and those individual tests are high-cost tests. Therefore, most such tests require clinical review and are managed through prior authorization. Even though there's some automation in how health plans and LBMs manage genetic tests, most of those tests are reviewed one at a time.

"The reason is because about a third of genetic tests ordered today are in error," Davis commented. "When it comes to genetic testing, physicians don't know what to order for their patients. That's why we have a component of our genetic testing management program to educate physicians in a peer-to-peer arrangement. In this way, we help the doctor and lab order the right test for each patient.

"Avalon also wants both the physician and the lab to understand which test the patient needs in a process that includes getting the insurer to approve payment for that test," he said. "This approach allows us to improve clinical outcomes and eliminate unnecessary testing." TDR

—Joseph Burns

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Separate cases in federal courts allege uninsured consumers are overcharged

Lawsuits Allege LabCorp, Quest Overcharged Uninsured Patients

CEO SUMMARY: Court documents filed in U.S. District courts in New Jersey and North Carolina provide details about how each of the two lab companies set lab test prices differently—as much as 10 times higher—for cash-paying patients than for patients who have Medicare, Medicaid, or commercial health insurance plans. In court filings, plaintiffs allege that lab testing is highly profitable and that insurers pay well above labs' costs. The plaintiffs also argue that the defendant labs should disclose lab test fees before testing.

First of Two Parts: Section One

Two of the nation's largest clinical laboratory companies face separate lawsuits in which uninsured consumers complain that the companies overcharged them for medical laboratory testing services by two to three—and sometimes as much as 10—times higher than what the companies charged consumers whose health insurers fully covered their testing.

The lawsuits are proceeding in federal courts against **Laboratory Corporation of America** and **Quest Diagnostics**, according to Robert C. Finkel, an attorney with **Wolf Popper**, a law firm in New York. An expert in consumer and financial fraud, Finkel represents the defendants and is pursuing class-action status for both cases.

What makes these two lawsuits interesting for pathologists and clinical lab administrators is that they both deal with transparency and whether prices should be made available to patients in advance of service. Transparency in the prices hospitals, physicians, labs, and other healthcare providers charge patients is a trend that continues to gain momentum—in part because so many patients have high-deductible health plans.

Court documents plaintiffs filed in both cases provide details about how each of the lab company defendants set lab test prices differently—and typically substantially higher—for cash-paying patients than for patients who have Medicare, Medicaid, or commercial health insurance plans.

The information in the court filings offers insights into the alleged pricing strategies of both laboratory companies. It may also help pathologists and clinical laboratory administrators understand why patients and consumers support state and federal efforts to pass laws requiring price transparency for healthcare services, including medical laboratory tests.

In this first part of a two-part series, The Dark Report provides information about the lawsuit Finkel filed against Quest on behalf of 19 plaintiffs who allege violations of consumer fraud statutes in eleven states. The second part will cover the details of Finkel's lawsuit against LabCorp and will be in a future issue of The Dark Report.

Plaintiffs' Common Claims

This intelligence briefing is presented in two sections. The first section addresses the common claims that plaintiffs raise in the two lawsuits. The second section follows on pages 16-18 and provides more information about the charges in the lawsuit against Quest and how the court has ruled on pretrial motions.

Two issues raised in both lawsuits are likely to be most concerning, not just for Quest and LabCorp, but also for all clinical laboratories. First, the Quest lawsuit charged that lab testing is highly profitable and that health insurers, Medicare, and other third parties pay well above the costs Quest, LabCorp, and other labs incur to do such testing.

Potential for More Price Cuts

While most clinical labs would dispute this charge, if a court issued a ruling or affirmed this claim to be true—that payers pay labs well above labs' costs—such a finding could cause many payers to further reduce reimbursement for clinical laboratory tests, as labs have seen over the past several years.

A second issue of concern for all labs is how court documents challenge whether LabCorp or Quest has the right to charge more to some consumers than to others and not disclose those charges before the testing is done. In both cases, court documents allege that both Quest and LabCorp have list prices for clinical lab tests that are as much as 10 times higher than the negotiated rates that Medicare, Medicaid, and third-party commercial insurers pay.

This issue of disclosing what consumers will be charged before testing could be a problem for all labs because, if consumers make such demands, labs would need to verify that consumers are eligible for insurance payments for such tests and that such testing is covered.

Complicating this process is that consumers owe varying amounts for lab testing (and for all healthcare services) because most consumers are responsible for deductibles and coinsurance payments at the point of care, thus making each consumer's billed amount different.

