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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

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COMMENTARY & OPINION by...

R. Lewis Dark
Founder & Publisher

Are Feds Now More Serious about Prosecuting Fraud?

IS IT A COINCIDENCE THAT, IN THIS ISSUE OF **THE DARK REPORT**, we cover two related developments, both involving the federal government's efforts to control healthcare fraud and abuse?

First, you'll read about the new federal rule scheduled to take effect on Nov. 4. It gives federal healthcare investigators new powers to exclude individuals and organizations that pose undue risk of fraud, based on their current or previous relationships with those who have committed healthcare fraud. The **Centers for Medicare and Medicaid Services** (CMS), which issued the new rule, calls this new power its "affiliations authority." The new rule also introduces the term "sanctioned entities." *(See pages 3-6.)*

Will this be bad news for the bad guys, the fraudsters, and scamsters who repeatedly hit the government health programs with fraudulent claims? CMS now has the power to ban individuals and organizations from billing government health programs for between 10 and 20 years. Previously, it could only exclude an individual or entity for a maximum of three years.

The second related development is the federal crackdown on Medicare fraud, with indictments of 35 individuals, at least six of whom are laboratory owners. Announced on Sept. 27, federal prosecutors say these individuals collectively and illegally were paid $2.1 billion from federal health programs. Most of these claims involved genetic testing performed on Medicare beneficiaries. *(See pages 17-18.)*

For decades, clinical laboratory executives and pathologists decried the illegal practices of certain medical laboratory operators and others who induce physicians to order unnecessary or inappropriate lab tests simply so they can submit often-outrageously-priced lab test bills to Medicare, Medicaid, and private health insurers. Honest lab professionals regularly wondered why federal prosecutors seemed reluctant to pursue obvious cases of fraud, or accepted a negotiated civil settlement instead of a criminal indictment. In those cases, the culprits were free to organize a new company and commit fraud all over again.

Given that recent weeks have brought us the new Medicare rule governing associations, along with what federal prosecutors say is the largest Medicare fraud case in history, might it be true that federal officials are ready to take a much tougher stance against healthcare fraud and abuse? TDR

Labs Must Respond to New CMS Anti-Fraud Rule

Under enrollment rules, labs and other providers will need to disclose their affiliates' previous actions

CEO SUMMARY: Clinical labs and pathologists providing tests for patients in Medicare, Medicaid, or Children's Health Insurance Program should become acquainted with new enrollment rules that go into effect Nov. 4. The new rules allow CMS to revoke or deny enrollment to help stop fraud before it occurs in the federal healthcare programs. CMS intends to identify individuals and organizations that pose an undue risk of fraud based on their current or earlier relationships with previously-sanctioned entities.

ANNOUNCED LAST MONTH, a new rule gives the federal **Centers for Medicare and Medicaid Services** (CMS) more powers to stop fraud before it happens. Effective Nov. 4, the new rule allows CMS to revoke or deny enrollment if it finds that a provider's or supplier's current or previous affiliations pose an undue risk of fraud.

When it announced the rule on Sept. 5, CMS said, "This first-of-its-kind action—stopping fraudsters before they get paid—marks a critical step forward in CMS' longstanding fight to end 'pay and chase' in federal healthcare fraud efforts and replace it with smart, effective, and proactive measures."

Under the final rule, titled "Program Integrity Enhancements to the Provider Enrollment Process," CMS established new measures that allow the agency to revoke and deny enrollment in an attempt to stop fraud in the Medicare, Medicaid, and Children's Health Insurance (CHIP) programs.

One key fraud-fighting element in the new final rule permits CMS to deny or revoke enrollment based on certain current or previous relationships—which CMS calls "affiliations" with "sanctioned entities"—that pose an undue risk of fraud.

A newly-enrolling organization that has an owner or managing employee who is "affiliated" with an organization that previously had its enrollment revoked could be denied enrollment in Medicare, Medicaid, and CHIP, CMS said.

Or, if that organization is already enrolled and is affiliated with an organization or individual that has had enrollment revoked, the already-enrolled entity could have its enrollment revoked because of the problematic affiliation, CMS added.

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CMS Administrator Seema Verma praised the new final rule. "For too many years, we have played an expensive and inefficient game of 'whack-a-mole' with criminals—going after them one at a time—as they steal from our programs," she said. "These fraudsters temporarily disappear into complex, hard-to-track webs of criminal entities, and then re-emerge under different corporate names. These criminals engage in the same behaviors again and again."

The final rule's affiliation disclosure measure requires enrolling or re-enrolling providers and suppliers to disclose current and previous affiliations (within the past five years) with other providers or suppliers who have been subject to any of the following disclosable events:

- Has uncollected Medicare, Medicaid, or CHIP debt;
- Has been or is subject to a payment suspension under a federal healthcare program;
- Has been excluded by the Office of Inspector General from participation in Medicare, Medicaid, or CHIP;
- Has had billing privileges denied or revoked.

➤ 'Phased-In' Approach

The final rule adopts a "phased-in" approach. It means for now, CMS will require disclosures only from enrolling and re-enrolling providers or suppliers that CMS determines have at least one affiliation that has had a disclosable event.

Moreover, even the "phased-in" affiliation disclosure measure will not take effect until after CMS revises its enrollment forms (Forms CMS-855) to facilitate the disclosures, a process that will require further notice and comment rulemaking.

Labs should note that the rule defines "affiliation" broadly to include:

- A 5% or greater direct or indirect ownership interest.
- A general or limited partnership interest (regardless of percentage).
- An interest in which an individual or entity exercises operational or managerial control over, or directly or indirectly conducts, the day-to-day operations of another organization currently or formerly enrolled in Medicare, Medicaid, or CHIP. (Note that the individual or organization can exercise managerial control through a contractual or other type of arrangement and is not required to be a W-2 employee.)
- An interest in which an individual is acting as an officer or director of a corporation currently or formerly enrolled in Medicare, Medicaid, or CHIP.
- Any reassignment relationships.

