Volume XXX, Number 13 Monday, September 11, 2023

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Learn How Labs Help Payers Increase Their Risk Adjustment Rates!

Clinical laboratories can earn revenue for adding value from diagnostic information.

(See pages 12-17)

Rick VanNess

From the Desk of R. Lewis Dark...

THE DARK REPORT

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

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COMMENTARY & OPINION by...

R. Lewis Dark
Founder & Publisher

Is Lab and IVD Consolidation Ready to Hit the Wall?

IN HUMAN HISTORY, ALL ERAS COME TO AN END. The majority of the time, the end of an era is disruptive and a new status quo emerges, with different winners and losers. Today, there is growing evidence that one era in clinical laboratory testing and IVD manufacturing may be close to ending.

We present our evidence that a three-decades long era of consolidation within the clinical laboratory, anatomic pathology, and *in vitro* diagnostics (IVD) sectors is reaching a point of maturity. Whether or not this is the end game to this 30-year era is still uncertain.

As you will read on pages 6-7, consolidation of independent clinical lab companies (that performed mostly routine and esoteric testing) enabled **Labcorp** and **Quest Diagnostics** to become almost ten times larger than their next two largest public lab competitors. In that vacuum, hospital and health system laboratories doing lab outreach testing have filled whatever demand remains in their communities for routine and reference testing.

It is the same story in IVD manufacturing: consolidation among the IVD manufacturers has resulted in just six huge corporations controlling 63% of the global market. *(See TDR, "2022 Ranking of the World's Top 12 IVD Corporations," July 31, 2023.)* In fact, **Thermo Fisher** (ranked first), **Roche Diagnostics** (ranked second), and **Abbott Laboratories** (ranked third) captured 45% of the global market in 2022. This substantial concentration of market share on the supply side of the diagnostics market has reduced the choices available to clinical labs and pathology groups when it comes time to replace existing instruments and automation.

But that is just part of the story associated with three decades of consolidation. Our industry has now reached the point where just two behemoth public lab companies control an overwhelming share of the demand for lab instruments, test kits, and reagents. We explain to you how this situation now favors the IVD manufacturer who wins the business of either or both Labcorp and Quest Diagnostics. It gives that IVD company economies of scale to underbid its IVD competitors for the business of hospital labs, health system labs, and specialty testing labs.

Once again, THE DARK REPORT is first to deliver to you actionable business intelligence on how the market for IVD systems and tests is shifting. Whether an IVD seller or lab buyer, you are better informed when negotiating the purchase of these diagnostic products and services. TDR

No Surprises Act Sparks a Slew of Court Decisions

Law's independent dispute resolution procedure triggers federal court challenges against HHS

CEO SUMMARY: Multiple lawsuits filed by the Texas Medical Association against the federal government have resulted in key decisions that affect provisions in the law. Qualifying payment amounts and resolution processes are key areas of disagreement between the opposing sides. Pathologists and clinical labs will be affected by the final outcomes of these court challenges.

FOUR COURT DECISIONS OVER THE LAST 18 MONTHS REGARDING THE NO SURPRISES ACT—including two just in August—may be leaving pathology practice administrators and clinical laboratory managers scratching their heads about the best ways to react.

However, rather than focusing on the legal back-and-forth over the law, it's more important for labs to pay attention to the sites where they they provide diagnostic services. "Labs need to consider the location of where their services are being provided," said attorney Christine Parkins Johnson, JD, MSPH, an Associate at law firm **Davis Wright Tremaine LLP** in Los Angeles.

"That location will determine whether the laboratory can balance bill a patient, which is allowed in non-hospital and non-ambulatory surgical care settings, but is prohibited at hospitals and ambulatory surgery centers if the patient is at an in-network facility," Johnson added.

The No Surprises Act aims to protect patients covered under health plans from getting unexpected medical bills when they receive most emergency and non-emergency services, such as lab tests, from out-of-network providers at in-network facilities. A provision in the law allows independent dispute resolution (IDR) with an arbitrator if providers, emergency facilities, and health plans need to settle payment disagreements.

Four court decisions in cases involving compliance with the No Surprises Act stemmed from a series of lawsuits filed by the **Texas Medical Association** against the **U.S. Departments of Health and Human Services, Labor, and the Treasury**. The statute required those federal departments to issue a rule outlining the independent dispute resolution process and other concerns, which appeared as an interim rule in July 2021 and a final rule in August 2022.

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THE DARK REPORT Intelligence Briefings for Laboratory CEOs, COOs, CFOs, and Pathologists are sent 17 times per year by The Dark Group, Inc., 21806 Briarcliff Drive, Spicewood, Texas, 78669, Voice 1.800.560.6363, Fax 512.264.0969. (ISSN 1097-2919.)

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One issue that came up repeatedly in the court rulings is the Qualifying Payment Amount (QPA). The QPA is the basis for determining individual cost sharing for services covered by the No Surprises Act.

Qualifying Payment Amount

"QPA is thorny," stated attorney Danielle Tangorre, JD, Partner at **Robinson & Cole LLP** in Albany, New York. "The government and the Texas Medical Association have taken very different approaches to interpretation of the statute regarding QPA. Part of the issue from the Texas Medical Association's perspective—which represents the providers—is that the QPA can be an amorphous number that is hard to judge because a lot of the data used to calculate it is held only by the insurance companies."

On Aug. 24, Judge Jeremy Kernodle in the **U.S. District Court for the Eastern District of Texas** struck down parts of the government's interim final rule that dealt with QPA calculation.

The No Surprises Act requires insurers to determine the QPA based on contracted rates for the same or a similar service that is delivered by a provider in the same or similar specialty and in the geographic region in which the service is furnished.

'Contracted Rates' Dispute

"But, plaintiffs complain, the departments interpreted 'contracted rates' in the July [2021] rule broadly to allow insurers to include 'ghost rates' in calculating the QPA—rates for items or services that providers have no intention to provide," Kernodle wrote. "The court agrees with plaintiffs that the departments' interpretation of the July rule conflicts with the act in this respect."

The federal judge vacated these provisions and remanded them back to CMS for further consideration. However, he upheld a provision on what information insurers must disclose concerning their QPA calculations.

Meanwhile, on Aug. 3, Kernodle ruled that HHS had improperly bypassed public-notice-and-comment requirements when it increased fees for arbitration hearings under the No Surprises Act. *(See TDR, "Federal Arbitration Fees Struck Down by Court," Aug. 21, 2023.)*

The **Centers for Medicare and Medicaid Services** (CMS) then largely suspended IDRs while it works to make the changes required to comply with Kernodle's rulings.

Johnson noted that clinical laboratories that are considering IDR should keep records of their progress despite the CMS suspension. "We are confident the IDR process will eventually come back," she explained.

Early Decisions Set the Stage

Two earlier decisions Kernodle made included:

- In February 2022, the court vacated a small portion of IDR provisions in the interim rule that put more weight behind the QPA than six other criteria listed in the statute. *(See TDR, "Judge Vacates Provision in No Surprises Act," April 4, 2022.)* The government later released a final rule implementing QPA and IDR in August 2022.
- In February 2023, Kernodle vacated parts of the final rule. He determined that the final rule still too heavily relied on the QPA at the expense of other factors.

