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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

Healthcare Reform Puts Local Labs at Risk

THESE ARE DANGEROUS TIMES for local clinical labs and community hospital-based pathology groups. Although several elements of healthcare reform and emerging models of integrated clinical care favor local labs, there are equally powerful trends at play with the potential to concentrate ever more market share and economic power into the hands of a dwindling number of huge national lab companies—to the extreme disadvantage of local labs.

At this year's *Executive War College on Laboratory and Pathology Management*, the consequences of healthcare reform, the Accountable Care Act (ACA), and other prominent healthcare trends were the subject of several important presentations by expert speakers. Collectively, these speakers did not have good news for the long-term viability of smaller laboratory organizations if current, unfolding developments go unchecked.

One particularly relevant presentation on this subject was delivered by Paul Mango, Director of **McKinsey & Company**. He provided attendees of the *Executive War College* with a lucid, detailed strategic analysis of the key trends now reshaping the healthcare system of the United States. You can read our analysis of his remarks on pages 10-17 of this issue. However, I would recommend that you also purchase the audio recording of his presentation, along with his slide deck, so you and your lab team can listen and get the full impact of his message to the attendees, along with the important nuances that are tough to capture in a written intelligence briefing.

In particular, I am proud to say that, as you read about how Paul Mango analyzes the impact of the ObamaCare bill on socializing what he calls the "financial accountability for medical risk," you will acquire insights into the construction and intent of this legislation that I have never seen reported on by a major media source. THE DARK REPORT is first to help you access this invaluable strategic information.

Based upon the collective wisdom and predictions offered by the 90 speakers at this year's *Executive War College*, my primary message to you today is that a range of trends and healthcare market dynamics are underway that will prove unfavorable to local labs, hospital lab outreach programs, and pathology groups. It will require foresight and proactive effort by our industry leaders to forestall the worst consequences of these trends. It is a time for all the parochial interests in lab medicine to come together and work for the common good. TDR

Cleveland Clinic Lab Aims To Grow Reference Testing

Big new laboratory facility doubles space to support planned growth in outreach testing

CEO SUMMARY: In the national market for reference and esoteric testing, Cleveland Clinic Laboratories (CCL) is preparing to expand its presence. It has just moved into a $75 million state-of-the-art laboratory facility and wants to increase its outreach reference testing by four-fold within five years. A doubling of the national sales force is in the works. CCL says it wants to work with hospitals and health systems while also competing against national specialty lab testing companies.

IT MUST BE BOOM TIMES in the esoteric and reference testing sector of laboratory medicine. **Cleveland Clinic Laboratories** (CCL) is actively expanding its national presence, backed by a new, state-of-the-art laboratory facility in Cleveland, Ohio.

"In January, our lab moved into a new $75 million building—a 138,000 square foot addition that doubles our laboratory space," stated David Bosler, M.D., Head, Cleveland Clinic Laboratories. CCL is the outreach division of the Cleveland Clinic's Pathology & Laboratory Medicine Institute. Moving to a new building positions CCL to support its planned double-digit year-over-year increases in reference testing volume.

This news from the Cleveland Clinic is mirrored by the announcement last month that **ARUP Laboratories** in Salt Lake City, Utah, also plans to increase reference testing volume. ARUP is introducing a new automation line designed to boost specimen-handling capacity by 60% within two years and could accommodate a capacity increase of 300% above current levels if needed. *(See TDR, May 14, 2012).*

These expansion plans by two major sources of reference and esoteric testing are a response to the robust demand for advanced diagnostic tests by the nation's hospitals and health systems. CCL is now positioned to capitalize on this fast-growing sector of lab testing. Out of a total of 12 million tests that the Cleveland Clinic's main campus lab runs each year, only about 1 million tests currently come from the clinic's outreach program.

"We project that the number of total tests at our lab will rise by 3% to 5% annu-

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ally," noted Bosler. "However, the clinic plans to increase testing volume in the laboratory outreach program by double-digit percentages over each of the next three to five years. In that time, we project outreach lab test volume will grow to more than 3 million tests annually."

New Lab Designed for Lean, New Technology

TO ACCOMMODATE PROJECTED GROWTH and new technologies, the newly-opened laboratory facility of Cleveland Clinical Laboratories (CCL) has incorporated Lean principles and lots of input from lab staff.

"Front line medical technologists offered design suggestions in multiple sessions to optimize their ideal workspace," stated David Bosler, M.D., Head of CCL. "Lean methods were used to translate staff input and develop optimal work flow. They increased efficiency by identifying wasteful activities, inefficient walking patterns, and unnecessary waiting times.

"Another factor central to the design of the new lab is that it was constructed in a modular fashion," he explained. "This increased flexibility was intentional. The casework is mobile and modular. Changing the configuration of workspaces won't require a redo of the plumbing, utilities, and data lines. If market conditions change, we can allocate space in each of the four laboratories in the new building to take up more or less space. Everything is deployed in a flexible manner.

