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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...

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Survival Essentials for Local Labs

IF THERE IS ANY SINGLE SIGN OF TOUGH TIMES FOR LOCAL LABS, it is decreasing access to patients due to the exclusionary contracting tactic of health insurers. That tactic is the subject of our lead story in pages 3-5.

Unhappy with this tactic, a number of lab administrators and lab management consultants are starting to say: "I'm as mad as hell and I'm not going to take it anymore!", just as the news anchor Howard Beale, in the 1976 movie *Network*, encouraged his listeners to shout from their windows.

I am moved to make that comparison because, here at THE DARK REPORT, we are hearing some lab managers and consultants who want the profession of lab medicine to better understand the back-room dealings done between private health insurance companies and some of the nation's largest laboratories. These individuals are willing to share their knowledge of the inside deals being done that specifically exclude some of the nation's finest local laboratory organizations from providing lab test services to patients in their communities.

In such managed care contracting situations, it does "take two to tango." The health insurer has to be tempted by ever-decreasing lab test prices offered by the national labs in order to agree to exclude the toughest lab competitors of the winning lab company from the provider network. Moreover, that same health insurer must then take proactive steps to pressure physicians and patients to stay in network.

One question we are regularly asked by these lab managers is "at what point do these types of contracting arrangements cross the line and begin to violate federal and state antitrust and anticompetitive business practices?" That is a reasonable question, because often the line between legal and illegal business practices is unclear and government prosecutors are hesitant to pursue a case where the outcome in court has much uncertainty.

On the other hand, it was Supreme Court Justice Louis Brandeis who famously said that "Sunlight is the best disinfectant." This is something to remember because a increasing number of lab consultants and lab executives with knowledge of these events are interested in having the full story told—not just to the profession of lab medicine, but to the legislators and government officials who, once informed of the situation, are in a position to correct the worst offenses. That would be a useful step forward in helping community labs across the nation. TDR

Excluding Lab Competitors Helps Big Labs in Market

With greater frequency, the largest labs are asking payers to exclude their competitors from contracts

CEO SUMMARY: Changes in healthcare are motivating health insurers and the nation's largest lab testing companies to enter into contracts in which the large lab company lowers its lab test prices to the payer in return for having the payer exclude that lab company's toughest competitors from the payer's provider network. A number of lab consultants and executives say that this tactic is being used more frequently and the biggest lab firms are taking market share as a result.

CLINICAL LABORATORY CONTRACTING with many health insurers has always been somewhat predatory. But lab industry consultants now say that in the past 24 months the predatory nature of contracting has become overt.

In simplest terms, certain large health insurers and national lab companies are entering into provider contracts in which the national lab agrees to reduce lab test prices and the health insurer agrees to exclude that national lab's toughest lab competitors from the insurer's provider networks.

Increasing use of this tactic is altering the competitive market in lab testing services. Several consultants and lab executives say that **Laboratory Corporation of America** and **Quest Diagnostics Incorporated** have been grabbing market share with this tactic while also, whenever possible, leaving their lab competitors with no access to health plan contracts, the consultants say.

LabCorp and Quest Diagnostics are the nation's largest clinical lab companies. All of the consultants and lab executives interviewed for this article asked not to be named.

According to several consultants, one example of this tactic occurred in recent months. Late last year, during negotiations with one large national health plan, the consultants say that Quest Diagnostics and LabCorp sought to outbid each other for the work.

"LabCorp and Quest both bid for the **Humana** work separately, so that no one could say there was any collusion involved," stated one consultant. "In those

separate conversations with Humana's executives, each lab company offered lower test prices for most routine lab testing in exchange for access to Humana's sizeable number of patients."

To this point, the negotiating process was straightforward. It is what knowledgeable individuals say happened next that shows how the nation's biggest lab companies are becoming more aggressive at restraining competitors.

"The Humana executives took the lowest price offered and awarded the contract to LabCorp," stated a lab consultant who is often involved in managed care contracting activities. "Certainly that is what health plans do: They take the lowest price whenever they can.

"But then LabCorp went one step further," she continued. "It handed over a list of labs that it wanted out of the Humana network. One lab company excluded from the Humana network as a result of these negotiations was **BioReference Laboratories, Inc.** (BRLI). A number of other labs were excluded as well, including small community labs and labs that do molecular testing.

Overtly Predatory Actions

"As we all know, contracting for lab services has always been somewhat predatory," stated the consultant. "What's changed is that the national lab companies are struggling just to stay even and health insurers are under pressure to manage costs and keep shareholders happy. So the tactic of excluding the competitors of the national lab in exchange for significantly lower lab test prices is happening more overtly and this Humana contract is an example," the consultant said.

"With more health insurers willing to contract for lab testing services on this basis, a lot of lab organizations are destined to fail, particularly the smaller labs," observed one lab executive familiar with other managed contracts similar to the Humana deal with LabCorp.

In the June 9 issue of THE DARK REPORT, we reported that health plans throughout the nation may be at war with labs. One lab consultant disagreed with this assessment, instead suggesting that it was the nation's two largest labs that were at war with smaller labs and with specialty labs.

Issue Of Payers Vs. Labs

"I see the 'payers at war against labs' issue differently," noted this individual. "If you ask the health plans if they are trying to put labs out of business, they would say, 'No, we're just trying to run our business and keep costs down at the same time.