"Healthcare providers already believed that the Qualifying Payment Amount should not be considered when determining the amounts that providers receive for out-of-network services, and then the federal departments implementing the No Surprises Act doubled down on the importance of the QPA," noted attorney John Barnes, JD, a Partner at Davis Wright Tremaine in San Franciso.

"What prompted these lawsuits is the departments' attempt to favor the QPA over other factors that have equal footing within the No Surprises Act," he added.

Use of Independent Dispute Resolution Process Leads to Substantial Number of Arbitrations

PASSED IN 2020 AND MADE EFFECTIVE AS OF JAN. 1, 2022, the No Surprises Act was intended to prevent out-of-network providers from balance billing patients for emergency and non-emergency services provided at an in-network provider.

It was a response to patients complaining after they received out-of-network treatment without their knowledge, and who then got large bills for the amounts not covered by their health insurers. Those unexpected bills are part of the balance billing problem where providers (often hospital-based ER physicians, radiologists, and pathologists) bill patients for amounts that were unpaid by the health insurer.

The No Surprises Act has language that requires a patient's insurer and the out-of-network provider to negotiate a fee for the service. In cases where they cannot agree, there is an independent dispute resolution (IDR) process that they can use to resolve the dispute.

It is this IDR process that is the subject of court action by providers. *360Dx* reported that demand for IDR arbitrations greatly exceeded predictions made by the Centers for Medicare and Medical Services (CMS) when it drafted the rule.

According to *360Dx*, CMS reported that the number of disputes had exceeded 75,000 for the third quarter of 2022. In response to this, CMS increased the arbitration fee from $50 to $350. That created a new problem, because many of the claims under dispute are for clinical laboratory tests with a price less than the $350 arbitration fee.

Many Lab Test Disputes

"Of the top 50 CPT codes most frequently submitted for dispute, 11 are lab tests, and only one—a multiplexed molecular respiratory panel—has a payment rate under the 2023 Medicare Clinical Laboratory Fee Schedule ($416.78) that exceeds the new $350 dispute filing fee. In fact, none of the remaining 10 codes have CLFS reimbursement levels exceeding $50, with the majority of those codes reimbursed at under $10," *360Dx* wrote.

CMS reported that 66% of all disputes were for emergency services. Lab testing represented 5% of disputes, compared to radiology (9%), anesthesia (7%), and surgery (5%). Because health insurers continue to narrow their provider networks, out-of-network surprise billing disputes may continue to be a problem.

Meanwhile, Johnson observed Kernodle's 2022 decision provided the foundation for the other rulings.

"Specifically, a particular district court signaled that—in reviewing challenges to No Surprises Act regulations—it was going to require strict adherence to the language of the No Surprises Act rather than deferring to government interpretation in rulemaking," she said.

Tangorre reminded clinical lab managers and pathologists that the No Surprises Act does not apply to all diagnostic testing, which is an important delineation.

"There are discrete circumstances where laboratories are impacted by the No Surprises Act," she said. "If a lab gets referrals from a hospital or an urgent care center, then the lab needs to be following the No Surprises Act.

"But if a lab gets its referrals from a doctor's office or substance abuse facility, for example, the majority of the No Surprises Act doesn't apply," she added. TDR

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IVD and Lab Consolidation Reduces Choices for Labs

➤Three decades of IVDs buying IVDs, labs buying labs, has steadily concentrated economic power

Robert L. Michel

➤➤CEO SUMMARY: Since the launch of THE DARK REPORT IN 1995, consolidation of hospitals, physician groups, clinical labs, pathology groups, and IVD manufacturers has been a major trend every year. Today, that consolidation has handed unprecedented economic power to the nation's two multi-billion-dollar lab corporations and to the IVD manufacturers who sell them automation, analyzers, and tests.

by Robert L. Michel

FOR THE PAST THREE DECADES, CONSOLIDATION has been the sustaining, powerful market trend in three primary areas of laboratory medicine: clinical labs, anatomic pathology groups, and *in vitro* diagnostic (IVD) companies.

The economics of consolidation are compelling. Over the past 30 years, economics are the single most important reason why consolidation continued as a dominant force in reshaping many aspects of diagnostics and laboratory medicine.

➤30 Years of Consolidation

Since its founding in 1995, THE DARK REPORT has tracked consolidation as both a transformational and a powerful market dynamic in all three sectors of laboratory medicine. This intelligence briefing continues that tradition. It describes a new aspect in the diagnostics marketplace that is a direct consequence of this trend.

Because of consolidation, the clinical lab marketplace is now dominated by a new factor influencing the way lab analyzers, automation, and tests are *sold* by the manufacturers and *purchased* by clinical and pathology laboratories. This new dynamic is driving both sides of the IVD seller/lab buyer equation.

Today's new dynamic in the lab testing marketplace is a consequence of **Labcorp** and **Quest Diagnostics** gobbling up literally any independent general testing lab company of size over the past 35 years. With 2022 sales of $9.2 billion (diagnostics business) at Labcorp and $9.9 billion at Quest Diagnostics, these two companies are the behemoths in today's clinical lab marketplace.

The next two largest public clinical lab companies in the United States are **Sonic Healthcare USA** (2022 sales of US$1.4 billion) and **BioReference Laboratories**, (2022 sales of about $755.6 million), a division of **OPKO, Inc.**

This shows that Labcorp and Quest are each almost ten times the revenue and testing volumes of their next biggest competitors! It also means that they have the biggest economies of scale of any lab company, both within the United States and across the globe.

One competitive advantage from the huge volumes of tests that flow through

the two blood brothers every year is it enables them to offer the lab industry's lowest prices to health insurers, particularly for high-volume, routine tests. At the same time, the high volume of tests performed at Labcorp and Quest also gives them unprecedented buying power with the IVD manufacturers.

This is the new market dynamic that I want to describe for you today. It has two consequences. On one hand, the huge purchasing power of the two blood brothers is changing the ability of individual IVD manufacturers to compete across all sectors of clinical laboratory testing.

On the other hand, with growing frequency, it means that those IVD companies that don't have sizeable contracts with the two blood brothers cannot offer fully-competitive prices to all other labs—whether these labs are large or small buyers of analyzers and tests.

Purchasing Clout of Big Labs

Simply stated, the huge volumes of routine tests run at the two blood brothers give them purchasing clout. They can demand that IVD companies give them rock-bottom prices for instruments, test kits, and reagents.

In return, the IVD vendor gets to manufacture a high volume of products for the client blood brother. That gives the IVD vendor its own economies of scale. It can now undersell its IVD competitors for that category of the instruments and tests.

In this fashion, it means that the two blood brothers are picking "winners" among those IVD companies that capture these contracts. First, the IVD company with the blood brother contract enjoys the revenue generated from that billion-dollar lab customer. Second, that IVD company now has the economies of scale for those instruments, tests, and reagents, enabling them to undersell its IVD competitors.