Different Lab Test Prices

In both court cases, court documents show that—for the same tests—LabCorp and Quest routinely charged different rates for different customers. For the consumers in each case, LabCorp and Quest charge rates that often are called the "undiscounted retail rate," the "fee schedule rate," the "list price," and the "chargemaster rate," according to court filings. In this intelligence briefing, the term list price refers to the highest rates that both companies charge.

At the heart of both cases is that the plaintiffs do not dispute that the defendent lab companies have the right to charge high rates, court papers show. Rather, plaintiffs assert that each lab company should get their patients' consent before demanding payment, and—if there is no written agreement to pay list prices—the companies' rates must be limited to reasonable prices, according to the lawsuit.

The legal argument in this case is based on a fact that the plaintiffs (as individual patients) have no contract with Quest or LabCorp. Therefore, the plaintiffs and the lab companies "are subject to a contract either implied-in-law or implied-in-fact," the lawsuit says. Under such an implied contract, the lab companies are entitled to recover only a reasonable price for clinical lab testing services, according to the lawsuit.

Financial Responsibility

Further, the lawsuit argued, neither clinical lab company attempts to make such arrangements with patients until after the testing is done, the insurance billing process is completed, and the patient is found to be financially responsible for the lab tests that were performed.

In the case against Quest, the lawsuit says, "Although the list prices are exorbitant amounts intended only as a tool for negotiating with equally sophisticated third-party payers and are generally not paid, Quest remains unwilling to meaningfully negotiate the amount owed by its least-sophisticated consumers who lack any real bargaining power."

In the case against LabCorp, the lawsuit said the lab company could advise its patients in advance and get their consent to charge list prices, as the company does for Medicare patients when coverage denial is expected.

Such consent is completed through Medicare's Advanced Beneficiary Notice (ABN) form, wrote the plaintiffs' attorney. "Indeed, absent such disclosure, there is no meeting of the minds as to price," the court papers added. "Without a meeting of the minds, LabCorp must be limited to charging reasonable, market prices."

Collection for Unpaid Bills

One other problem for uninsured consumers in both cases is that the lab companies send uncollected charges to collection agencies when bills are unpaid after a certain time, the court documents charged.

Once the lab tests are completed, patients of both Quest and LabCorp have limited recourse and are forced to pay the charged amounts or be subject to collection efforts, lawsuit alleged. Such efforts include being barred from receiving clinical lab tests from the two companies in the future, threats of the debt being sold to a collection agency, and the risk of a negative report being submitted to credit rating agencies, it added.

In May 2018, Finkel filed an amended complaint against Quest in the U.S. District Court of New Jersey on behalf of all Quest patients in the United States who were charged fees for clinical lab

In Separate Federal District Court Cases, Each Clinical Lab Company Denies Charges

BOTH QUEST DIAGNOSTICS AND LABORATORY CORPORATION OF AMERICA (LabCorp) deny the allegations filed in two pending U.S. district court cases over complaints that the companies overbilled patients who were uninsured or underinsured.

In separate complaints, plaintiffs in these cases charged that the companies overcharged them for laboratory testing services by two to three—and sometimes as much as 10 times—more than what the companies charged patients with more comprehensive insurance coverage.

Quest denied the allegations filed by attorney Robert C. Finkel of the firm **Wolf Popper** on behalf of 19 patients from 11 states, court filings showed. The plaintiffs' case against Quest is pending in U.S. District Court of New Jersey. On Nov. 8, Quest filed a 171-page answer to the amended complaint in which the company denied the plaintiffs' allegations and denied liability. Also, Quest asserted that a class action was not appropriate in this case.

In its court documents, LabCorp also denied the plaintiffs' allegations. On Oct. 4, LabCorp filed a 285-page answer to an amended complaint, saying that the company denied "each and every allegation" in the complaint that Robert C. Finkel filed in on behalf of 14 plaintiffs from eight states. That case is pending in U.S. District Court for the Middle District of North Carolina, Greensboro division. Discovery is scheduled to begin next month and filings in the case will continue at least through next year.

LabCorp said the amended complaint violates federal civil procedures because it seeks to present an argument and conclusion to which no response is required. "LabCorp expressly states that all purported statements and conclusions of purported law are denied for purposes of this answer, and legal arguments and discussions of legal authority are expressly reserved for future motions and arguments," court documents showed.