➤ Revoke or Deny

The new rule also allows CMS to revoke or deny Medicare enrollment if it determines that the provider or supplier is currently revoked under a different name, numerical identifier, or business identity, and the applicable re-enrollment bar has not expired.

CMS also can revoke or deny enrollment if a provider or supplier bills for services from a non-compliant practice location, exhibits a pattern of abusive ordering or certifying of Medicare Part A or Part B services or drugs, or has an outstanding debt to CMS that CMS has referred to the Treasury Department.

If a provider or supplier's enrollment is revoked because of a non-compliant practice location, the revocation will apply to all of the provider's or supplier's practice locations, regardless of whether the entity is part of the same enrollment.

In addition, the new rules permit CMS to impose a re-enrollment bar of as long as three years if a provider or supplier submits false or misleading information during enrollment. Also, the new rule expands the bar to re-enrollment in new two ways:

- If CMS revokes a provider's enrollment, it can block that provider from re-entering the program for as long as 10 years. Previously, revoked providers were prevented from re-enrolling for three years.

How Clinical Laboratories May Be Challenged to Identify 'Problematic' Owners or Managers

CLINICAL LABORATORIES AND ANATOMIC PATHOLOGY GROUPS FACE one significant challenge under Medicare's new anti-fraud rules. They must identify owners or managing employees with disclosable events in their past.

Caitlin Forsyth, an attorney with the law firm of Davis Wright Tremaine, explained why doing so is challenging. "Imagine a situation in which the CEO of your lab is, or formerly was, a practicing pathologist whose Medicare enrollment was revoked at one time because he accidentally put his FedEx mailbox as the practice location on his Medicare enrollment application," she said. "Under the new rules, your lab would need to know about this moment in your CEO's history and—if and when CMS requests you report—you must disclose it on your enrollment application.

"Enrolling in Medicare, Medicaid, and CHIP is already fairly burdensome for laboratories and pathology groups to ensure their reporting to CMS is accurate and complete under the new rules," noted Forsythe, who serves as general regulatory counsel for clinical, molecular, and toxicology laboratories. "Compounding the problem is the fact that what CMS considers to be an 'owner' can be anyone or any company with a 5% or more direct or indirect ownership interest in the enrolled provider or supplier.

"Labs should be concerned, because a revocation of Medicare enrollment could be caused by a minor clerical error," explained Forsyth. "I've seen people who do the enrollment paperwork make honest mistakes or fail to submit the enrollment paperwork in time when responding to a request for revalidation, for example.

"It was already an unfortunate outcome for any provider's enrollment to be revoked for a clerical error," she added. "Now, any person or entity that had a managing or ownership interest in the revoked provider would need to disclose that fact to all the practices to which it is currently affiliated with, so that they can report the disclosable event.

"Also, under the new rules, CMS could revoke the current practice's enrollment if it determines—seemingly in its sole discretion—that the practice's affiliation with the revoked provider poses an undue risk of fraud," Forsyth noted.

"Theoretically, the rule could have a chain effect, especially with a large pathology practice that has multiple enrollments with a common, complicated ownership structure, with lots of owners holding 5% or more ownership interests," she concluded. "If one enrollment is revoked, the fact of that revocation will now need to be disclosed on all enrollments where any of the revoked practice's owners are listed."

- If Medicare revokes a provider's billing privileges for a second time, it can now block that provider from re-entering the program for 20 years.

"We have seen lab companies that commit fraud in one place and then break apart," said David W. Gee, an attorney with **Davis Wright Tremaine** in Seattle, who has nearly 30 years of experience advising labs and pathology groups. "Then, they show up again with the same people, but under different names and operate the same fraud in different places. For that reason, there's some good here.

"Even if there is no fraud in the lab's past or in its owners' or managing employees' past, all labs would still need to comply with the new rules and perhaps hire attorneys or other advisers familiar with the final rule to ensure that they comply as required.

"In the phase-in period, one of CMS' first orders of business will be to make some

changes to the 855 Medicare Provider/ Supplier Enrollment Applications form," Gee said. "CMS has to revamp each of the enrollment forms.

Additional Time to Prepare

"Also, most labs and pathology groups will have additional time to prepare since during the phase-in period CMS will require disclosures only from enrolling and re-enrolling labs and pathology groups that CMS determines have had at least one affiliation that has had a disclosable event," he advised.

"But if CMS determines your lab or any of your lab's owners, officers, or directors had an affiliation with a provider or supplier that's had a disclosable event, then CMS will require you to identify and disclose all of your affiliations that have had disclosable events," Gee said. "That means you'll need to review and work through each of the affiliations of your company and each of your company's owners and managing employees during the past five years. Then, you'll have to ferret out whether any of those affiliations also involved a disclosable event at any time in the past.

"Although most labs won't have any obligation during the phase-in period to begin the exhaustive inquiry to determine whether they have any reportable affiliations, there are steps they can take now," he suggested.

"First, it is essential for labs and pathology groups to understand the four types of conduct that constitute 'disclosable events' involving Medicare, Medicaid, or CHIP," Gee said. "They are:

- Uncollected debts
- Payment suspension
- Exclusion, and
- Denied or revoked billing privileges.

"Second, labs and pathology practices also must become familiar with the expanded range of additional 'affiliations' they must now have on their radar," he said. "Labs should begin to identify all of their firm's own affiliations during the past five years, meaning all direct and indirect owners holding 5% or greater interest in their firm, any partnership between their firm and another, any relationship in which their firm has management or operational control over another provider or supplier, and any reassignment arrangements.

"Then, labs and pathology groups essentially must repeat that same inquiry with each of the firm's officers, directors, and owners, and whether any of the firm's officers, directors, and owners have served in the past five years as an officer or director of an entity that is or was enrolled in Medicare, Medicaid, or CHIP.