"But make no mistake: LabCorp and Quest Diagnostics are out to crush labs, and the health plans benefit by taking the lowest lab test prices these two multibillion-dollar lab companies offer to them," said the consultant. "Payers are willing to exclude competing labs in exchange for getting lower lab test prices. For health plans, it's all about costs. The people in charge of lab contracting at payers simply need to reduce unit costs wherever possible. They don't care which labs are in network and which ones are out."

In Philadelphia recently, another example of the tactic of excluding competing labs as the *quid pro quo* for getting lower lab test prices happened. "LabCorp did a deal with **Independence Blue Cross** that was similar to the one LabCorp did with Humana," noted an attorney familiar with details of this process. "By bidding extremely low prices for its routine tests, LabCorp won the bid. It then asked Independence Blue Cross to eliminate Quest Diagnostics and a well-known molecular lab from the network.

Contract With Molecular Lab

"All the while, executives from Independence Blue Cross were negotiating a new contract with that molecular testing company," continued the attorney. "In fact, it was very late in the contract review stage. Both sides had seen the contract and sug-

Do Agreements Between Big Labs and Payers that Exclude Competing Labs Violate Antitrust Laws?

FEW PATHOLOGISTS AND LAB ADMINISTRATORS understand federal and state laws governing antitrust activity and monopoly behavior.

That is why many lab professionals believe it is unfair, if not illegal, when health insurers and big lab companies collude to exclude competing labs from the insurers' provider networks in exchange for lower lab test prices from the national lab companies.

THE DARK REPORT contacted two university professors with knowledge of anti-trust law. Based on a general understanding of this tactic, and with the understanding that such cases would be complex to litigate in court, each provided an answer indicating that a health insurer and its contract lab company would need to carefully craft an agreement that complies with existing federal and state antitrust and anticompetitive trade laws.

"Normally, vertical exclusive contracts are addressed under the rule of reason," stated Herbert Hovenkamp, Ph.D., J.D., Professor of Law at the **University of Iowa**. "This means that market power and anticompetitive effects need to be proven and this is a highly fact-specific inquiry. In general, exclusive contracts in health care delivery are common, but that does not mean that they are automatically legal."

Professor Hovenkamp is said to be "the most influential antitrust scholar of our generation." The *New York Times* has written that many consider Hovenkamp to be "the dean of American antitrust law."

At the **Tuck School of Business** at **Dartmouth University**, Robert. G. Hansen, Senior Associate Dean and Professor of Business Administration, addressed this same issue. "The quick answer would be that this sounds like exclusive dealing, which can be illegal. However, it would need to be judged under the rule of reason analysis, looking at the overall impact on competition.

"Excluding competitors is something that looks bad on the surface," continued Hansen. "This was part of the St. Luke's problem with the Idaho merger case; by acquiring physician groups, the hospital would get *de facto* exclusivity on the referrals and close out other [competing] hospitals." *(See TDR, February 24, 2014.)*

Similar to the tactic of a lab company getting a health insurer to exclude competing labs in exchange for lower lab test prices "hospitals of course do this too, by telling insurers that they have to leave other hospitals out of a network," added Hansen. "This is a borderline practice... [and depending on the specifics of each contract or agreement, is] not going to be *de facto* or *per se* illegal."

As both experts in antitrust law noted above, health insurers regularly negotiate contracts with one provider that exclude that provider's competitors. Whether such deals violate federal and state antitrust and antibusiness laws depends on multiple and complex factors.

gested changes. It was all marked up and ready to go into a final version.

"When the contracting executive from the molecular testing company went to Independence Blue Cross to sign the contract, he was told the deal was off," noted the lawyer. "This molecular lab has a lot to offer in terms of life-changing tests. But now, due to the payer's contract with LabCorp, it is excluded as a network provider."

"In situations such as these, is it a violation of antitrust laws to ask a health plan to exclude your competition or is this a legal method for establishing narrow networks?" asked one lab management consultant. "At the moment, the biggest lab companies are using this tactic to handcuff their toughest lab competitors to gain market advantage and to increase their market share." TDR

—Joseph Burns

Lab M&A

Aurora Diagnostics Acquires Two Pathology Group Practices

Each seller is an independent pathology group that decided to merge into a large lab company

TWO MORE PATHOLOGY GROUPS gave up their independence in recent weeks. Both groups were acquired by **Aurora Diagnostics** of Palm Beach Gardens, Florida.

Early in June, Aurora announced the acquisition of **Mid-Atlantic Pathology Services, Inc.** (MAPS), of Sterling, Virginia. MAPS has four pathologists and serves physicians in Northern Virginia, Maryland, and Washington D.C. This group describes itself as "a full service dermatopathology laboratory."

Last Thursday, Aurora disclosed an agreement to purchase **Hallmark Pathology, P.C.**, located in Medford, Massachusetts. The group services two community hospitals in Melrose and Reading that are owned by **Hallmark Health System**. Five pathologists are associated with Hallmark Pathology, which serves **Lawrence Memorial Hospital**, a 134-bed acute care hospital in Medford, and **Melrose-Wakefield Hospital**, a 234-bed nonprofit hospital in nearby Melrose, Massachusetts.

Terms Not Announced

No terms for either transaction were disclosed. A closing date for the acquisition of Hallmark Pathology was not provided.