Third, it means that hospital and health system labs—already under severe financial pressure—cannot justify paying a premium to buy another IVD company's products. Simple economics argues that the low-price IVD leader will gain market share. Again, that IVD leader has competitive advantage as a direct result of its contracts with either or both Labcorp and Quest Diagnostics.

Economies of Scale Example

Here's an example to illustrate this new market dynamic. Imagine that Labcorp gave **Sysmex** an exclusive contract to provide hematology automation, instruments, test kits, and reagents for all its labs across the nation. Sysmex can now manufacture with very high volumes. The resulting economies of scale give it the lowest production cost of any other manufacturer of hematology products.

Now Sysmex can go into the market with confidence that it can underbid the **Roches**, **Abbotts**, **Siemens**, etc. for hematology products, regardless of whether it is a major 20-hospital health system laboratory or a 300-bed tertiary care center.

In this fashion, Labcorp and Quest may be selecting the winners in the IVD industry. Their purchasing decisions give winning IVD firms the economies of scale they need to squeeze down prices, thereby enabling them to increase market share across the entire lab industry.

Fewer Competitive Bids

At the same time, hospital and health system laboratories will find it more difficult to get truly competitive bids from multiple IVD suppliers, as they have in past years. As noted earlier, health system labs are under extreme financial pressure. They no longer have the luxury of purchasing higher-priced IVD products because their clinical pathologist wants "best of class" in the lab.

Based on future comments about this new market trend from both IVD executives and senior lab executives, THE DARK REPORT will provide additional analysis and recommendations. TDR

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Don't Automate Bad Work Processes in Microbiology

Labs should focus first on process improvement, then evaluate whether automated instruments are next step

Anne Beall

CEO SUMMARY: Automation is not always right for every lab's microbiology department, according to consultants from bioMérieux. When evaluating automated instruments, it is necessary to review work flow and manual processes in microbiology to identify inefficiencies. Once those are addressed, automation may be a logical next step.

Angie Myers

IT'S OFTEN ASSUMED BY CLINICAL LABORATORY LEADERS in the microbiology department that automation will improve workflows and increase efficiencies. In the best of cases, that is true.

However, when a microbiology lab operates with poor or inefficient work processes, that becomes a stumbling block that automation on its own cannot overcome. "If microbiology goes full out with automation without looking at processes, the lab will just throw a lot of capital at a bad process," observed Anne Beall, Senior Director of Lab Consultancy at *in vitro* diagnostics company **bioMérieux** based in Marcy-l'Étoile, France. "In such cases, adding automation could leave the microbiology lab with a very expensive bad process."

The lab consultancy group at bioMérieux helps clients streamline and optimize their processes for microbiology, with automation as a potential solution. Laboratory managers should consider the observations from Beall and her team regarding automation in microbiology, particularly given the expense of installing the technology.

A return on investment for automation is not a guarantee if inefficient workflows and work processes are not corrected first.

Teams evaluating automation for microbiology—and even other departments within the lab—should early on ask this key question: Do the department's existing workflows and processes contribute to waste and inefficiency?

Measuring Work Processes

"My experience is that lab professionals don't necessarily know that they have a poor process because not many work proceses are measured in microbiology," Beall told THE DARK REPORT. "They might measure things like turnaround time for stat Gram stains or blood culture contamination rates, but other than that, there are very few things that are measured in microbiology.

"Compare that to a routine chemistry laboratory," she continued. "A chemistry laboratory measures turnaround time, for example, for the emergency room. They expect a stat to take less than 60 minutes

from the time they receive it to the time they report the results. And chemistry and hematology have been monitoring these kinds of turnaround times for a long time because of the demand from the emergency room.

"However, in microbiology, there's not a huge demand for stat testing," Beall added. "The science of microbiology centers on the fact that the organism has to be grown on a culture media surface, and then it has to go through incubation for identification or susceptibility testing."

Incubation Variances

There are plenty of wasteful and inefficient activities in microbiology. "In microbiology, the cadence has been established that the lab receives a sample and at best, it will give physicians a preliminary result the next day," she said. "There's loosely a 24-hour cadence in microbiology.

"However, the common disconnect is an incubation period is 18 to 24 hours," she observed. "If a sample is received at 7 a.m., and it's stuck in the incubator at 8 a.m., 18 hours later is 2 a.m. the next day. But no one's there to read the culture, so the sample sits in the incubator. That's over-incubation."

A similar situation can occur if a sample goes in at 8 p.m. Microbiology staff arriving for the morning shift may pull those specimens out at 6 a.m., well short of the 18-hour incubation window.

"It's bad practice," Beall contended. "At bioMérieux, we have statistics that show more than 50% of microbiology cultures are too old, which means they've had more than 24 hours of incubation, or they're too young, which means they've had less than 18 hours of incubation.

"One of the most important things a microbiology lab can do to change a bad process is to make sure staff read cultures at the right time," she said. "It has to be based on when the lab is getting and processing samples."

Urine cultures can also lead to clinical laboratory inefficiencies.

Urine Culture Reads

"We've gone into labs that conduct an enumeration of urine culture counts," said Angie Myers, Strategic Account Director for the Vitek Reveal product line at bioMérieux and former Manager of Lab Consultancy at the company. "They will count every single colony-forming unit and spend time counting 99 colonies, 52 colonies, or 19 colonies, instead of having groupings of zero to 10, 10 to 25, and 25 to 50.

"At the end of the day, anything less than 50 is probably not going to be treated, but anything 50 and above for a pure culture will be treated," Myers noted. "So, some labs will spend twice as much time on counting simply because their policy is to count every single colony, which is an inefficient practice."

Simple Fixes to Start

In the above examples of incubation time and urine culture counts, relatively simple adjustments to the work process can bring about positive changes, all without automation.

"The first fix is really understanding when samples are coming in so that the lab can look at how it will handle reading those cultures at that 18-hour sweet spot," Beall said. "Is there enough staff available to read those cultures? If microbiology receives and processes samples 24/7, then it needs staffing to perform the downstream culture reads 24/7. Or alternatively, the lab needs to adjust what samples it processes 24/7 to reflect what's most important to the clinicians."

Aspects of this approach are influenced by Lean Six Sigma learnings, which promote the elimination of waste and inefficiencies as part of continuous improvement. *(See TDR, "Lean Is Smart Approach to Major Lab Cost Savings," Sept. 19, 2022.)*

Micro Automation Can Ease Stress for Overworked Staff

It may be tempting for clinical laboratories to equate automation with a chance to reduce full-time equivalents (FTEs), but given the staffing shortage affecting the lab industry, that notion is not realistic.

"We try not to put things into FTE perspective because we know there are no FTEs to save with automation, given lab staffing shortages," said Anne Beall, Senior Director of Lab Consultancy at bioMérieux. "But you can offset time savings to another function. For example, an automated streaking instrument saves a lot of hands-on time.

"Recently, at a lab we worked with, there were two staff members each working eight-hour days streaking urine cultures, plus they had to do overtime," Beall added. "Combined, those two people were probably working 20-plus hours a day streaking urine cultures. That lab was able to reduce that number significantly through automation. The lab was done streaking by 11 in the morning."