"Once labs and pathology groups are aware of the expanded range of their 'affiliations,' they will want to proactively identify any 'disclosable events' and avoid any new affiliations with persons and entities that have had disclosable events," Gee advised. Labs also may want to identify and sever any such relationships as soon as possible.

Proactive Separation

"Taking that step alone may help them avoid the need for disclosure if the five-year clock runs out before the new rule is fully implemented," he said. "Even if the clock doesn't run out, the proactive separation should serve as a mitigating factor in CMS' assessment of whether the affiliation poses an undue risk of fraud.

"Labs and pathology groups not online need to run a check with the **Office of Inspector General** on the new people they hire or engage as contractors, a process most labs already undertake faithfully," Gee explained. "You've got to look at your current (and former) owners and managers and anyone with operational or managerial control. Then, you've got to determine whether any of them has a problematic affiliation." TDR

—Joseph Burns

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Alverno Labs Adds Eight Hospitals to Its Network

One of nation's largest regional laboratory networks now includes 34 hospitals in two states

CEO SUMMARY: In September, Alverno Laboratories, one of the largest networks of regional laboratories in the Midwest, added two Chicago hospital laboratories and six other hospital labs from the AMITA Health system to its network. The additional AMITA Health facilities joined Alverno as a result of health system consolidation. The consolidation of hospitals into health systems is an ongoing trend that contributes to the growth in both the number and size of regional lab networks.

REGIONALIZATION OF CLINICAL LABORATORY SERVICES continues to reshape the lab industry. In the latest example of this important trend, last month **Alverno Laboratories** in Hammond, Ind., added the labs from eight Illinois hospitals to its network.

Six of the new labs joining Alverno's lab network are **AMITA Health** system hospitals, which serves Chicago and surrounding suburbs. Those six hospitals have 1,377 combined beds. The other two labs are in the 319-bed **Mount Sinai Hospital** and the 294-bed **Holy Cross Hospital**, both in Chicago, bringing the total number of beds added to the network to 1,990.

Eight Labs Join Alverno

The AMITA facilities joined Alverno Laboratories after AMITA merged with **Presence Health**. The Holy Cross and Mount Sinai hospitals joined due to Alverno's ability to cut costs and improve care and outcomes for its hospital members, said Alverno Labs' CEO Sam Terese.

Based in Hammond, Ind., Alverno Labs was already one of the nation's largest regional networks of clinical laboratories. It now manages 34 system hospital labs, along with five contracted hospital labs, and a central laboratory serving those hospitals and hundreds of physicians and other healthcare providers in Illinois and Indiana.

"To accommodate the added test volume from these hospitals, Alverno will add 20 associates to its central lab in Hammond, raising the total number of lab staff to about 2,100 employees," Terese said. "We project that billable test volume will increase by 30% to 35% and the total number of patients served will reach about 10 million this year. Before adding these eight hospitals, we were probably serving about seven million or eight million patients annually."

Included among the test volume that Alverno acquired from these eight hospitals is a good portion of outreach testing, although Terese could not estimate how much of the volume was due to outreach testing. "The majority of outreach tests are acquired right along with the volume from the hospital labs joining the network," said Terese. "We have all the tools to add in the appropriate billing processes and necessary customer relationship management capabilities.

"These days, the hospital laboratory outreach business is a challenging endeavor because reimbursement levels are not what they once were," he commented. "Another reason is because hospitals are acquiring more and more physician practices and those employed physicians are now part of the hospital networks.

"The market for the traditional outreach business is shrinking, but we need to capture whatever outreach volume that is within reach because of the inherent value of patient data to support population health and other core efforts."

In the 20 years since its formation, Alverno has grown steadily. "In the past 10 years, revenue has increased 20% annually," noted Terese.

Nationwide, labs have seen revenue decline, in part because Medicare has reduced what it pays for clinical lab testing by 10% per year for the past two years under the Protecting Access to Medicare Act. In addition, health insurers have made deep cuts in what they pay for clinical lab tests and anatomic pathology services.

Despite these trends, Alverno's experience has been much different. "Over the past 20 years or so, Alverno's volume and revenue have continued to grow due to a number of reasons," Terese said in an interview with THE DARK REPORT. "One reason is the trend in which health systems form larger and larger networks. In response, regional laboratories have evolved to serve those health systems within certain geographies.

Several Joint-Venture Models

"In our case, we participate in several joint-venture models with multiple health systems so that we now serve 34 hospitals," he said. "Across the country, there are not many integrated laboratory networks serving such a large number of hospitals." In 2005, Alverno served 18 hospitals, just over half of the number it serves today.

"In addition to the laboratories we operate in our hospitals, Alverno also has partnerships in which we serve as the reference laboratory for some hospitals," Terese commented. "In addition, we do the clinical and molecular lab testing for the physicians who are affiliated with or employed at those hospitals.

"Each hospital laboratory does all the on-demand testing onsite to support their needs," Terese explained. "Those hospitals send the remainder of the lab tests to our central laboratory in Hammond.

Central Laboratory

"The largest volume of testing that we do in the central laboratory is for anatomic pathology, histology, infectious disease, and microbiology. Also in the central lab, we perform tests requiring advanced technology in molecular biology and precision medicine-related testing," he said. "A courier service delivers those specimens to Hammond every day.

"We are firm believers in automation whenever possible," Terese noted. "We use automation for general lab testing, and we are among the leaders in microbiology automation. In our central lab, we are introducing what's called 'robotic process automation,' or RPA, moving beyond the traditional definition of laboratory automation. RPA allows automation to perform beyond what a lab can do with other forms of automation.

"Also, we are religiously focused on standardization across all of our sites," he explained. "In our central laboratory, we have standardized equipment as much as possible. And we have standardized our test menus as well.