The Hallmark deal complements Aurora's other labs in Massachusetts and New Hampshire. Last fall, **Partners HealthCare** of Boston agreed to affiliate with Hallmark, a deal that would allow Partners to become the sole corporate owner of Hallmark and integrate the two facilities into its system, according to *Becker's Hospital Review*.

Aurora Diagnostics' announcement of the two acquisitions caught some pathologists by surprise. In recent years, the company posted net losses of $160.8 million in 2012 and $73 million in 2013. During this time it has not been as active in purchasing pathology groups as it had in the years following its organization in 2006.

Acquisition Capital

However, that may be changing. Earlier this year, Aurora's Executive Vice President Bruce Walton said Aurora has the capital to acquire pathology labs and practices and is seeking strategic opportunities. "Consolidation is coming to our industry and we believe we are well-positioned for that consolidation," he said.

Consolidation of anatomic pathology groups will be one of the dominant trends in coming years. Shrinking reimbursement and the shift to integrated care organizations will mean less revenue for independent pathology groups.

Particularly vulnerable are smaller anatomic pathology groups that have five or fewer physicians. For these reasons, THE DARK REPORT expects to see a growing number of independent pathology groups take steps to sell or merge. *(See TDRs, February 24 and March 17, 2014.)* TDR

— Joseph Burns

Lab Copay on the Table, But for Now, It's Australia

Pending legislation would require copayment for GP, medical lab tests, and diagnostic imaging

CEO SUMMARY: Patient copayment is the idea that always appeals to government health officials who want to control healthcare costs. In Australia, Parliament has yet to vote on a bill that would, starting in July 2015, institute a patient copayment of $7.00 Australian for general practice visits, medical laboratory tests, and diagnostic imaging services. Reaction to this proposed new law was immediate and some GP clinics have already seen a significant decline in patient visits in reaction to the news.

SOME IDEAS NEVER DIE and that's certainly the case for the lab test copay. In the United States, Congress regularly considers reinstituting the clinical laboratory copay as a way to find money it can spend elsewhere.

In Australia, the federal government has announced its intention to institute copayments beginning in July 2015. Pending legislation proposes that patients will be required to make a copayment for general practice office visits, medical laboratory testing, and diagnostic imaging services.

Attempt To Control Costs

The initiative is part of a federal government strategy to control the year-to-year increase in healthcare costs in that country. The announcement of this change triggered a vocal and emotional debate in the Australian media.

The **Australian Broadcasting Company (ABC)** reported that the Department of Human Services Medicare office was playing a recorded message to callers about this copay—despite the fact that the law has yet to be passed.

ABC reported that callers to that government office heard a message that said: "From the first of July 2015 the Medicare benefit will be reduced by $5 for all patients for non-referred general practitioner consultations, out-of-hospital pathology episodes [and] out-of-hospital diagnostic imaging services."

ABC noted that "The recording also suggests the controversial $7 GP co-payment has also already been approved." That would be the equivalent of US$6.57.

The copay requirements are part of the proposed 2014-2015 budget that includes other changes designed to save money. In Australia, healthcare costs are currently 4.1% of GDP and projected to reach 7% if no changes are implemented.

Should this legislation pass and the proposed copays take effect for GP visits, clinical lab tests, and imaging studies, Australia will become a case study for the positive and negative consequences of implementing a patient copay requirement.

That experience might help inform the debate in the United States about the reimposition of a 20% patient co-pay for Part

B Clinical Laboratory Tests. This is a concept that resurfaces regularly when Congress looks for sources of Medicare cost savings that it can use to fund other needs.

Change In Patient Behavior

One element in the Australian experience that may be of interest to policymakers here in the United States is the fact that patients are already responding as if the copay had been implemented. Last month, the *Sydney Morning Herald* reported that general practice physicians in poorer areas had already seen a decline in patient visits.

"The **Australian Medical Association** has confirmed anecdotal reports that some clinics have reported a sharp fall in visits," noted the *Herald*. "A doctor in the Blacktown-Mount Druitt area said he was already considering cutting back on one of his two trainee placements due to a 10% fall in patient visits since last week's budget announcement... Another doctor in the area estimated the downturn [in patient visits] at closer to 30%."

Medical laboratory professionals in Australia pointed out the obvious fact that pathology labs [the Australian term for medical labs] don't see the patient and this increases the difficulty of collecting the copayment. "The copayment can't be collected in the 40% of patients having tests who are never seen by the pathology practice," stated Dr. Bev Rowbotham, Associate Professor of Pathology at the **University of Queensland**. "Who will collect a copayment on our behalf when they [the GPs] are already struggling to collect their own copayment for the service they have just performed?"

For healthcare advocates who are concerned about restricting access to care, the Australian experience may be highly instructive, assuming that the Australian government does implement the copay requirements in 2015. It will be one more real-world demonstration that copayments come with at least as many disadvantages as benefits. TDR

Cost to Implement Copay Is a Factor in Australia

OPPOSITION AND CRITICISM of the proposed copayment requirements for Australian patients was immediate. On June 24, *The Australian* newspaper wrote an opinion piece, stating:

The government has proposed that people pay $7 each time they visit a GP, get an X-ray or a blood test from July next year. A patient who visits a doctor and needs a pathology test and an X-ray will be slugged with $21 in upfront fees.

The $7 fee is applicable to everyone except concession card holders and children under 16 who will pay for the first 10 services combined.