In that situation, the time savings resulted in elimination of overtime for streaking and freed up the two staff members to handle other tasks during their regular shifts.

"When we do process improvement projects, we actually start the week with a brief overview of Lean Six Sigma training for the client team because we want them to step back and look at their processes from a different perspective," Myers said. "Many times, labs don't ever question their processes unless they're given a Lean lens and the opportunity to make changes."

Where Automation Fits In

All that said, there are situations where automation will indeed improve a microbiology process. There is no hard line that a lab crosses to justify an automated approach, but there are some telltale characteristics, such as a willingness to expand operations beyond one shift.

"It's case by case," Myers said. "If microbiology is considering a full line of **BD** Kiestra or **Copan** WASPLab, but the lab doesn't intend to operate more than a day shift for eight hours, that lab may not get the full benefits from investing in automation.

"It's a waste of money because the lab won't reap the benefits that automation provides," she continued. "Instead, the lab could just revise its processes without any automation. However, if the lab is willing to at least expand to a second shift for processing, reading of cultures, and sending out final results, then that's where automation can help."

Automating Urine Cultures

Urine cultures that have a solid manual process for streaking and reading can be good candidates for automation if the volumes permit it. "Urine cultures come in large batches, and the techs sit under the hood and streak out these urine cultures," Myers noted. "But labs will also have some specimens that require manual processing. So, an ideal situation is for automation to free up tech time for them to work with those more difficult specimens under the hood.

"All of the standard activities—such as swabs—will now go on automation," she added. "The specimens will all have the same streaking pattern. That type of standardization is helpful. Then, when the techs read the cultures the next day, that streaking pattern is going to look the same on every single plate because it didn't involve a human who got tired the day before doing their 60th streak in an hour."

In conclusion, microbiology labs may be interested in automated instruments, particularly if they perceive that activities, such as culture reads, take too long or that labor shortages affect productivity.

"Automation will not be a solution for everything," Myers said. "Lab managers may have staffing issues, but automating a bad process is not going to fix those problems. The first step is to improve a process and then think about automation as a next step."

Lean Six Sigma principles can play an important role in uncovering process flaws in microbiology, Beall said.

"The best approach is to identify the waste, eliminate it, and fix the problems," she explained. "Clinical labs should make sure those solutions are efficient before they go to automation. Then laboratories have a better understanding of what additional gains they can achieve with automation.

"From there, labs can then decide whether it's worth an investment in automation," Beall added.

Two Evaluations to Consider

Since the arrival of the first significant lab automation solutions in 1997, THE DARK REPORT has noted the opportunities and advantages automation brings to clinical diagnostics.

In these years since since then, it became clear that automation is a double-edged sword of sorts: Yes, it can improve efficiencies in the lab, but only if solid processes are already in place. Otherwise, as Beall and Myers point out, installing the technology can become an expensive dead end.

For microbiology laboratories that are considering automation, the path forward relies on two evaluations: 1) Do existing manual microbiology processes deliver proper turnaround times for tests? 2) If yes, will automation enhance those processes and free up staff time?

Answers to those questions should provide clear guidance for labs. TDR

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Indicators of Success with Micro Automation

BIOMÉRIEUX has gathered statistics that indicate the level of improvement automation can bring:

MICROBIOLOGY INCUBATION. "We've seen examples where labs that run a day shift operation read only 50% to 60% of their cultures at the right time," said Angie Myers, Strategic Account Director. "Once we put a new process into place or automation—both of which force right-time reading—100% of the cultures are read at the right time."

URINE CULTURES. "With bad processes, we've seen positive urine culture turnaround times of 72 hours," Myers recalled. "After process improvement and automation, microbiology labs can achieve a 32-to-35-hour turnaround time for a positive urine culture if they read cultures around the clock and release those results immediately."

BLOOD CULTURES. "For laboratories not using a good process for blood cultures, their negative blood culture turnaround time will be anywhere from 122 hours to sometimes 136 hours," said Anne Beall, Senior Director of Lab Consultancy. "That's almost a half day longer than they should be and is because the lab has a manual process and the results wait for somebody to be available.

"When that process is fully automated, all negative blood cultures have a turnaround time of 120 hours, with no variability," she added. "And for positive blood cultures, with automation, 52 to 56 hours would be a good turnaround time.

"In all of these cases, automation is able to take advantage of a large volume of specimens coming through microbiology, which is an important starting factor," Beall noted.

With Medicare Advantage payers, clinical labs can be paid for adding value

Lab Data Crucial to Insurer Risk Adjustment Models

Teofilo Borunda Duque, PharmD

Rick VanNess

CEO SUMMARY: Payers who use risk adjustment models as part of Medicare Advantage need diagnostic data that helps them document ICD-10 diagnoses that earn them higher premium payments for sicker patients. Clinical labs have lab test data that can identify undiagnosed disease and share in the higher risk-adjusted payments.

In transitioning from fee-for-service models to value-based care, savvy medical laboratory leaders are looking for ways to get paid based on the value lab services provide to patient care. Diagnostic data is one of the prime avenues to demonstrate such value.

An area that few lab leaders have thought about is how their test results may be of use to payers operating **Medicare Advantage** plans. Such data can help payers increase their risk adjustment rates, which are a hallmark of Medicare Advantage plans.

"Not many clinical lab managers know about the risk adjustment model," said Teofilo Borunda Duque, PharmD, MS, Clinical Innovations Specialist at **Rhodes Group** in Albuquerque, New Mexico. "And those lab managers who do know about it may not understand the strategy necessary for their labs to penetrate that market."

Rhodes Group is a data analytics and technology company owned by **TriCore**, a regional lab and research organization.

Through laboratory data obtained from TriCore, Rhodes Group has developed algorithms that examine diagnostic data that may benefit risk adjustment efforts. Clinical laboratories that offer such information can quickly raise their value in the eyes of payers. "This is definitely a business model that can help labs transition out of the fee-for-service environment while bringing additional revenue to the laboratory," Borunda observed.

Clinical Lab 2.0 Opportunity

TriCore Laboratories and its Rhodes Group division are national leaders in the Clinical Lab 2.0 movement. TriCore is a founding member of the **Project Santa Fe Foundation**, founded in 2016 by forward-looking lab leaders from five major health system laboratories.

They recognized that the current lab model—Lab 1.0—emphasizes reporting accurate and reproducible lab test results while using economies of scale to lower the average cost per test. But payment for Lab 1.0 services is fee-for-service and payers price tests as a commodity.

By contrast, Clinical Lab 2.0 uses Lab 1.0 as its foundation (accurate, reproducible results and a huge pool of patient test data). It combines this lab test data with other patient data, demographics, and regional data to create insights that physicians and payers can use to close care gaps, identify patients with undiagnosed chronic conditions (think diabetes and chronic kidney disease, for example), and patients at risk for an acute episode.