"In smaller lab facilities, we don't have the identical analyzers, but we have the same brands so that we have analyzer standardization," he said. "Also we have standard approaches to competency, scheduling, job descriptions, quality programs, and we use standard metrics in our hospital labs.

"The one area in which we are not standardized is our laboratory information systems (LIS)," Terese commented.

"We have **Sunquest** sites, **Meditech** sites, and **Cerner** sites, and our central laboratory supports **SCC Soft**.

"We serve 34 hospitals. Standardizing our LIS systems in all these hospital labs would be impractical. That said, all of our LIS systems are interfaced," he added.

"The reality is, when serving labs in multiple health systems, it's not feasible to have one health system dictate to another what the IT solution should be," Terese explained. "It would be impractical to ask every new partner to convert to a new IT or LIS system. That's not our call to make.

"Instead, we can connect each new hospital lab with a direct interface or through one of our interface partners," he added. "Either way, we can achieve the same functionality."

Looking Ahead

While much of its efforts to improve efficiency focus on the clinical laboratory, Alverno also seeks to improve turnaround time in anatomic pathology.

Last May, Alverno said it would be the first regional network laboratory in the nation to install the **Philips** IntelliSite Pathology Solution for anatomic pathologists interpreting histology specimens and diagnosing pathology cases.

When the system is fully installed next year, whole-slide imaging will improve quality, patient care, and cut turnaround time by as much as one day, said Brian Wellborn, Alverno's Manager of Anatomic Pathology.

Terese commented that Alverno has long been relentless about growth and retaining each customer. "You can't have one without the other," he said. "Our success is a tribute to the dedicated folks working in our customer experience department.

"That relentless approach to create an outstanding customer experience allows us to deliver customer retention rates above 99%," he added. "This is not to say that we don't lose business, but often that happens when independent physicians become employed by hospital systems or medical groups.

"We are equally relentless in protecting margins by watching our expenses and our unit costs closely," he added. "We are as tight with our unit costs as we can be."

In closing, Terese commented that Alverno's next goal is to investigate expansion into neighboring states by adding hospital labs wherever possible. TDR

—Joseph Burns

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New Alverno Labs Serve Chicago and Suburbs

FROM ITS CENTRAL LABORATORY LOCATION in Hammond, Ind., Alverno Laboratories has steadily expanded its geographical coverage in Indiana and Illinois.

Last month, Alverno increased its presence in Chicago and the surrounding suburbs. The two Chicago facilities are **Mount Sinai Hospital**, which has 319 licensed acute care beds and provides medical, surgical, and other services; and **Holy Cross Hospital**, which is licensed for 264 beds and is a community hospital that provides inpatient and outpatient care including medical, surgical, intensive care, emergency, labor and delivery, primary care, and other services.

Alverno added the following AMITA facilities in the Chicago suburbs:

- **AMITA Health Adventist Medical Center** (134 beds), in Bolingbrook;
- **AMITA Health Adventist Medical Center** (138 beds), in Glen Oaks;
- **AMITA Health Adventist Medical Center** (261 beds), in Hinsdale;
- **AMITA Health Adventist Medical Center** (176 beds), in La Grange;
- **AMITA Health Alexian Brothers Medical Center** (354 beds), in Elk Grove Village; and
- **AMITA Health St. Alexius Medical Center** (314 beds), in Hoffman Estates.

➤➤ ***CEO SUMMARY: Four trends are disrupting the nation's healthcare system in ways that no one would have predicted just a few decades ago. Ted Schwab, a healthcare strategist, described these trends during his keynote presentation at the 24th Annual Executive War College in May. His insights and predictions will help clinical laboratory directors and pathologists develop effective strategies in response to these trends. The steep rise in healthcare costs is one of the four trends and a primary reason why many community hospitals are struggling to remain open and avoid bankruptcy.***

Hospitals, physicians, and health insurers rapidly changing how they do business

Strategist Explains Key Trends in Healthcare's Transformation

First of Two Parts

Most pathologists and clinical lab administrators know that healthcare in the United States is transforming at a pace unseen since the birth of Medicare in 1965.

This unprecedented speed of change raises the stakes for every clinical lab and pathology group. Hospitals, physicians, patients, and payers are interacting in new and different ways. That makes it essential for clinical labs and pathologists to have appropriate strategies in place that enable them to serve the new—and often very different needs—providers have for diagnosing patients, selecting therapies, and monitoring progress.

One individual who has significant insight into the transformation of the US healthcare system is Ted Schwab, a healthcare strategist and entrepreneur. In his career, Schwab has worked with **Alegent Health**, the **Oliver Wyman Group**, the **Strategy&** division of **PwC**, and the **Huron Consulting Group**. Most recently, he has worked with **Babylon Health**, a company that promotes remote consultations for patients with physicians and other caregivers.

At the 24th Annual *Executive War College* in New Orleans in May, Schwab addressed a record crowd of almost 900 clinical laboratory professionals and pathologists on the current and future state of healthcare in the United States and abroad. It was the third time Schwab addressed The Dark Report's premier conference for innovative lab executives and pathologists, previously speaking in 2014 and 2016. Since then, much has changed in healthcare and those changes have validated many of his insights from those earlier presentations.

"Things are happening in healthcare in the United States today that none of us would have predicted when I started in this business in the mid-1980s," commented Schwab during his keynote presentation. "Healthcare's transformation is in response to four significant trends. These trends involve how clinical care is organized, how that care is delivered, and how providers are being reimbursed."

The four trends are:

1. The rising cost of healthcare and whether the current rate of increase is sustainable.
2. The rapid increase in spending for prescription drugs—particularly specialty drugs—as a main driver of increased healthcare spending.
3. The struggle of community hospitals to remain open, as many have closed in recent years and more may close in the coming years.
4. The shortage of primary care physicians (PCPs) and changes in how patients enter the healthcare system. This shortage creates an opening for retail health clinics and artificial intelligence.