The controversial plan has drawn the ire of consumers and many in the healthcare fraternity who say it marks the demise of universal access to healthcare in Australia.

One of the biggest challenges with the proposal is there is no way to determine—in real time—the number of times a patient has made a copayment.

The federal Department of Human Services, which runs Medicare, declined to say how long it would take to develop special software or a portal to provide the real-time information and how much it would cost.

The Australian raised the legitimate issue of the cost, time, and challenges faced by officials at the federal health program to create an information system that would allow physicians and other providers to accurately track how many copayments had been made by patients.

Physicians are against the copayment proposal. As noted in *The Australian*, "The **Australian Medical Association** is one of the loudest critics of the controversial proposal which it says will disadvantage Australia's poorest and most vulnerable."

Lab QA/QC

Local Labs vs. Central Labs Assessed in HER2 Test Study

When it comes to HER2neu testing, a study of accuracy just published by the journal *Cancer* may raise interesting questions for pathology groups across the nation.

"Assessing the discordance rate between local and central HER2 testing in women with locally determined HER2-negative breast cancer," was the title of the study published by *Cancer* on June 13, 2014. (Kaufman et al., *Cancer*, doi: 10.1002/cncr.28710.)

To determine what discordance might exist between local labs and central labs, the researchers obtained and retested tumor specimens from 530 women. Their goal was to determine if the initial HER2 negative classification had been correct.

Each specimen was retested using both the immunohistochemistry (IHC) and the florescence *in situ* hybridization (FISH) assays. Each test has FDA clearance.

Researchers determined that the tumor type classification was incorrect for 22 out of the 530 patients. That represented 4% of the patients. Researchers noted that this 4% of patients did not get potentially-efficacious therapy because their HER2 positivity was not determined as a result of those first tests.

Local Pathology Lab Testing

One notable finding was that 18 of the 22 specimens that were categorized incorrectly had been processed at a local laboratory using only one testing method. That caused researchers to hypothesize that the staff at smaller pathology laboratories may be more inclined to use one of the two approved testing methods rather than both. Other limitations of the study were identified.

Lead researcher Peter A. Kaufman, M.D., of **Dartmouth-Hitchcock Medical Center**, stated: "We, and other groups, have previously shown that a certain percentage of cases found to be HER2 positive in local laboratories are in fact HER2 negative when tested in more experienced central labs.

Accuracy of Negative HER2

"There has, however, been almost no research evaluating the accuracy of a negative HER2 result," he continued. "This is the first large study to look at this. What is comforting is that we found that re-testing in experienced larger labs confirmed the original local lab results in the majority of cases."

In their conclusion, the authors wrote: "This study highlights the limitations of employing just one HER2 testing methodology in current clinical practice. It identifies a cohort of patients who did not receive potentially efficacious therapy because their tumor HER2-positivity was not determined by the test initially used. Because of inherent limitations in testing methodologies, it is inadvisable to rely on a single test to rule out potential benefit from HER2-targeted therapy."

This study is an example of how improving technology, better use of lab test data, and more rigorous QA/QC methodologies are raising the bar on the quality and accuracy of clinical lab and pathology lab testing. It is a reminder to all lab administrators and pathologists that yesterday's standards of quality, accuracy, and reproducibility may not meet today's expectations of physicians, payers, and patients. TDR

HEALTHCARE CEOS PREPARING FOR THREE BIG TRENDS

Futurist Predicts Less Margin, More Consolidation in Market

PREDICTING HEALTHCARE'S FUTURE is what Ted Schwab does for a living. He's a partner with **Strategy&** (formerly **Booz and Company**), a global consulting firm now associated with **PwC**.

Schwab recently interviewed 40 CEOs of big hospital corporations, physician groups, and delivery systems. His goal was to find out what these CEOs expected to happen in healthcare over the next three years.

What Schwab learned from these interviews was radically different from the expectations he had about future events. "During my interviews with these 40 senior executives, I learned that these individuals see the future in ways that are quite different than the assumptions most of us hold today," he said. "This alone was significant, because these executives are my clients and I already knew much about their businesses!"

CEO SUMMARY: Based on interviews with 40 CEOs of major healthcare companies, one expert says that the next three years will bring major changes to healthcare. In his presentation at the Executive War College, Ted Schwab noted that these changes include a swift adoption of budgeted care (and not value-based care), more consolidation that creates behemoth health systems, and a shift from a vertical business model to a horizontal business model. For labs, he predicts that this consolidation will reduce the number of customers.

Predicting Coming Changes

Schwab made that comment during his presentation in April at THE DARK REPORT'S *Executive War College* in New Orleans. He provided lab executives and pathologists in the audience with an intriguing range of insights about how these 40 healthcare CEOs are preparing to deal with the changes unfolding today in the American healthcare system.

There were 10 key predictions that emerged from these interviews. Schwab chose to emphasize three predictions as the most important. "First, like most of you, I've been talking about value-based care for a long time," he explained. "That's no longer true for these CEOs. They have moved beyond value-based care and are now preparing their healthcare organizations to deal with budgeted care.

"The second really important change is consolidation," continued Schwab. "During my interviews with the CEOs, they talked about the massive consolidation that's coming in the next three years. You think **HCA** is big? You think **Tenet** is big? Wait until you see what's about to happen in the next three years as not-for-profit health systems come together. That development has major implications for your laboratories, since your customers just went from many to one.