Also, LabCorp did not answer the allegations contained in one of the counts in the amended complaint because the court dismissed that count in an order issued in August. "For this same reason, LabCorp does not answer the allegations contained in counts three through 11 based on aggregate billing or nondisclosure of current procedural terminology codes as those allegations also relate to claims that have been dismissed ...," the documents showed. "To the extent LabCorp must provide an answer to these allegations, LabCorp denies those allegations ...."

If there are any headings or footnotes in the amended complaint that constitute an allegation, LabCorp denied those charges, the court documents showed. "LabCorp further denies any remaining allegations of the complaint, if not expressly admitted herein," the documents added.

'Are Rates Unreasonable?'

For its part, Quest has argued that the plaintiffs failed to state a claim for breach of implied contract because Quest never agreed to charge the consumers a negotiated third-party rate, nor did it omit the price. Quest also said the plaintiffs failed to demonstrate that the chargemaster rates were unreasonable. Therefore, the court should dismiss the plaintiffs' claims of an implied contract, the company said.

Quest also argued that the consumer-protection claims should be dismissed and that the plaintiffs' request that the court set reasonable rates for lab tests was improper. In addition, Quest argued that the plaintiffs' claims of consumer fraud and deceptive billing were prevented under a legal theory called the "learned professional rule."

testing "that were in excess of the reasonable market rates" for such tests, the lawsuit alleged. These 19 patients from 11 states either were not insured or their insurer denied coverage for the tests their physicians ordered, court papers show.

Also, these patients did not have an agreement with Quest that established the fees that the patients needed to pay, and, as a result, these patients were treated differently from the way Quest treated patients who had commercial health insurance, Medicare, Medicaid, and other coverage from other third-party payers that negotiated reasonable and customary rates with Quest, the court filings alleged.

The plaintiff-consumers were charged Quest's list prices, the lawsuit said, adding the list prices, "far exceed the usual and customary rate for the services provided."

'Usual and Customary'

The usual and customary rates are the market rates that health insurers and other third parties, such as Medicare, typically paid for the same services, the lawsuit explained. In the lawsuit, the plaintiffs charged Quest with unjust enrichment and unfair and deceptive trade practices in violation of state law.

The rates that Quest charged for uninsured or underinsured consumers are "a grossly excessive markup on Quest's cost to provide the services," the court documents said.

The patients who are uninsured or underinsured make up less than 1% of Quest's clinical lab testing volume, but contribute up to 3% of Quest's net revenue, the court papers showed. The list prices that Quest charges these plaintiff-consumers are "up to 10 times higher than the negotiated rates" that insurers and other third parties pay, it added.

"While healthcare service providers such as Quest maintain exorbitant list prices for their services, those list prices are never paid by sophisticated third parties," the lawsuit explained. "The list prices are solely a starting point to negotiate with third-party payers (e.g., insurance companies) who obtain huge discounts, and for charging patients whose insurance denies coverage or are uninsured (e.g., the class members)."

The court documents showed that 1% of Quest's patients are uninsured or whose health insurers have denied payment for Quest's tests when the patients' physicians have ordered those tests. For these patients, "there is no express agreement as to the appropriate price and Quest chooses to bill the patient at its exorbitant list rate," the documents explained.

The patients who are uninsured or underinsured make up less than 1% of Quest's clinical lab testing volume, but contribute up to 3% of Quest's net revenue, the lawsuit showed. The list prices that Quest charges these plaintiff-consumers are "up to 10 times higher than the negotiated rates" that insurers and other third parties pay, it added.

What's more, Quest's list prices are substantially higher than what other lab companies get paid for similar testing services, the lawsuit charged. "For instance, when comparing the list prices Quest charged plaintiffs to the median third-party payer rate across the United States (as reported by the **Centers for Medicare and Medicaid Services** in relation to Medicare's 2017 rates), the implied markup averaged 3.32 times the third-party payer rates, with a median of 3.18 times," it added.

Last year, what Quest charged these patients was even higher, the lawsuit alleged. "Comparing the same list prices to the 2018 Medicare rates, which are equal to the median third-party payer rates … the implied markup averaged

5.29 times the 2018 rates, with a median of 5.23 times," it added.

Complicating the process of determining rates is that the amounts commercial insurers pay Quest are considered to be proprietary and highly confidential, the documents showed. Early in the Quest case, a judge denied plaintiffs' application for discovery of those rates after Quest argued that they were proprietary.