Actionable Clinical Intelligence

This is the secret behind Clinical Lab 2.0. The lab now can provide actionable clinical intelligence that health insurers and physicians can use to improve patient outcomes while lowering the cost of care. Importantly, the lab can be paid for this actionable intelligence, thus creating a new and substantial source of revenue. It also makes the lab a valued clinical partner in the ongoing diagnosis and management of individual patients and pools of patients. *(See TDR, "Message to Labs: Improve Outcomes, Get Paid More Money!", June 5, 2017.)*

Medicare Advantage is the opportunity for labs to benefit from providing Clinical Lab 2.0 services because the **Centers for Medicare and Medicaid Services** (CMS) pays each Medicare Advantage organization a monthly premium for each beneficiary enrolled in its health plan. The per person amount is adjusted to account for differences in health status among enrolled beneficiaries, according to CMS. This is referred to as "risk adjustment," and the approach uses hierarchical condition category coding to calculate risk scores for patients.

Broadly speaking, Medicare Advantage plans that disproportionately enroll the sickest patients will be paid more per month than if they had enrolled beneficiaries with average health risks. Viewed another way, risk adjustment focuses on the idea that sicker patients will require more spending to treat their illnesses.

"With healthcare moving into a more value-based care approach, payers are no longer allowed to deny coverage for their patients," Borunda said. "So, payers must enroll patients regardless of the clinical risk. This can put a strain on payers. It is difficult for payers to take patients who may be at higher risk, because at the end of the day, those patients may be more costly.

"Therefore, CMS created the risk adjustment model that compensates payers for covering these patients," he continued. "It is an incentive for payers to take patients, no matter the risk. Depending on the risk—and the estimate of how costly a patient's care will be for the following year—payers may get a higher premium payment per month from Medicare for that at-risk patient. Risk isn't the only consideration. The model

Algorithm Does Not Predict Disease

Rhodes Group's algorithms do not predict that a patient has a certain condition. Rather, the algorithms explore different data points—such as from lab tests results, clinical care guidelines, and clinical studies—that may indicate high-risk conditions.

"That's why we say it's 'highly suspected' that a person has a condition," said Teofilo Borunda Duque, PharmD, MS, Clinical Innovations Specialist. "It's based on the patient's laboratory history, what lab tests were ordered at what time, and even some intervals in between them. We even look at the primary literature to identify what are the important lab tests to monitor in a patient, whether it is for a condition or the drug therapy they're on."

It's up to payers and ultimately physicians, when presented with this information, to follow up with patients and verify any suspected disease or illness.

"We are not predicting anything," cautioned Rick VanNess, Director of Product Development. "Clinical guidelines state, for example, that if your hemoglobin level is less than 12 and you're female, that's the definition of anemia. We're simply following what each state uses for diagnosis in our algorithm, which under similar circumstances would indicate that a patient was highly suspect for anemia."

also considers the patient's demographics, such as age and gender.

"For example, a patient with diabetes and complications receives a higher risk score than a diabetic patient without complications," Borunda explained. "A patient with complications typically receives a higher premium payment through the risk adjustment model."

Rick VanNess, Director of Product Development at Rhodes Group, who leads the company's analytics team, said Medicare Advantage pays insurance plans roughly $1,000 per month per member.

"But an insurance company may have a patient with diabetes and related complications, and care for that patient is going to cost more than $1,000 per month, he noted. "Before granting that higher monthly premium, CMS requires the insurer to prove that the patient has a condition and is sicker than the normal person. Once the insurer documents the higher acuity, CMS will pay more under the risk adjustment model."

Risk Adjustment Visits

The risk adjustment model also requires payers to schedule patients for a risk adjustment visit annually to close care gaps. This step ensures that riskier patients receive treatments they need in a given calendar year.

"If a payer has 10 patients with diabetes and complications, but the payer only manages nine of those patients during the calendar year, then CMS is going to only pay for those nine cases under the risk adjustment model," Borunda said. "It is in the payer's best interest to have a good understanding of what the patient population looks like for early and timely visits. And this is where laboratory data is essential for the health insurers."

There are three notable areas where a clinical laboratory can provide diagnostic data that supports risk adjustment models:

- Lab data can identify patients suspected of a disease.
- Labs can provide this information quickly.
- Lab records follow a patient if that person changes physicians or clinics.

Rhodes Group has developed software that improves risk identification for payers based on clinical lab data.

Rhodes Group saw a need for these algorithms because, at times, health complications are unknown by clinicians.

"Claims data is subject to human error," Borunda said. "If a patient sees his doctor for diabetes, but it turns out that he also has chronic kidney disease, the payer may never know about the chronic kidney disease if the doctor didn't code for it, even if the condition was treated. But a physician's diagnosis uses laboratory data, which is key.

"Rhodes Group attested these algorithms with a small New Mexico payer and interpreted its members' laboratory data to identify certain conditions," he added. "The algorithms may note that—based on lab data—a patient is suspect for chronic kidney disease. This can then be verified by a physician."

Borunda and VanNess emphasized that the algorithms do not predict a disease, but instead suggest a condition is likely based on data points. *(See the sidebar on page 14 for more on this aspect.)*

Timely Information

To capitalize on risk adjustment models, payers need to quickly identify at-risk patients and get their conditions treated. Clinical labs can help in this regard.

"With most test results, the lab has them within a couple of days," Borunda noted. "Once the result is in the data warehouse of the laboratory, Rhodes Group's algorithms automatically interpret the data and assign whether the patient is highly suspect for a certain condition. That provides timely insight to the payer.

"Remember, the risk adjustment models require payers to meet with at-risk patients during a calendar year," he added. "If a payer is reviewing claims data to identify those patients, then being optimistic, a typical claims review could lead to a crucial delay of three months, or sometimes even more, before that at-risk patient is seen for the suspect condition.

"Whereas, using our approach, lab test data is automatically fed to the payer such that the payer quickly knows a patient is suspected of a condition," he said.

Lab Test Data Provides New Revenue Path

OBSERVANT LABORATORY LEADERS WILL NOTE A CONSPICUOUS THEME of how diagnostic test data and results can provide a new revenue opportunities for clinical laboratories.

For example, this growing trend played out during this past April's *Executive War College on Diagnostics, Clinical Laboratory, and Pathology Management*.

Corralling and analyzing the ever-increasing volume of diagnostic data that genetic testing produces should be a high priority for clinical laboratories, said William Morice II, MD, PhD, CEO and President of **Mayo Clinic Laboratories**.

"There will be an increased focus on getting information within the laboratory … for areas such as genomics and proteomics," Morice told a general session audience at the *Executive War College*.

As our main story notes, Medicare Advantage arrangements can benefit a laboratory's bottom line, too.

"As fee-for-service models end, clinical laboratories must be looking forward because they can be paid for the value they originate that makes a difference in patient care," noted Robert Michel, Editor-in-Chief of *The Dark Report* and Founder of the *Executive War College*, during his opening keynote address.

"Lab leaders should be studying Medicare Advantage for how to integrate associated incentives into their lab strategies," he added.

"Medicare Advantage highlights the new influence of risk adjustment models, which use diagnostic data to predict health condition expenditures and from which clinical laboratories can derive new revenue," Michel said.

"Rhodes Group can tell payers in real time how their patient population is changing based on laboratory data."