"The third significant change is the shift from a healthcare organization organized around a vertical business model to a business model that is horizontal," he continued. "Today, these CEO's are in a vertical business: the hospital business, the insurance business, the doctor business. And how do you run a vertical business? You optimize. You build a bureaucracy, you have redundancy. It is command and control.

"That all changes in the next few years," stated Schwab. "The business they will be in—the business to which they are migrating—is a horizontal business. It is about partnerships. It is about joint ventures. I look at some of my clients, and they have no idea how to do this.

Horizontal Business Structure

"We all know that a horizontal business has a radically different management structure," he added. "Plus, this business model requires very different strategies and governance. Moreover, this is a system that won't be designed by government or commercial health insurers. It is a system that is designed by consumers."

Schwab encouraged the audience to see these three big changes in terms of: 1) economic transformation (budget-based care); 2) clinical transformation ("where clinical labs play every day," noted Schwab); and, 3) the transformation of the organization into one anchored by partnerships, joint ventures, and network management.

The next bombshell that Schwab dropped on the audience was the prediction, that, as of January 1, 2017, the profit margin in healthcare disappears.

Affordable Care Act

"On that day, health insurance incentives in the Affordable Care Act will lead small businesses to flip into the public exchanges," he said. "Remember all the hubbub that resulted last December from the cancellation of individual policies that forced these individuals to move to the public exchanges? On January 1, 2017, a much greater number of people with coverage from small businesses will be shifted into the public exchanges.

"This single development is huge because, when it happens in 2017, all the money—all the profit margin for providers—disappears!" stated Schwab. "Let me share an example with you.

"Recently I did a study for a client," he said. "This big delivery system wanted to know where its operating profit margin comes from.

"Does it come from Medicare? Does it come from Medicaid? Does it come from the individual market? Does it come from the large market?" he asked. "The answer was unexpected and a surprise to everyone.

"For this client, more than 250% of their margin came from the small group business market!" stated Schwab. "That's because, at best, Medicare, Medicaid, large group commercial, and individual lines of business generate no margin or negative margin.

"It is the excessive profitability of small group business that generates margin," he said. "Yet, this margin disappears January 1, 2017, when small business health benefits shift to the public exchanges."

Schwab related this expected loss of margin to the change in reimbursement. "What this means for my clients—and for clinical labs—is that we are entering the era of budgeted care.

"The 40 CEOs I interviewed no longer talk about value-based care; now they speak of budgeted care," he noted. "This means healthcare systems are beginning to internalize all the workings of financial and clinical risk.

"So, if you don't think that your piece of the pie will become budgeted, think again—and that includes lab testing services," stated Schwab. "The risk element means, as one executive I interviewed put it, 'Everybody's an insurance company now.'"

The transition to budgeted care and the need to assume and manage risk are factors fueling the coming surge of consolidations among hospitals, physicians, and other providers. "This is also what fuels the creation of accountable care organizations," noted Schwab.

Coming Soon: 1,000 ACOs

"Today, more than 50% of the population lives in a geography served by the 500 ACOs that currently exist," he said. "However, in just three years, there will be 1,000 ACOs.

"So if your customers include ACOs, your market has doubled from 500 to 1,000 potential customers," he noted. "However, due to consolidation, in 10 years there will be just 50 ACOs.

"The market will grow from 500 to 1,000, then shrink to about 50 within 10 years," predicted Schwab. "Thus, even as a huge explosion in these networks happens, the shakeout and consolidation will be quick.

"So, what does that mean to you?" he asked. "It means your lab better pick the right partner. Some of these ACOs are going to lose massive amounts of money, even as other ACOs are going to control wide swaths of geography. Those 50 surviving organizations will be huge and my advice is to pick as partners those organizations that have figured out what they are doing and how to be one of those survivors."

Healthcare's Rationalization Will Include Shift From Fragmented Care to Integrated Care

HEALTHCARE WILL UNDERGO MUCH RATIONALIZATION IN THE COMING YEARS. "Every ACO will go through a natural progression from fragmented care to clinical and financial integration," observed Ted Schwab, partner at Strategy&.

"Provider organizations will take a more rational approach to healthcare and, as they do, redundancy will be eliminated," he commented. "For example, does Indianapolis really need five heart hospitals? Does Dallas need seven oncology centers? Probably not. Redundancy in our healthcare system is going to come to a rather swift end.

"Part of this process will cause healthcare administrators to consider that, in the process of rationalization, they need to achieve clinical integration," said Schwab. "Think about the difference between rationalization and integration.

"Rationalization says: 'I have too much of something, so I am going to close it,'" he continued. "I will then bring things together by consolidation while using my ability to achieve scale in ways that increase my margins. Compared to rationalization, integration is very different.

Rationalization Of Services

"Here's an example that shows the difference between rationalization and integration," he stated. "Last year, one of the largest delivery systems in the United States recognized that it needed to change. Two years ago, it made almost $1 billion in profit. Last year, it lost $100 million. To respond to this new reality, it adopted strategies for clinical integration but not rationalization."

Schwab described how this health system revamped a still-booming oncology business. "Pathologists and lab directors know how oncology has transformed in recent years," he said. "Oncology has gone from being an inpatient-focused business—where hospitalized patients received extensive care, including radiation therapy and chemotherapy—to where it is now becoming almost like primary care. The goal today is to keep patients out of the hospital.