"The first trend is the rising cost of healthcare," Schwab said. "The question raised by this trend is whether those costs are rising so fast that the rate of increase has become—or soon will become—unsustainable. The idea that rising healthcare costs are unsustainable has been heard many times over the past 20 to 30 years. Yet this prediction has not yet come true.

"That said, the numbers show that this time, predictions about how the current rate of increase is unsustainable may actually come true," he commented. "Less than 20 years ago, the income for the average family of four in the United States was roughly $60,000. Out of that $60,000, the family spent about $6,500 on healthcare, or about 11% of the gross income. That was the year 2000.

"Then, in 2008, came the great recession,"stated Schwab. "By 2018, inflation-adjusted income for that same family of four was still about $60,000, yet that family now spends about 35% of its gross income on healthcare expenses.

➤Unstainable Rate of Increase

"If this rate of increase continues, by the year 2046, a family of four will spend 100% of its income on healthcare," Schwab predicted. "Obviously, this rate of increase in healthcare spending is not sustainable."

The second trend is the fast-growing rise in prescription drug spending. "Currently, the main driver of the increased cost of healthcare is our consumption of prescrip-

tion drugs, especially specialty drugs," he said. "A friend of mine runs one of the largest pharmacy benefit management companies in the United States. His biggest worry is that within five years, 50% of what we spend on healthcare will be for prescription medicines.

"Today, about 20% of every dollar spent on healthcare in the United States goes for prescription drugs and spending on these drugs is rising by 13% annually," Schwab explained. "But it is not widely recognized that 44% of the year-over-year increase in prescription drug costs comes from spending on specialty drugs."

Schwab gave two examples of high-cost specialty drugs but did not name the medications. "Just one course of treatment for one specialty medication costs $475,000," commented Schwab. "Another drug costs $375,000, and, again, that's for just one course of treatment," he explained. "These are bioengineered prescription medications, each of which is much more effective than other drugs. But bioengineering comes at a high cost."

"Consumers, health insurers, or taxpayers have to pay for both of those specialty medications—and that's before you add in the cost of the physicians who prescribe those drugs, the pharmacy that fills the prescriptions, and any hospital bills for those patients," commented Schwab.

➤'Zombie Hospitals'

"The third trend—community hospitals struggling to stay open—is important for pathologists and clinical laboratories to consider because these hospitals are like the walking dead. To call them zombie hospitals is not far off the mark," Schwab noted. "If it hadn't been for the rise in stock market valuations over the last 10 to 12 years which made their stock portfolios worth much more money, a third of all community hospitals in the United States would be closed today.

"Here's why I say that: Last year, 39% of all hospitals in the United States had a negative operating margin," he said. "Hospitals are one of the core pillars of the healthcare value chain, and yet four out of 10 community hospitals were underwater last year. The only thing that propped them up was their investment income from a rising stock market.

"If you exclude all of **HCA's** hospitals and all academic medical centers, the average net operating margin for the hospital industry is minus 3%. So, the next time the stock market has a severe and sustained downturn, we could lose somewhere between 20% and 25% of our community hospitals," he predicted.

➤Shortage in Primary Care

"The fourth trend changing healthcare involves the shortage of primary care physicians and how patients can access primary care services," commented Schwab.

"Primary care physicians as we've known them—such as Marcus Welby, MD, of TV fame—are no longer part of the landscape," he stated.

"When I was growing up, Dr. Reed was our neighborhood physician and a pillar in the community," Schwab continued. "He delivered all the babies in the neighborhood, gave us our vaccinations, and set our broken bones. In 1971 he even performed an experimental surgery on my mother's ear and restored her hearing.

"The primary care doctors of that era were business folks and entrepreneurs. They also were individual practitioners," he noted. "Today's primary care physicians don't deliver that kind of care anymore.

"Primary care has changed and will continue to change well into the future," Schwab predicted. "One of the first ways we can tell that primary care has changed is that hospitals employ about 42% of all primary care physicians (PCPs) today.

"Hospitals that employ PCPs pay them an average annual salary of about $250,000. That is completely unsustainable," he noted. "As employed physicians, they are no longer required to keep the

Expect an Explosion in How Artificial Intelligence Becomes Involved in Patient Healthcare Services

MANY ORGANIZATIONS ARE WORKING TO INCORPORATE ARTIFICIAL INTELLIGENCE in how they deliver healthcare services, explained Ted Schwab, a health strategist and entrepreneur. He made this comment during his presentation at the *Executive War College* in May.

"You can expect artificial intelligence (AI) to have a growing role in healthcare," he predicted. "As technology takes on a larger role in healthcare, hospitals and other provider organizations are testing how AI can aid physicians.

"Today I spend most of my time with companies attempting to get artificial intelligence (AI) to solve healthcare problems," commented Schwab. "That simply means that machines are learning and doing what humans currently do.

"In AI, there are three trends to watch," he explained. "The first major AI trend will affect clinical laboratories and pathologists. This trend involves how diagnosis will be done on the Internet and via telehealth.

"The second AI trend is care delivery, such as we've seen with **Amazon's** Alexa," continued Schwab. "You should know that Amazon's business strategy is to disrupt healthcare. One way Amazon will do so is by announcing that Alexa will deliver behavioral health this year. I have no idea how that will work, but I'm fascinated by the process.

"The third AI trend to watch involves biological engineering," Schwab said. "Look at what's happening with T-cells and how AI supports much of what's happening with bioengineering. T-cell therapy is five times as effective as the chemically-induced therapy used today.

Concept of Singularity

"In AI, there's a concept called singularity, which is when machines have the ability to think as humans," he explained. "Experts predict that singularity may be achieved somewhere between 2050 and 2075, when machines will be on par with humans.