The New Mexico payer that Rhodes Group worked with received a monthly report of suspected at-risk patients. "From there, the payer could verify whether the patient should have been coded for an at-risk condition on the claim," Borunda noted. "That lab data is a catalyst for a payer to ensure the patients have the necessary claims codes for risk adjustment."

Longitudinal Records

Rhodes Group's approach capitalizes on the idea that a patient's lab records will follow the patient for years, if not most of their lives.

"Lab data is longitudinal in nature," Borunda explained. "Patients can change payers, they can change physicians, but if they use a laboratory system, that lab likely will have history on these patients. With Rhodes Group's algorithms, we can tell payers, 'You have a new patient enrolled, and by the way, did you know that the patient is highly suspect for chronic kidney disease?'"

Rick VanNess

➤"Helping a payer with risk adjustment data is a way to show others that lab testing is more than an ancillary commodity service."

"That's useful information to a payer, "he continued. "And at least in New Mexico, payers are entitled to three years of the data before new member enrollment. Rhodes Group can analyze longitudinal lab records for those enrollments and explain to a payer that X amount of their members this month have suspected at-risk conditions. Knowing that information can help a payer plan its risk adjustment visits for a given year, to ensure it addresses suspected at-risk conditions so that the payer gets the most appropriate payment per member per month from risk adjustment," he said. "It's similar to giving a targeted intervention on suspected at-risk patients."

Benefits to the Lab

Clearly, having access to lab data helps a payer that is tracking Medicare Advantage patients and seeking risk adjustment when appropriate. For a clinical laboratory or pathology group, providing that data is also beneficial, but in a different way.

"Helping a payer with risk adjustment data is an approach that demonstrates to others that lab testing is more than an ancillary commodity service," VanNess said. "The lab knows the patient has a condition and uses that information in a more valuable way to inform the payer.

"A lab can perform a hemoglobin A1C test for diabetes for $9 on the Clinical Laboratory Fee Schedule, but that $9 might be worth $1,200 in risk adjustment," he added. "So, if a lab helps a payer with risk adjustment, that A1C test is more valuable than what the Clinical Lab Fee Schedule says. Therefore, the lab should get a piece of that $1,200 risk adjustment."

Here's an example from a partnership Rhodes Group has with a payer in which approximately 7,000 Medicare Advantage members received lab testing of some sort through TriCore. Among the surprising findings was that—out of 667 patients verified with diabetes—the payer did not know that 383 had the condition until the information was presented via TriCore lab data from Rhodes Group analytics.

Risk Adjustment Premium

That increase of 135% in the number of documented patients with diabetes triggered increased risk adjustment premium of more than $1 million to this payer for the additional diagnoses.

"The moment a clinical lab goes outside its four walls and asks for 10% of that risk adjustment, for example, that lab starts generating revenue from the value

of its data," VanNess observed. "It gets more value out of the lab tests it runs. This is the future. Lab administrators and pathologists understand that cutting costs by negotiating better reagent costs or accepting reduced operating margins is no longer a viable way forward."

More Value from Labs

As *The Dark Report* has noted in recent months, increasing a lab's revenue does not always simply mean adding more tests to a menu. Today, the opportunity to earn more revenue by providing more value comes from reexamining existing business partnerships.

"There is potential for clinical labs to add more value and be paid for that value," VanNess said. "If a payer creates a preferred laboratory network for Medicare Advantage, it may ask labs to prove their value if they want to be in that network.

"And in response, a smart lab will note that an A1C test helps document a diagnosis of diabetes. In turn, that results in a $1,200 risk adjustment payment for a payer," he said. "This illustrates the lab's value to a preferred network where the lab is testing 1,000 patients every month in that payer's Medicare Advantage plan."

Getting Paid for Adding Value

The team at Rhodes Group is demonstrating that clinical laboratories have the capability today to contribute more value in patient care and be paid for that additional value. This is consistent with the concept of Clinical Lab 2.0.

Best of all, the fast growth in Medicare Advantage plans creates the opportunity for a lab to show a health insurer how the lab can identify specific patients with undiagnosed chronic conditions, thus enabling the payer to document those conditions and receive the higher, risk-adjusted premiums for these patients. TDR

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Clinical Labs Ready to Take Next Step

IT IS POSSIBLE FOR CLINICAL LABORATORIES TO CREATE THEIR OWN ANALYTICS to provide to payers who are working with Medicare Advantage patients. But doing so takes effort and resources.

"A clinical laboratory interested in providing analytics to payers would need subject matter experts who could help develop the needed algorithms, as well as somebody who knows the data and knows how to structure it," said Teofilo Borunda Duque, PharmD, MS, Clinical Innovations Specialist at Rhodes Group.

"Another factor that is very important is the relationship with the stakeholders and the payers," he continued. "Decision-makers need to be at the table with the lab discussing how risk adjustment could be done. That was integral in the development of the algorithms by Rhodes Group. We had an idea of what conditions to focus on, but we also had early engagement with the payer we piloted this within New Mexico."

In Rhodes Group's case, having those early discussions helped outline what the payer needed in terms of lab data, which guided the partnership.

"As we developed our product, we consulted with pathologists given they are the experts in laboratory medicine," he said. "And we also used pharmacists, who we see as chronic disease management experts. Most of the chronic conditions that you see in hierarchical condition category codes are managed with medications. It's helpful to have a pharmacist at the table."

THE DARK REPORT has previously noted that placing pharmacists in clinical labs can close patient care gaps. *(See TDR, "New Lab, Pathology Trends at Executive War College 2021," Nov. 8, 2021.)*

Virchow
Medicine ➤ Money ➤ Managed Care

This column is named after the famous German pathologist, Rudolf Virchow (1821-1903), and it presents opinions and intelligence about managed care companies and their laboratory test contracting practices.

Private Health Insurers Are Aware of Problems with CPT Code 81408

EDITOR'S NOTE: Our new column, Virchow, is written by anonymous insiders working within the managed care world. The column aims to help clients of THE DARK REPORT better understand the decisions, policies, and actions of payers as they manage their laboratory networks, establish coverage guidelines, process lab test claims, and audit labs.

RECENTLY, THE DARK REPORT detailed an audit from the **U.S. Department of Health and Human Services' Office of Inspector General** (OIG) regarding pathology billing code 81408.

The audit concluded that up to $888.2 million in **Medicare** payments made under Current Procedural Terminology (CPT) 81408 were at risk of improper payment from 2018 through 2021. *(See TDR, "OIG: Billing Code 81408 Is at 'Risk of Improper Payment,'" July 31, 2023.)*

➤ Problems with CPT 81408?

An OIG report of this type will get the attention of private payers. I imagine most payers were aware of the problem with 81408. However, I don't think they realized it was almost a $1 billion problem just for the Medicare Program!

Today, I am going to explain what commercial health plans already knew about CPT code 81408 and the difficulty payers have with genetic testing claims. To understand the problems with 81408, we need to go back to what seems like ancient times in 2013, which was when genetic testing started to explode.