"These market-based rates are therefore unavailable to patients and physicians, which creates an opaque marketplace that fails to reflect the true value of the services being invoiced," the lawsuit argued. On the other hand, the amounts that Medicare and Medicaid pay are available, it added.

Quest's Average Payments

In the documents, the lawsuit showed an average payment per requisition. In 2017, Quest processed some 164 million clinical lab test requisitions and reported $7.71 billion in net revenue for the year, producing an average payment per requisition for four groups of payers: insurers, government payers, client payers, and patients. Among the four groups, patients paid the highest average payments, court documents alleged.

For this comparison, the court papers defined client payers as those who pay wholesale rates that are billed on a negotiated fee schedule, including physicians, hospitals, accountable care organizations, integrated delivery networks, and other laboratories and institutions. These client payers contribute 37% of Quest's clinical lab testing volume but only 29% of its revenue, showing that the negotiated rates client payers pay are below that of other third-party payers, the lawsuit explained.

In the lawsuit, the average payment per requisition for each of the four groups of payers is reported as follows:

- Health insurers (including the amounts Quest collected from patients for coinsurance and deductibles): $51.01,
- Government payers: $53.28,
- Client payers: $36.85,
- Patients: $141.04.

Seeking Restitution

Because the group of patients do not have an "express contract" that establishes the fees to be paid, these consumers were charged amounts "in excess of the reasonable market rates" for lab tests, the lawsuit explained. They are seeking restitution equal to the amount of overcharge, which the court papers defined as the difference between the amount paid and the reasonable market rate.

Under causes of action, the case against Quest lists 14 counts as follows:

- Count 1: A declaratory judgment based on principles of implied contract,
- Count 2: Breach of implied contract or unjust enrichment on behalf of some plaintiffs,
- Counts 3 through 14 relate to violations of consumer protection and unfair competition laws in Arizona, California, Colorado, Florida, Illinois, Maryland, Michigan, Nevada, New Jersey, North Carolina, and Pennsylvania.

Quest did not respond to a request for comment. LabCorp said it did not comment on such cases. Details of LabCorp's case will be covered in an upcoming issue of THE DARK REPORT as part two in this series.

Rulings That Affect Labs

Some useful insights can be drawn from these court documents. First, today there are patients willing to file legal challenges when they believe they have been overcharged by a clinical laboratory. Second, these two lawsuits, as they move through the federal court system, could result in rulings and judgements that would require all labs to change pricing policies. **TDR**

—Joseph Burns

Contact Robert Finkel at 212-451-9620 or rfinkel@wolfpopper.com.

Plaintiff and defendant each get something

Judge Issues Split Ruling on Quest's Motion to Dismiss

Lawsuit filed by uninsured patients alleges Quest overcharged them for their clinical laboratory tests

CEO SUMMARY: There have been significant developments in the case against Quest Diagnostics for allegedly overcharging uninsured patients for clinical laboratory tests. This second section covers the federal judge's most recent decisions, along with an assessment of how the plaintiffs and the defendant each received favorable rulings.

First of Two Parts: Section Two

In the federal lawsuit filed against **Quest Diagnostics** (Quest) by uninsured patients who claim they were overcharged for lab tests Quest performed, the judge has made several rulings and has allowed the lawsuit to move forward.

This second section in part one of our two-part series covering this case explains the latest developments that specifically involve Quest Diagnostics.

In September, U.S. District Judge Esther Salas addressed issues Quest raised in an earlier motion to dismiss all charges in the lawsuit brought by 19 plaintiffs from 11 states. In her order, Salas denied some of Quest's motions to dismiss claims in the plaintiffs' amended complaint and granted some of Quest's motions to dismiss.

Most importantly, however, Salas found that the plaintiffs alleged sufficient facts to support their theory of unfair trade practices based on excessive pricing.

As mentioned in the previous intelligence briefing, both Quest and **Laboratory Corporation of America** (LabCorp) face lawsuits in which plaintiffs complain that the companies overcharged them for laboratory testing services by two to three times—and in some instances as much as 10 times—more than what the companies charged consumers whose health insurers fully covered their tests. *(See "Lawsuits Allege LabCorp, Quest Overcharged Uninsured Patients," pages 10-15.)*

Federal Lawsuit

The lawsuit against Quest was filed in U.S. District Court in New Jersey. In that lawsuit, the plaintiffs' attorney, Robert C. Finkel of the firm **Wolf Popper**, cited 14 counts under causes of action. In count one, the plaintiffs seek a declaratory judgment based on principles of implied contract, and in count two, they charge breach of implied contract or unjust enrichment on behalf of some plaintiffs.