Horizontal Integration

"This large and now-profitable oncology business worked hard to become a horizontally integrated business," said Schwab. "That's the difference between integration and rationalization. Rationalization is the elimination of redundancies, the cutting of services. By contrast, integration involves radically changing services into a new model of care delivery that is horizontal.

"You a see a similar integration happening with physicians," he observed. "Today, fewer physicians go to hospitals. For example, most primary care physicians haven't gone into hospitals for years. Cardiologists don't go into hospitals as much anymore. Even ob-gyns don't practice in hospitals as they formerly did.

"Instead, physicians are transforming hospitals into what **Harvard Business School** Professor Regina Herzlinger calls focused factories," noted Schwab. "These are smaller shops that specialize in delivering specific kinds of healthcare. Soon, we will see many focused factories being launched within the healthcare system."

Schwab called attention to the erosion of profit margins happening in healthcare. "The single most important thing I will discuss today is the great profit margin shift that we see in healthcare," declared Schwab. "Margin is important because it triggers the formation of capital. And until recently, most of the margin and most of the capital in the American healthcare system came from

hospitals and the growth of inpatient services.

"This enabled hospitals to form capital and that allowed them to go to the bond market," he explained. "However, for those of you following the bond ratings of the big delivery systems, you've seen many of their ratings fall dramatically.

"Their bond ratings are degrading because they invested their capital into bricks and mortar," explained Schwab. "Today, bond companies point out that hospitals are losing money on those bricks-and-mortar investments.

"And here's a big prediction. It came from the survey of CEOs; not from me," he emphasized. "Within three years, one of the biggest health care systems in the United States will fail. It will fail financially because it will have gotten too big and too financially unstable to refinance its debt in the bond market.

Shift To Budgeted Care

"This will be a consequence of the shift to budgeted care and the shift in margins," continued Schwab. "You will see this organization (which was not identified by the CEOs)—and others like it—investing in the new healthcare business on the backs of an old business that no longer has margin. This will contribute to the financial turmoil within healthcare that triggers more consolidations and bankruptcies of major healthcare organizations."

Next, Schwab addressed the coming change in healthcare leadership and a growing role for clinicians in management and administration. "My clients talked to me about what they call the new force of leadership," he said.

"Here's an interesting statistic: in the next five years, 50% of the CEOs of hospitals, provider organizations, and insurance companies in the United States will reach retirement age," noted Schwab. "You'll see administrators and executives hoping to just hang on for the next two to three years to make it to the retirement finish line.

"Following them is a new generation of leaders of hospitals and healthcare organizations that talks a different language," he said. "These leaders are powerful and they use terms like 'radical change.' As the current generation retires, you will see this new and more forceful leadership put more emphasis on clinical services.

More Power To Clinicians

"These new leaders are thinking about new forms of clinical partnerships," he said. "They think it makes sense to turn the industry over to clinicians and those who support clinicians."

As he prepared to conclude his remarks, Schwab identified three questions that lab executives and pathologists should answer as part of their strategic planning. "Question number one is how do you play in a multi-chain healthcare world?" he asked.

"Number two, as the horizontal business model becomes dominant, do you compete or do you partner?" he asked. "Question number three is: Will your clinical lab or pathology organization have the speed to market and the speed of change that is essential to survive and prosper in an era of budgeted care and horizontal healthcare organizations?

Partner For Now & Future

"All of these trends are background for pathologists and clinical laboratory directors who are trying to decide how to proceed and how to choose an appropriate partner for now and in the future," concluded Schwab. "That's because the lines between various segments of the industry are blurring."

Another element of healthcare's transformation that Schwab uncovered during his interview with the 40 healthcare CEOs is what he describes as "Culture continues to eat strategy for lunch." Schwab said that "healthcare leaders are increasingly concerned about

Democratization of Care, Rise of the 'New Patient' and How it Relates to Kaiser Permanente's 'Thrive'

CONSUMERS WILL HAVE PLENTY OF INFLUENCE in how healthcare is organized and delivered. Futurists such as Ted Schwab, a partner at the consulting firm of Strategy&, consider patient engagement to be a significant trend.

"Larger numbers of patients are moving into health insurance programs that require substantial annual deductibles and out-of-pocket requirements," noted Schwab. "At the same time, efforts that increase transparency will make it easier for these patients to shop for providers based on price and quality.

"A client described this to me as the 'democratization of healthcare,'" he said. "This is an excellent term and aptly describes how the influence of patients and consumers will become a major driver in defining the quality of clinical services delivered by hospitals, physicians, labs, and other types of providers."

Schwab then described how **Kaiser Permanente** was tapping the power of this trend. "While conducting market studies, Kaiser did not speak to its physicians. Nor did it speak to its hospitals or its insurance arm," stated Schwab. "Rather, it went out to this new 'democracy of healthcare.' It talked to consumers and patients and asked them: 'What do you want to do? What do you want to be?' The answers that came back were: 'I want to live. I want to live well. I want to thrive!

"These findings sent Kaiser off in a very interesting direction," he explained. "It caused this organization to discuss the concept of the 'free labor of healthcare.'

'Free Labor Of Healthcare'

"This is a term that I love," continued Schwab. "Kaiser defines it as all the things that happen among family and friends when no healthcare professionals are around. Think of when, in the middle of the night, a mother deals with her child's earache. Or when an adult goes to his/her father's bedside to help with hospice care. Another example is when a neighbor picks somebody up off of the ice who slipped and takes him or her to the emergency room.