Many providers were stacking genetic test panels, and in response the Medicare Program said, "OK, we're going to put these tests in categories to stop this code stacking." *(See the sidebar on page 20 for more details about code stacking.)*

At this time, the **Centers for Medicare and Medicaid Services** (CMS) categorized lab test codes as follows:

- Tier 1 molecular pathology procedures (MPP) codes, which are CPT codes 81105 through 81364. These codes are for single-analyte tests.
- Tier 2 MPP codes, which are 81400 through 81408 (the latter number being the CPT code on the hot seat right now). These codes are largely for rare childhood disease tests.
- Proprietary Laboratory Analyses (PLA) codes, which are 0001U through 0241U. These codes allow labs and manufacturers to specifically identify their tests.
- Multianalyte Assays with Algorithmic Analysis (MAAA) codes, which are 81490 through 81599 in conjunction with 0002M through 0016M. These codes refer to tests that combine results from two or more molecular biomarkers into a risk-based algorithm.
- Genomic Sequencing Procedure (GSP) codes, which are 81410 through

81470. The codes are for DNA or RNA sequence analysis that simultaneously test multiple genes.

- Finally, unlisted molecular pathology procedures fall under code 81479.

Payers were aware of some of the early problems with 81408 back in 2013. The OIG's review window—which was from 2018 through 2021—took into account the changes made in 2013.

Rare Disease Focus

CPT code 81408 generally addresses tests for rare childhood diseases, such as Stargardt disease or Usher syndrome. It's easy to see from the OIG's perspective why the overpayments are concerning, given that most Medicare patients are 65 years or older and thus not suddenly the victim of a rare childhood illness. A child with a rare disease could in some cases be covered by **Medicare Advantage**, but the percentage of those cases is miniscule.

So, generally, private payers—given they cover children under their commercial plans and possibly under Medicare Advantage—may have seen more legitimate use of 81408, but there should not have been a surge over the last several years. If a payer has noted a large volume of 81408 claims, That is a red flag because those claims should be low volume.

How MACs Fit In

The OIG report squarely aimed its criticism at CMS and Medicare Administrative Contractors (MACs). The OIG noted that five of the seven MACs had Local Coverage Article (LCA) guidance that limited the use of 81408; however, two MACs' LCAs did not limit its use.

Those LCA policies affect private payers who offer services for Medicare Advantage patients. MACs that have LCAs limiting 81408 need to put in edits that outline what they will and will not cover. But it's hard for the MACs to put in the appropriate edits because there is inadequate direction to guide labs for the certain diagnosis codes needed to claim 81408. It is simply not specific enough.

Because these CPT codes are so vague, genetic test claims remain a problem. This is what led to the use of Z-codes by some MACs and, recently, by at least one private payer, **UnitedHealthcare**.

Everybody likes to say the commercial plans don't want to pay claims. That's really not true. Before they pay a genetic test claim, health plans want to know what the test does and how it benefits the patient.

For example, the plans don't mind paying for a serious hereditary genetic disease in a child. Yes, the plan will have to pay $10,000 for the test, but the patient can't get the test more than once in their lifetime. So, plans want to know specifically that it is this child, it is this disease, and it is this diagnosis code.

Two MACs Raise Concerns

THE DARK REPORT noted that the two MACs that didn't have any LCAs about 81408 during the OIG audit window are largely believed to be **Novitas** and **First Coast Service Options** (FCSO).

The OIG said 97% of the potential overpayments for 81408 came from claims filed with Novitas and FCSO. Those two MACs subsequently added LCAs about 81408, according to the OIG.

The gossip is that these two MACs don't have the appropriate manpower to take care of what is needed to appropriately deal with these claims. I'm surprised that these two haven't been booted by CMS, given that CMS selects the MACs.

Furthermore, some genetic testing companies purposely chose to locate in states overseen by these MACs. For example, Texas is notorious in that regard, given the number of laboratory companies located there that have gotten into trouble with the OIG in recent years. It would not surprise me if unscrupulous labs in those regions took advantage of the vagueness of 81408 to file inflated claims for genetic testing.

Some of those lab owners figured they'd pocket millions of dollars from genetic testing. Then, by the time CMS or other payers figured it out, those owners planned to be on another continent living in million-dollar condos.

The COVID-19 public health emergency exacerbated all that because the pandemic gave disreputable lab firms greater cover from investigators. Medicare and payer resources were dealing with more pressing issues at the time.

No Established Relationships

The OIG was also critical of lab companies that performed genetic testing on patients that did not have established relationships with ordering providers, particularly in situations where telemedicine was involved.

There are some tests that a private citizen can order from a clinical laboratory on their own and for which they can pay out of pocket, such an HIV test. But genetic tests should not be performed without a doctor's order and that doctor should be either the patient's primary care physician or a specialist to whom the patient was referred.

A genetic test claimed under 81408 is not going to be ordered by general family practitioners. They're going to refer patients to a specialist if a rare childhood disease test is needed. It is also common in these situations for a genetic counselor to work with the physician and the patient to help with genetic test selection and results interpretation.

So, any clinical laboratory company that files a claim for 81408 after a patient only had a brief conversation with a random physician over the Internet will probably get flagged by a payer, especially given the strongly worded conclusions from the OIG.

To me, the big question stemming from the Office of Inspector General audit is: Did private payers separately overpay nearly a billion dollars for 81408 claims? Probably not that much, but it is likely they overpaid some amount.

CPT Code Stacking for Genetic Test Panels

WHEN GENETIC TESTING BECAME MORE PREVALENT 10 YEARS AGO, stacking was a problem. That term refers to the inclusion of dozens of individual CPT codes in a genetic testing panel, and in many cases, large numbers of those assays were not medically necessary.

In my experience, some CPT codes in a stacked panel were specific, others were vague, and a few were for diseases so rare there were no medical treatments. Labs were stacking all these genetic tests into a panel—maybe 20 to 30 tests at once—at $200 bucks a gene. But in reality, the provider only needed to know about three of those genes to treat a patient.

Most private payers picked up on the problem of stacking quickly and recognized the shenanigans of certain genetic testing companies.

Remember, lab contracts and fee schedules may be negotiated in a variety of ways:

- As a percentage of the current-year CMS rate,
- As a fee-for-service negotiated rate, or
- A combination of methodologies.

If a lab under a commercial plan is lucky, it gets 60% of what CMS pays—or it could be much less. If a genetic testing lab company filed a claim under 81408 in 2018 and it received $2,000 from Medicare, it maybe got $1,000 for that test from a private payer.

Thus, any overpayments for claims under 81408 to private payers were probably less than the $888 million Medicare may have overpaid, but the total could still have been significant for private payers.

In its report, the OIG recommended that CMS retroactively review 81408 claims. Private payers will probably go back and look, too, to see if they caught any overpayments. But payers never catch all of the overpayments—never. TDR

Payer Update

UHC Will Delay Enforcement of Z-code for Genetic Test Claims

Oct. 1 transition date is no longer listed on a reimbursement policy update, though compliance is urged

In the latest backpedal on its new policy, **UnitedHealthcare** (UHC) appears to have dropped its requirement for genetic testing laboratories to use Z-codes for claims under commercial health plans—for now.