Counts three through 14 relate to violations of consumer protection laws and of unfair competition laws in Arizona, California, Colorado, Florida, Illinois, Maryland, Michigan, Nevada, New Jersey, North Carolina, and Pennsylvania.

The most important part of Salas' opinion involves some of the plaintiffs' consumer-protection claims. The judge dismissed consumer protection charges

that plaintiffs from New Jersey and North Carolina brought, but she found that the plaintiffs from the nine other states alleged sufficient facts to support their theory of unfair trade practices based on excessive pricing.

"Plaintiffs allege that the prices billed by Quest were 500% to 1,000% more than the prices paid by 99% of Quest's customers," Salas wrote. Therefore, she denied Quest's motion to dismiss the plaintiffs' claims based on a theory of excessive pricing.

Implied-in-Fact Contract

On the issue of breach of an implied-in-fact contract, Quest argued that the plaintiffs failed to state a claim for breach of implied-in-fact contract because they did not allege, "that the contract between the parties included an agreement to charge uninsured patients the same rates as insured patients," she wrote.

On this issue, the judge made an important ruling regarding the plaintiffs' claims that they did not know what they would be charged before the testing was done. It is important for all clinical laboratories to understand this ruling.

"Quest argues forcefully that plaintiffs' theory based on a 'missing' price term has not only been rejected by the Third Circuit [court], but also by other federal and state courts, each of which concluded that the 'chargemaster' rates were incorporated into the parties' service agreements and were thus properly passed on to un- or under-insured plaintiffs," she explained.

In its filing in this case, Quest cited case law supporting its argument. Salas countered that the parties in the cases Quest cited had specified prices in their written agreements. In their case against price, plaintiffs argued that they did not know what they would need to pay before the testing was done.

The plaintiffs' amended complaint, "contains no allegations that plaintiffs had any similar written agreement with Quest," about the price of the tests, Salas explained. The judge also wrote, Quest did not argue that the amounts billed to plaintiffs were based on a written agreement.

Therefore, the judge rejected Quest's request to dismiss counts one and two. "Rather, the court finds the amended complaint sufficiently alleges an implied-in-fact contract with a missing term: price," she wrote.

On the question of whether Quest's charges were unreasonable, Salas wrote that the court had determined that—at least at this stage—Quest's prices were unreasonable.

The patients who are uninsured or underinsured make up less than 1% of Quest's clinical lab testing volume, but contribute up to 3% of Quest's net revenue, the lawsuit showed. The list prices that Quest charges these plaintiff-consumers are "up to 10 times higher than the negotiated rates" that insurers and other third parties pay, it added.

As a result, she denied Quest's motion to dismiss the plaintiffs' claims for breach of implied contract-in-fact and she denied Quest's motion to dismiss the plaintiff's request for a declaratory judgment regarding that implied contract.

Also in her September opinion, Salas addressed the two theories the plaintiffs alleged in the amended complaint: breach of implied contract and violations of the consumer protection laws. She also addressed the plaintiff's claims regarding breach of consumer protection laws and the issues related to contracts that are implied in law and implied in fact.

In her 17-page opinion, Salas began by restating the plaintiffs' arguments and then cited Quest's arguments that the plaintiffs failed to correct deficiencies in the original complaint, therefore the case should be dismissed with prejudice, meaning permanently.

Here are some of the arguments Quest made in its defense.

Quest argued that the plaintiffs failed to state a claim for breach of implied contract because Quest never agreed to charge the consumers a negotiated third-party rate, nor did it omit the price, Salas wrote. In addition, Quest argued that the plaintiffs failed to demonstrate that the chargemaster rates were unreasonable.

"According to Quest, these defects require dismissal of plaintiffs' implied-contract claims," Salas wrote.

Regarding the state consumer-protection claims, Quest argued that the plaintiffs did not make significant changes in its amended complaint versus the initial complaint. Therefore, the consumer-protection claims fail for the same reasons Salas cited in an earlier opinion she made in a case last year.

'Learned Professional Rule'

Also, Quest argued that the plaintiffs' request that the court set reasonable rates for lab tests was improper because legislatures or regulators should do so. In addition, the judge wrote, Quest argued that the plaintiff's claims of consumer fraud and deceptive billing were prevented under a legal theory called the "learned professional rule." Under this rule, Quest is like hospitals and other healthcare providers that must follow state regulations.