"This has triggered a change in strategy," concluded Schwab. "People at Kaiser have begun to ask how they can engage this type of family contribution within the overall care continuum. I find this fascinating and the organization's first step down this path was the 'Thrive' campaign. In this regard, Kaiser is moving in a very different direction than most healthcare organizations."

how change is affecting their corporate culture. Phrases like 'change fatigue,' 'initiative overload,' and 'organizational stress testing' crept into the interviews, showing a clear concern with both the scale and speed of transformation."

This is a significant finding with profound implications for pathologists and lab administrators. It is widely-recognized that medical laboratory scientists value stability and constancy and consider change to be highly disruptive. Schwab wrote that change-fatigue is why CEOs "are keenly focused on managing their cultures. They are addressing change overload by retooling into teams built around patients. ...flexibility and focus will be keys to success."

Lab managers and pathologists would be wise to concentrate efforts within their labs and pathology groups to help staff accept and adapt to the new reality of constant change. **TDR**

—Joseph Burns

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Partners Consolidates AP Using Common IT System

This method of integration is distinct from having AP groups create a single organization

CEO SUMMARY: Partners HealthCare of Boston, Massachusetts, is creating a single informatics platform for CP and AP across all six of the hospitals that it operates. It will replace 19 different pathology systems currently used at six sites with just seven integrated pathology systems. As this happens, the anatomic pathology and clinical pathology systems will be consolidated and integrated, even as the three pathology groups serving these hospitals remain as independent group practices.

CONSOLIDATION OF INDEPENDENT PATHOLOGY GROUPS in a region can take many forms, not all of which require mergers or acquisitions to create a single, much bigger pathology group.

In Boston, Massachusetts, constituent pathology groups within **Partners HealthCare** are taking steps to adopt a common information system. As that happens, they will consolidate both anatomic pathology and clinical pathology services even as the groups themselves remain independent.

Consolidation Using IT

In May, Partners HealthCare announced it would implement solutions by **Sunquest Information Systems** throughout the laboratories of most of its healthcare facilities. Founded by **Brigham and Women's Hospital** and **Massachusetts General Hospital**, Partners HealthCare is a teaching affiliate hospital of **Harvard Medical School**.

This method of pathology integration via information systems is distinct from having the individual pathology groups create a single operating organization. Instead, it is a form of consolidation via information systems infrastructure.

What adds interest to the approach of integrating pathology services via a common pathology information system is that the mix of contributing pathology groups at Partners Healthcare has its own complexity. Although Partners shows 14 hospital "members" on its web site, there are just six departments of pathology.

Departments of pathology exist at **Massachusetts General Hospital** (MGH), **North Shore Medical Center**, **Newton-Wellesley Hospital**, **Brigham and Women's Hospital** (BWH), the **Brigham and Women's Faulker Hospital**, and **Cooley Dickinson Hospital**. Because Cooley Dickinson has been in the Partner's system for only one year, it will not be included in the first phases of the anatomic pathology information technology integration.

Currently, the six departments of pathology listed above are serviced by three independent pathology groups. These groups are located at MGH; BWH

and BWH Faulker; and North Shore and Newton Wellesley.

The integration of pathology information systems is part of a broad IT integration project within Partners. John R. Gilbertson, M.D., is the Director of Pathology Informatics for Partners HealthCare. He is involved in this IT integration project.

"Within Partners, we will simultaneously implement both the new CP LIS and the new AP LIS," stated Gilbertson. "Also, a common blood bank system for the community hospitals will be implemented during this phase.

Enterprise-wide EMR Is EPIC

"As this is being done, Partners will also implement an enterprise EMR," he continued. "So actually there are four distinct projects in this one integration effort."

According to Gilbertson, the four information technology integration projects include the following:

1. *An enterprise CP LIS implementation*: this involves implementation of an enterprise CP LIS (Sunquest) across the Partners' enterprise.
2. *An enterprise AP LIS Implementation*: a single enterprise AP LIS (Sunquest Copath) across the enterprise—except that BWH and BWH-Faulkner will stay on Sunquest Powerpath for now.
3. *A Blood Bank implementation*: Implementing the Sunquest Blood Banking Module (part of the Sunquest CP system) at the community hospitals (Newton Wellesley, North Shore Medical Center, and the BWH-Faulkner Hospital). The academic medical centers will remain on their independent implementations of **Mediware** for blood banking.
4. *The Enterprise EMR Implementation*: (**EPIC**) will achieve integration of the new LIS systems with the new EMR system.

"The academic medical centers (AMCs) will remain on their independent HLA Systems for now," observed Gilbertson. "This project was agreed on in 2012. It began in 2013 and will be completed in early 2017.

"For anatomic pathology, the project takes Partners from 19 systems in pathology to six (Sunquest Lab, Copath, Powerpath, Mediware at the AMCs and HLA at the AMCs)," he said. "This is actually seven implementations because the two Mediware systems and two HLA systems are independent implementations.

"When we are done, we expect to have a single informatics platform for CP and AP together," added Gilbertson, an Associate Professor at the **Harvard Medical School**.