"Already today, machines do amazing things in healthcare," added Schwab. "But within five years, 90% of every invasive surgical procedure in the United States, except dermatology, will either be robotic or computer-assisted."

hours that Dr. Reed or Dr. Welby kept in the days when they worked what seemed like 24 hours a day, seven days a week.

"Another important way to view how primary care has changed is to consider that in the 1980s, almost 90% of PCPs were sole practitioners or worked in groups of three or fewer physicians," stated Schwab.

"By last year, those numbers were almost completely flipped. Now, 80% of primary care physicians work in groups of 20 physicians or more," he said.

In addition to the fact that hospitals employ so many physicians today, Schwab saw two more signs that primary care is changing. One is that the **Optum** subsidiary of **UnitedHealthcare** has a division called the **OptumCare Medical Group** that employs 47,000 physicians. The fact that a division of the nation's largest health insurer employs so many physicians is an important sign that shows how insurers are changing the delivery of primary care. The other sign showing how primary care is changing is that an ever-greater number of pharmacies have opened retail health clinics to deliver primary care, Schwab said.

Retail or Office Care?

"If we think about the components that go into offering a medical service in a retail setting versus a typical healthcare offering, we see that those two settings are very

different," he commented. "Despite those differences, the goal of delivering care in both settings is to provide a medical service that is more tightly integrated. This will continue as more companies open clinics in pharmacies and other retail stores.

"Here are some facts about this trend," he said. "There are 9,560 **Walgreens** stores in the United States, and there are 9,800 **CVS** stores, 6,363 **Walmarts**, 597 **Sam's Clubs**, and 2,277 **Albertsons**. What do each one of those stores and those companies have in common? Each one is developing strategies to put primary care offerings into its retail stores.

"Some of the most interesting ideas about this trend come from California and the Pacific Northwest," he commented.

"**Providence Health and Services** in Renton, Wash., says that within five years they will offer free care to any of their members, constituents, and beneficiaries who have any of the 75 most common primary care diagnoses.

"For those patients Providence Health will offer prescriptions and everything else needed for their care for free," added Schwab. "Here's how their math works: Right now Providence subsidizes primary care physicians at about $250,000 per practice per year. Therefore, it's a win for Providence to give away care for free because they will do it in two ways.

"First, they will do it through their retail offerings in their drug stores and grocery stores in the Pacific Northwest. Second, they'll do it through their digital or telehealth offerings," he said.

Virtual Patient Visits

Another example comes from **Safeway**, a grocery chain in Arizona. "In Arizona—and particularly in the Phoenix area—Safeway has opened health clinics in its stores this year," Schwab said. "What's interesting about these clinics is that they are typically staffed with just a medical assistant. Otherwise, it's a completely augmented reality.

"The care a patient would get in one of these clinics would be a self-determined primary care visit with a virtual visit on the back end," he commented. "Such virtual visits via telehealth are increasing in frequency, particularly in rural areas where there are fewer PCPs.

"In addition, we now see a more interesting alternative to telehealth and retail offerings pop up over and over in healthcare," explained Schwab, who often consults on how patients use artificial intelligence for symptom checking.

Online Symptom Checkers

"If you use **Google** in the United States to check symptoms, you'll get five-million to 11-million hits," commented Schwab. "Clearly, there's plenty of talk about symptom checkers, and if you go online now, you'll find 350 different electronic applications that will give you medical advice—meaning you'll get a diagnosis over the internet. These applications are winding their way somewhere through the regulatory process.

"Recently, researchers in the UK ran an international symptom checker against a physician taking a medical board exam," he said. "The researchers found that a primary care physician makes an accurate diagnosis about 79% of the time, while the most advanced artificial intelligence machines in the world make an accurate diagnosis about 81% of the time.

"The FDA just released a report saying it plans to regulate internet doctors, not telehealth doctors and not virtual doctors," he explained. "Instead, they're going to regulate machines.

"This news is significant because, today, within an hour of receiving emergency care, 45% of Americans have googled their condition, so the cat is out of the bag as it pertains to us going online for our medical care," declared Schwab.

"Right now in China, health systems use robots as healthcare providers for in-home services," he explained. "In Japan, over 50%

Why 'Medicare-for-All' Could Gain Enough Support for Congress to Pass Enabling Legislation

IF HEALTHCARE COSTS HAVE RISEN AT UNSUSTAINABLE RATES, it will soon be necessary to make a broad, systemic change to get such spending under control, predicted entrepreneur and strategist Ted Schwab. One possibility is the introduction of Medicare-for-All, he said.

"I'm not a proponent of this idea, but folks in the millennial generation are likely to see Medicare-for-All," he said. "There's no question about that whatsoever.

"Here are some reasons why Medicare-for-All is coming: First, the federal government is already the biggest payer for healthcare services in the United States—by far," he said. "In California, which has about 40 million people, Medicaid covers 33% of the population, Medicare covers 11%, the **Veterans Administration** 5%, and the **Department of Defense** and **TriCare** 2%. The **Bureau of Indian Affairs** also covers 2% and random other programs cover 2%. Adding up those numbers, shows that the government covers more than half—about 55%—of California residents.

"In West Virginia, one of the smallest states, Medicaid covers 30% of the population, Medicare 15%, the Veterans Administration 7%, the Department of Defense 2%, and other government programs 2%," he said. "Again, it's more than half of the population, or 56% in this case.

"So, we've gone beyond the tipping point of the federal government providing the majority of healthcare coverage in the United States," Schwab comments. "But it's even more important to think about the next generation.

"About two months ago, the *Economist* magazine devoted an entire issue to millennials and what they think about socialism," he added. "What I took away from that article is that health insurance coverage is an important topic for millennials for three reasons.

"Number one, they believe government debt is no longer relevant, which is the opposite of what those of us in the baby boom generation believe about debt," he said. "Number two is that millennials believe that healthcare is a human right. Number three is that millennials believe they will never get sick.