Earlier, we reported that the enforcement date had moved from Aug. 1 to Oct. 1. Since then, the payer has changed language in its guidance to be vague while still encouraging Z-code compliance for incoming genetic test claims. According to a reimbursement policy update from UHC posted on Sept. 1, there is now no firm transition date for Z-codes.

"UnitedHealthcare is delaying the policy in order to allow additional time for providers to complete their molecular pathology test registrations for Z-codes on tests," the update stated. "The new policy date will be communicated in the network news prior to the publication of the policy."

Sources outside of UHC told The Dark Report that scuttlebutt suggested Jan. 1 may be the earliest date that UHC will enforce the Z-code requirement.

Reason for the Delay

Sources indicated two potential reasons for the Z-code delay. The first possible reason is that—as expected—genetic testing laboratories are experiencing two-month turnaround times for Z-codes.

Z-codes are administered through a molecular test identification system known as the DEX Diagnostic Exchange. **Palmetto GBA**, the Medicare Administrative Contractor based in Columbia, S.C, runs DEX under its Molecular Diagnostic Services (MolDX) Program.

Labs apply for a Z-code through DEX, and these applications may require technical assessments. The applicant lab needs to provide data about the analytical validity, clinical validity, and clinical utility of the molecular assay before a new Z-code is issued. The turnaround time to review a technical assessment is typically two months. *(See TDR, "Technical Assessment Challenges for Z-code Applications," July 10, 2023.)*

The second potential reason for the delay may be general disruption within UHC's ranks due to acquisitions and reductions in workforce, a source noted. **Optum**, a division of **UnitedHealth Group**, had layoffs in August.

Compliance Urged

The UHC update also urged labs that have already obtained Z-codes for their genetic tests to submit claims using the codes, even though that step is not currently required.

"In order to be prepared for the [upcoming] Molecular Pathology Policy … providers should continue to register their Phase 1 tests and complete the steps to obtain a Z-code," UHC wrote. "Providers who have obtained Z-codes are encouraged to submit them on their claims; however, claims for molecular pathology tests will not be denied at this time if they do not contain a Z-code." TDR

Lab News Briefs

Joint Commission Looks at Cyberattacks

The Joint Commission issued a Sentinel Event Alert for hospitals to address cyberattacks. The alert prominently mentions clinical labortory concerns.

The alert notes that laboratory systems and other critical technology could be down for four weeks or longer following a cyberattack. "Ensuring access to medical history/results and making sure laboratory, radiology, and pathology can rapidly communicate test results to multiple clinicians … are high priorities," The Joint Commission noted.

The accreditor recommended that hospitals form a downtime committee, which should include representatives from labs and pathology, to develop preparedness actions and mitigation in the event of a systems intrusion. The committee should develop procedures and resources needed if IT systems have to go offline unexpectedly.

Bon Secours Sues Anthem over Claims

Bon Secours Mercy Health Virginia (BSMH), a 10-hospital health system, has sued **Anthem Health Plans of Virginia** over unpaid claims. Anthem is now **Elevance**, while BSMH Virginia is part of the national **Bon Secours Mercy Health** system.

Clinical lab managers who believe that private payers are not processing lab test claims consistent with network agreements may want to study this court case.

"Anthem failed to pay BSMH Virginia in full, accruing an unpaid accounts receivable that is currently in excess of $73 million on claims aged greater than 30 days," according to the lawsuit, which was filed in August in **Circuit Court of Henrico County**. "Additionally, these practices have led to BSMH Virginia incurring more than $20 million in denial adjustments or 'write offs' since 2020."

A spokesperson for Anthem told *MedCity News* on Aug. 28 that the lawsuit is "another attempt to distract from Bon Secours' decision to leave Anthem's provider network and deny access to care for **Medicaid** and **Medicare Advantage** members."

Bon Secours went out-of-network for Anthem Medicare Advantage members in August and is set to go out-of-network for Medicaid members in the fall, *MedCity News* reported.

Anthem recently paid $300,000 to settle a finding by Virginia insurance regulators that it had not paid medical claims as quickly as state law requires, the *Richmond Times-Dispatch* reported. As part of the settlement, Anthem neither admitted nor denied violating the law.

Walmart Cuts Pharmacist Pay, Hours

Labs that work with retail pharmacies at **Walmart** should note that the company is cutting pharmacist pay and hours, according to *Reuters*.

"The cuts, which haven't been previously reported and are aimed at pharmacists in higher wage brackets, highlight the new pressures at Walmart pharmacies, where shoppers are lining up to buy weight-loss drugs that drag on profits, despite their high price," *Reuters* wrote.

Over the last few years, clinical laboratories and pathology practices have seen opportunity in developing business with local pharmacies, where patients are showing up in greater numbers for clinical testing. *(See TDR, "New Players May Alter Who Buys and Who Orders Lab Tests," June 14, 2021.)* TDR

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Here's another twist in the saga of **Theranos**, the defunct and discredited lab testing company. Consumers who received inaccurate results from Theranos' blood tests may get some measure of justice. **Walgreens Boots Alliance** agreed to settle a class action lawsuit with these consumers for $44 million, *Bloomberg* reported on Sept. 7. The proposal, which needs court approval, will give the plaintiffs each approximately double their out-of-pocket expenses for the tests, *Bloomberg* noted, citing court documents.

MORE ON: *Walgreens Settles with Consumers*

Theranos entered into a deal with Walgreens in 2012 to offer specimen collection and testing in about 40 stores in California and Arizona. The pharmacy chain terminated the agreement in 2016, about eight months after the *Wall Street Journal* published its exposé on Theranos' flawed technology. Walgreens customers later filed suit against the company, believing it had ignored warning signs about problems with Theranos tests. According to court filings reviewed by *Bloomberg*, $1.3 million of the fund will come from a deal with Ramesh "Sunny" Balwani, Theranos' former President and Chief Operating Officer, who is now serving prison time. A similar deal could not be reached with Elizabeth Holmes, the company's founder and former CEO, who is also in prison, *Bloomberg* reported.

IBEX RECEIVES $55M IN NEW FUNDING

Ibex Medical Analytics, which markets an artificial intelligence platform that integrates with digital pathology systems, secured $55 million in Series C financing. That brings total investor funding to more than $100 million since 2016, according to the company. Ibex uses its AI technology to improve the quality of cancer diagnostics, and the firm has made strong inroads in Europe.

TRANSITIONS

- **Invitae** in San Francisco named Robert Guigley as new Chief Commercial Officer. He previously worked at **Ambry Genetics** and **Omada Health**.
- Michael Messenger was named Regional Business Executive for Value-Based Care at **Labcorp** in Burlington, N.C. He earlier held positions at **Personalized Medicine Care Diagnostics**, **LabSavvy**, and **Sunrise Medical Laboratories**.
- Tapas Sarma is the new Senior Account Executive Central Region for the United States at **Siemens Healthineers**, based in Erlangen, Germany. He previously held positions with **Caris Life Sciences** in Irving, Texas, and **Biotheranostics** in San Diego.

That's all the insider intelligence for this report. Look for the next briefing on Monday, October 2, 2023.

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