It is important to understand that these projects are motivated by the need of the parent health system to develop a fully-integrated information technology platform that can support truly integrated patient care. Yet, as this is done, it is creating the capability for independent pathology groups within the health system to more fully integrate their anatomic pathology services to the benefit of physicians and patients.

IT-Driven Integration

Gilbertson explained that "this is an IT-driven integration and its primary goal is to both simplify our IT infrastructure and align it with our new enterprise EMR. The pathology practices will continue to operate independently, but governance of the IT systems be a combined effort of Partners IT and committees made up of pathologists from all of the practices.

"That said, the project will give the pathology practices a set of important capabilities that we did not have before," noted Gilbertson. "These capabilities include:

- "The ability to improve data quality, especially to provide consistent laboratory data across the Partners system.

- "The ability to improve our implementation of best practices and, over time, to better collaborate on clinical, educational, and research initiatives across the enterprise.
- "The ability to improve how we measure our efficiency and effectiveness, thus demonstrating pathology's value to the enterprise.
- "The ability for pathologists to work together on future informatics technologies and initiatives when appropriate.

"The extent of this collaboration will be determined over time," added Gilbertson. 'The federated model has been very good to Partners for many years. Thus, the extent of collaboration will have to judged against our successful history of independent pathology practices."

There will be many practical benefits for the clinical laboratories and the pathology groups within Partners. "One goal for this entire project is to provide integration between all departments and with all ordering physicians throughout the enterprise," he said. "We have the additional goal of improving data quality. To accomplish this requires a core enterprise system throughout the departments within Partners."

Rotation At Hospitals

Another benefit of the consolidated pathology informatics platform happens whenever pathologists rotate through the outside hospitals. "The system will provide a single consistent view of lab data and results from AP and CP testing across all sites," he noted. "It allows us to improve data quality and consistency across the enterprise.

"For example, you can view the AP results in the **Newton-Wellesley Hospital** lab and those results will look very much like the results you will see at the **North Shore Medical Center** and in the academic medical centers," he added. "By having the same systems across all the working pathology groups at Partners, we will have consistent lab orders and consistent lab test names while also ensuring data quality across the enterprise.

"Another benefit is that this integration allows us provide best practices across all Partners' sites," commented Gilbertson. "This is an IT integration driven by the departments of pathology in support of the need for a central IT system within Partners."

Measuring Effectiveness

Given the expected changes in reimbursement, the pathologists involved in this pathology informatics integration see it as an opportunity to measure the efficiency and effectiveness of the pathologists. "Having better data can potentially help us demonstrate pathology's value to the enterprise," stated Gilbertson.

"In particular, the ability to measure and report the value of anatomic and clinical pathology to the enterprise will be critically important as value-based payment arrangements become more common," he emphasized.

"The integrated pathology and clinical laboratory system will also be ideal for training residents," stated Gilbertson. "Partners has the two large academic medical centers in Boston and the pathologists rotate through the different hospitals in our system. Thus, having a common CP LIS and AP LIS will make it easier for residents to work at different locations and get support from our faculty."

Standardization of the AP LIS will have another important benefit for all the pathologists working within the Partners system. "Today, our multiple IT systems make it difficult for pathology residents to move from one site to another across our system," concluded Gilbertson. "Once implemented, our consolidated pathology and clinical laboratory IT system means that—no matter where a pathologist goes in the system—he or she will experience standard controls and a similar look and feel at each location." TDR

—Joseph Burns

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Will microbiologists soon be testing a patient's cellphone for clinical diagnostic purposes? Researchers at the **University of Oregon** recently conducted a study and determined that cellphones have a similar microbiome to the skin of the person who owns the device. The study determined that three microbial types could be found on the surfaces of cellphones and the fingers of the phones' owners. These were *Streptococcus*, *Staphylococcus*, and *Corynebacterium*. Another finding in the study was that each participant's microbiome had more in common with their personal phone than another participant. Researchers said their findings were consistent with other studies. In their abstract, the researchers wrote "Our results suggest that mobile phones hold untapped potential as personal microbiome sensors."

MAYO INTRODUCES HOTSPOT PANEL INVOLVING 50 GENES

Next-generation gene sequencing continues to make new inroads in clinical diagnostics. Last month, **Mayo Clinic** announced "CANCP", a test designed to help tailor chemotherapy for cancer patients. It looks at 50 different genes in solid tumors and is designed as a "hotspot" assay because it only looks at specific regions of each gene to identify tumor mutations that influence the response to chemotherapy and are clinically-actionable alterations. The testing is being conducted at the Next-Generation Sequencing Lab of the Mayo Clinic Department of Medicine and Pathology.

TRANSITIONS

With the closing of the sale of **Ortho-Clinical Diagnostics** by **Johnson & Johnson** to the **Carlyle Group** approaching, several executive appointments have been announced by Carlyle.

- This winter, Carlyle disclosed that, once the sale was completed, the CEO of Ortho-Clinical Diagnostics (OCD) would be Dr. Martin Madous. Formerly, he was Chair, President, and CEO of **Millipore Corp.**, and has held executive positions with **Roche Diagnostics** and **Beohringer Manheim Corporation**.

- On June 18, Carlyle stated that, post-closing, the new Chief Operating Officer for OCD will be Robert Yates. He has worked at **Merck Millipore**, **Millipore Corporation**, and **Roche Diagnostics**.

That's all the insider intelligence for this report. Look for the next briefing on Monday, July 21, 2014.