"In just a few years, millennials will comprise a majority of the workforce and voters," continued Schwab. "If these current beliefs and attitudes hold constant, the millennial generation may be the one that supports implementation of Medicare-for-All."

of home care is provided through computers and robots. South Korea is experimenting with nurse robots in hospitals."

Pathologists and clinical laboratory directors should be asking: How do we provide clinical lab testing or anatomic pathology services when more patients are diagnosed through telehealth or by AI via an online symptom checker? When new technology replaces patient visits to physicians, how will clinical labs and anatomic pathologists respond?

"My advice in these times of change is to do something," suggested Schwab. "What we know today is that providers—including clinical laboratories and pathology groups—who do nothing will get trampled. However, those providers that do something proactively will most likely be the winners as healthcare continues to transform." TDR

—Joseph Burns

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Lab Market Update

Quest Subsidiary Acquires True Health Assets for $8.5M

BANKRUPT LAB COMPANY **TRUE HEALTH DIAGNOSTICS** AGREED TO SELL some remaining assets priced at $8.5 million to **Cleveland HeartLab**, a subsidiary of **Quest Diagnostics**. True Health, with labs in Richmond, Va., and Frisco, Texas, filed a bankruptcy action in July.

Quest said it will use the acquired assets to expand its cardio-metabolic diagnostic services to new patients and physicians. Cleveland HeartLab will not acquire any of True Health's facilities or hire any of the company's remaining employees, a Quest spokesman said.

True Health's parent company, **THG Holdings LLC**, completed the deal on Oct. 1, the *Richmond Times Dispatch* reported. In September, a U.S. Bankruptcy Court judge approved a proposal from Quest and its Cleveland HeartLab subsidiary to buy the assets.

In July, True Health filed for Chapter 11 bankruptcy protection after the federal **Centers for Medicare and Medicaid Services** said auditors found "credible allegations of fraud," prompting CMS to stop paying any of True Health's claims. The dispute began in 2017. As of July of this year, True Health argued that the total loss in payments over two years came to more than $20 million. *(See "After Two-Year Battle With CMS, True Health Diagnostics on Verge of Collapse," TDR, Aug. 12.)*

On Oct. 1, the *Times Dispatch* reported that while True Health was selling assets, it had only about 130 employees remaining at its lab in Richmond and was expected to lay off more employees this month. In July, True Health notified state officials that 392 employees could be laid off because of the bankruptcy filing. Among those 392 workers were 90 phlebotomists who worked across the country, the newspaper reported.

Since late July, True Health has laid off or accepted the resignations of about 250 employees, the *Times Dispatch* reported. Clifford Zucker, the lab company's chief restructuring officer, told the paper those employees who remain are mostly in Richmond because almost all of the company's employees in its corporate offices in Frisco have left the company.

Founded in 2014, True Health bought most of the assets of **Health Diagnostic Laboratory** in 2015 after HDL filed for bankruptcy protection in June of that year. Among the assets True Health acquired were HDL's large laboratory facility in Richmond. HDL itself filed for bankruptcy protection after a federal investigation into the way it paid physicians for lab test referrals.

In September 2015, True Health bid $37.1 million for HDL's assets. But at the time some observers questioned the deal, saying ties existed between True Health and HDL and individuals who had worked for HDL's former sales firm, **BlueWave Healthcare Consultants Inc.** *(See "True Health to Buy HDL Pending Court Approval," TDR, Sept. 14, 2015.)*

In 2015 HDL had agreed with the **U.S. Department of Justice** to pay $100 million to settle allegations that it had violated the Anti-Kickback Statute and the False Claims Act between 2010 and 2014. After the DOJ settlement, two health insurers—**Aetna** and **UnitedHealthcare**—stopped paying HDL's claims. The loss of revenue forced HDL to file for bankruptcy. TDR

—Joseph Burns

DOJ Charges 35 Individuals In Genetic Testing Scam

Allegations involve Medicare fraud totaling more than $2.1 billion for unecessary testing

CEO SUMMARY: Federal prosecutors said those charged illegally lured elderly patients nationwide into giving cheek swabs for fraudulent genetic tests. The indicted individuals allegedly paid kickbacks and bribes to medical professionals working with telemedicine companies in exchange for referring Medicare beneficiaries for unnecessary genetic tests. Indictments were announced on Sept. 27 in an investigation that federal officials called Operation Double Helix.

Federal agents raided laboratories and charged 35 individuals in four states in connection with one of the largest healthcare frauds in history, a scheme that federal officials said generated $2.1 billion in fraudulent payments from Medicare and Medicaid Advantage plans.

In a crackdown on genetic testing fraud, the federal **Department of Justice** (DOJ) announced raids and indictments on Sept. 27. Among the 35 individuals indicted are nine physicians, at least six laboratory owners, and other individuals associated with dozens of telemarketing companies and genetic testing lab companies in Florida, Georgia, Louisiana, and Texas.

Calling the results of the investigation "one of the largest healthcare fraud schemes ever charged," the DOJ said it worked with the Inspector General of the federal Department of **Health and Human Services** to bring charges against individuals who were accused in an indictment of soliciting medically unnecessary genetic cancer tests and paying illegal bribes and kickbacks.

In recent months, federal agencies have issued warnings to the public—and particularly to Medicare beneficiaries—about fraud schemes involving genetic tests. What may also be significant is how quickly federal prosecutors moved against this new type of fraud involving genetic tests. It has only been in recent years that new understanding of the human genome has triggered a surge in the number of genetic tests offered for clinical use.

By contrast, fraud in such lab testing areas as toxicology, pain management, and specialty cardiology screening went on for between five and eight years before federal prosecutors began filing charges and announcing civil settlements intended to end these abuses.