Quest also argued that when the plaintiffs accepted Quest's clinical lab testing services, they agreed to the prices defined in the chargemaster at the then-existing rates, Salas wrote.

"Quest further points out that the amended complaint does not allege that plaintiffs were denied information relating to the chargemaster rates, but rather that they sought Quest's services, received those services, and were later displeased with the price," she added.

Quest also argued that the plaintiffs failed to demonstrate its prices were unreasonable.

In her discussion of state consumer-protection laws, Salas wrote that a plaintiff must show that a deceptive or unfair business practice caused the consumer an actual loss or damage.

However, Quest argued—and Salas agreed—that the learned professional rule prevented the plaintiffs' claims under New Jersey and North Carolina's consumer protection laws. Under this reasoning, Salas dismissed with prejudice (meaning permanently) counts three and 13, which relate to consumer protections in New Jersey and North Carolina.

All other claims that Salas dismissed in this case were dismissed without prejudice, meaning the plaintiffs can return to the court with new arguments.

In addition, Salas dismissed the plaintiffs' consumer-protection claims based on deceptive or fraudulent billing practices, saying the plaintiffs failed to plead the fraud-based claims successfully. She did not find that providing a non-itemized bill, or sending follow-up notices for unpaid bills, amounted to a fraudulent or deceptive trade practice, she added.

She then addressed the issue of breach of an implied-in-law contract, writing that the plaintiffs did not assert a claim of unjust enrichment. Therefore, she granted Quest's motion to dismiss the claims for breach of contract implied in law.

Case Will Continue

In the most recent development in the case, Quest filed a 171-page answer to the amended complaint on Nov. 8. In that court filing, the lab company denied the allegations the plaintiffs alleged and denied liability. Also, Quest asserted that a class action was not appropriate in this case.

Quest did not respond to a request for comment by our deadline. Details of the case against LabCorp will be covered in a future issue of THE DARK REPORT. TDR

—Joseph Burns

Contact Robert Finkel at 212-451-9620 or rfinkel@wolfpopper.com.

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Medicare lab test price cuts mandated by the Protecting Access to Medicare Act (PAMA) are eroding the finances of urology groups that do in-office clinical laboratory testing. In the November issue of *Urology Times*, urologist Robert A. Dowling, MD, wrote a news story that identified the cuts in Medicare Part B prices for the lab tests most frequently ordered by urologists. "2019 rates are about 19% lower than 2017 rates for almost all of these commonly-performed tests [ordered by urologists]," said Dowling. "For example, total PSA was reimbursed $25.23 in 2017 and $20.44 in 2019 (–19%). This was the 20th most common lab test reimbursed by the Medicare Part B program in 2017 and ranked 15th in terms of total payments."

MORE ON: *Urology Lab Tests*

Dowling also noted that, "Serum testosterone similarly declined 19% from $35.41 in 2017 to $28.68 in 2019 (ranked 57 in number of payments). Automated urinalysis codes also declined 19%, while the manual urinalysis codes with and without microscopy dropped 0.6% and 7.6% respectively over the 3-year period."

GIZMODO: DNA TESTS MAY BE 'BIGGEST SCAM'

On Nov. 20, online news outlet *Gizmodo* published a story with the headline "Consumer DNA Testing May Be the Biggest Health Scam of the Decade!" The story details the public failings of genetic tests offered to consumers by certain companies promising to deliver accurate, relevant, and useful results. Pathologists and clinical lab managers will find some of the examples to be noteworthy. The *Gizmodo* story can be found at this link: *https://tinyurl.com/sk8v98e*.

TRANSITIONS

- **Abbott Laboratories** issued a statement that Miles White would "step down" as CEO of the company as of March 31, 2020, but would continue to serve as Executive Chairman of the Board. White became CEO of Abbott 21 years ago. White started at Abbott in 1984 and previously worked at **McKinsey and Company**.
- On the same day, **Abbott Laboratories** announced the selection of Robert Ford as its new CEO. Ford is currently President and COO of Abbott, a position he has held since October 2018. Ford joined Abbott in 1996 and prior to that worked at **Becton, Dickinson and Company**.

That's all the insider intelligence for this report. Look for the next briefing on Monday, December 16, 2019.

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UPCOMING...

- ***Part Two in Our Coverage of Federal Lawsuits That Allege National Lab Companies Overcharged Uninsured Patients.***
- ***Academic Center Lab Moves Genetic Testing Beyond PGx and Into Predictive Medicine Best Practices.***
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