DOJ and CMS Collaborated

In cooperation with the DOJ, the federal **Centers for Medicare and Medicaid Services' Center for Program Integrity** announced that it took adverse administrative action against cancer genetic testing companies and medical professionals who submitted more than $1.7 billion in claims to the Medicare program.

The lab companies allegedly paid kickbacks and bribes to medical professionals working with fraudulent telemedicine companies in exchange for referring Medicare beneficiaries for unnecessary and expensive genetic tests to screen for cancer. Some of the defendants controlled a telemarketing network that lured hundreds of thousands of elderly or disabled patients nationwide, the DOJ said.

Medically-Unnecessary Tests

In addition, the defendants allegedly paid doctors to prescribe genetic tests without any patient interaction or after only a brief telephone conversation with patients they had never met or seen, officials said. Medicare does not pay for screening tests and genetic tests are rarely used to screen for cancer. "Often, the [genetic] test results were not provided to the beneficiaries or were worthless to their actual doctors," federal officials said.

NPR described how the alleged scheme worked. "First, telemarketing companies trolled elderly Medicare beneficiaries online or called them on the phone or even sent people to approach beneficiaries face-to-face at health fairs, senior centers, low-income housing areas, or religious institutions like churches and synagogues," *NPR* explained.

Seniors were offered no-cost genetic tests to estimate their risk of cancer or to evaluate how well they would metabolize certain medications, *NPR* wrote. For these tests, Medicare beneficiaries provided their Medicare account information, a driver's license, and submitted a cheek swab for DNA testing, *NPR* said.

These indictments support Medicare's plan to end its current "pay and chase" method of payment. Starting Nov. 4, new rules will allow Medicare to revoke enrollment and deny payment in an effort to stop fraud before it occurs in Medicare, Medicaid, and the Children's Health Insurance Program. *(See "Labs Must Respond to New CMS Anti-Fraud Rule," page 3.)* TDR

—Joseph Burns

DOJ Indicts Six Labs and the Lab Owners

OFFICIALS FROM THE FEDERAL DEPARTMENT OF JUSTICE (DOJ) NAMED six clinical laboratory owners and six clinical laboratories in an indictment that was announced Sept. 27 under Operation Double Helix.

The DOJ alleged that the labs submitted false claims to Medicare and Medicare Advantage plans for genetic tests that were not medically necessary.

Among the defendants was Khalid Satary, 47, of Suwanee, Ga., who owns **Performance Laboratories** in Oklahoma, **Lazarus Services** in Louisiana, and **Clio Labs** in Georgia.

The DOJ said the three labs billed Medicare for more than $547 million.

Federal officials also charged:

- Minal Patel, 40, owner of **LabSolutions** in Atlanta and Easton, Pa., which billed Medicare for more than $494 million.
- Kevin Hanley, the CFO of **Acadian Diagnostics**, in Baton Rouge, La. Hanley and others submitted false claims to Medicare of at least $127.4 million.
- Edward B. Kostishion, 59, of Lakeland, Fla.; Kacey C. Plaisance, 38, of Altamonte Springs, Fla.; and Jeremy Richey, 39, of Mars, Pa.

Kostishion, Plaisance, and Richey operated **Ark Laboratory Network**, a company that purported to operate a network of clinical laboratories that facilitated genetic testing, said the DOJ in its indictment.

Ark partnered with **Privy Health** and another company to acquire DNA samples and Medicare information from hundreds of patients through various methods, all without the involvement of a treating healthcare professional, the DOJ said.

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Two interesting partners are working on a project to map the human immune system with the goal of creating a knowledge base that can be used to develop diagnostic tests. **Microsoft** and **Adaptive Biotechnologies** of Seattle are collaborating on this project. "Google categorized the world's information on the internet. What we're essentially trying to do with Microsoft is to catalog ... what the interaction is between our immune system and all the diseases that they bind to," said Adaptive CEO Chad Robins at the recent 2019 GeekWire Summit in Seattle. Once we start building out this map disease by disease, this is actually a web-scale problem."

MORE ON: *Immune System Map*

Artificial intelligence is being used by Adaptive Biotechnologies and Microsoft to identify and map both the signals associated with diseases and the cell receptors that bind to them. Adaptive is using technology that decodes the genetic information associated with T-cells, a key element in immune response. Microsoft has invested $45 million in Adaptive and pledged to contribute $12 million in cloud services to support the immune system mapping project. This partnership is an example of how Silicon Valley and digital companies want to create products and services that can be used within the health system.

TRANSITIONS

- **Incyte Diagnostics** of Spokane, Wash., selected Antone Eek as its new Chief Financial Officer. Eek previously worked at **Maui Health System/Kaiser Foundation Hospital**, **Grays Harbor Community Hospital**, **Molecular Testing Laboratory**, **RS Medical**, **Providence Health System**, and **Oregon Health Sciences University**.

- **LabCorp** appointed John Ratliff to be CEO of **LabCorp Diagnostics**. Currently, Ratliff is CEO of LabCorp's **Covance** division. He previously served at **Quintiles**, **Acterna**, and **IBM**.

- **Becton Dickinson & Co.** (BD) selected Tom Polen as its CEO, effective with the retirement of existing CEO Vincent A. Forlenza on Jan. 28, 2020. Polen left **Baxter International** in 2008 to join BD.

- Joydeep Goswami was appointed by **Illumina, Inc.** as its new Senior Vice President of Corporate Development and Strategic Planning. He formerly held executive positions at **Thermo Fisher Scientific**, **Life Technologies**, **Invitrogen Corp.**, and **McKinsey & Company**.

That's all the insider intelligence for this report. Look for the next briefing on Monday, November 4, 2019.

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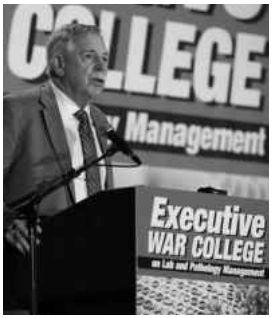

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