"Finally, it's no secret that clinical laboratory science—and medicine in general—is evolving quickly," he noted. "For example, informatics is being applied to clinical laboratory testing in the form of next-generation DNA sequencing and array-based technologies. Cleveland Clinical Laboratories is equipping itself to handle that type of testing and apply it to the personalized medicine that is becoming a big part of medicine today."

"CCL will grow incrementally by adding to the sales team this year and then by adding more next year," he said. "As we expand the sales staff, we will grow in the regions where we are actively soliciting business. In about 18 months, we could effectively double the sales staff.

"At Cleveland Clinic, the reference testing program has existed for more than 25 years, predominantly serving local hospitals here in Northeast Ohio," Bosler commented. "With this new lab facility, a big part of our business plan relies on the growth of the reference laboratory. We see that growth occurring in two segments.

Serving National Market

"The immediate segment will involve the expansion of local outreach work to physicians in the Northeast Ohio region," he said. "But long term—and ultimately much more significantly—we plan to expand our role as a reference laboratory for hospitals and commercial laboratories nationwide.

"Just to be clear, we are not planning to compete directly with hospitals," Bosler added. "Our strategy is to grow by supporting the growth of local hospitals.

"To the extent that these hospitals are focused on outreach services, we would partner with them," he continued. "Our lab can deliver value to these hospitals and hospital systems, particularly those just starting in the lab outreach business.

Subspeciality Expertise

"We do plan to compete, however, with other specialized national laboratory outreach players," Bosler noted. "It's a competitive environment, but we believe there is space for us. In our health system, each of our 80-plus pathologists are subspecialty trained. By expanding the reference lab, we aim to make that breadth and depth of expertise—combined with advanced diagnostics—available to clinicians around the country.

"When you consider the types of companies that compete in this sector, we are a

Putting Pathologists on the Front Lines of Healthcare Delivery May Boost Prospects

PATHOLOGISTS BELONG ON THE FRONT LINES of healthcare delivery where they can improve outcomes and cut costs, said pathologist David Bosler, M.D., who is Head, Cleveland Clinic Laboratories (CCL).

"Over the long term, being part of the Cleveland Clinic means we are well positioned within a major healthcare institution to drive the type of quality and value transformation that will be necessary under healthcare reform," he explained. "In the coming years, there will be sustained pressure on all clinicians to make sure that patients are not in the hospital longer than necessary and that they are not admitted if they do not need to be admitted. To reach those goals, pathologists will be required to place the right diagnosis in the hands of clinicians with the right clinical relevance.

"Healthcare reform will be the source for much of the pressure to improve patient outcomes," observed Bosler. "But that is not to discount the fact that hospitals, physicians, payers, and employers are—step-by-step—putting greater emphasis on improving quality and value.

"At the same, time, we predict continuing downward pricing pressure on all labs," continued Bosler. "One source is the recent cuts made by Congress to Medicare payments and labs certainly took a hit there. Cuts to lab budgets taken by hospital administrators as they look for places to slash costs is another source of downward pressure.

"Considering that the cost of lab testing represents only about 3% of overall healthcare expenditures, by continually cutting off smaller slices of an already-small slice, the healthcare system will get diminishing returns," Bosler added. "It is our long-term strategy to position lab testing to add substantial value. We want to leverage that 3% overall healthcare spend to provide better outcomes for patients and decrease costs within the episode of care.

"For pathologists, the current healthcare system offers big opportunities to get the right diagnosis done for the right patient at the right time," emphasized Bosler. "By ensuring that all patients get the right therapy quickly and that they get the optimal level of care, lab tests can contribute to these improved outcomes."

reference laboratory that's affiliated with a major healthcare system," explained Bosler. "We see ourselves as being more similar to ARUP and the **Mayo Clinic** than we are to **Quest Diagnostics Incorporated** or **Laboratory Corporation of America**.

"We aim to be a premium lab that leverages our quality and innovation to have a positive impact on patient care," he emphasized. "To compete at that level, we designed this new lab facility so that it could be very flexible—meaning that it is built for today, but the current design will support the changes that may be needed in the future.

"We moved four labs into the new building," he commented. "They are immunopathology, microbiology, molecular pathology, and special chemistry (including our mass spec and proteomics core). We project that these labs are the ones likely to be expanded most based on growing our reference lab work.

"But that's not the whole story," stated Bosler. "Once we opened the new lab facility, additional space was available in the existing building. That gives us the capability to expand the lab testing activities that remain in this facility. In response to increased reference test volume, each of our laboratories in both buildings is expanding by anywhere from 40% to 200%." TDR

—Joseph Burns

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HIPAA Update

Sonic Healthcare Acquires Labs from Aussie Competitor

Just as in the United States, lab consolidation is ongoing in Australia with this $100 million deal

LABORATORY CONSOLIDATION continues in Australia with news that **Sonic Healthcare Limited** of Sydney, Australia, has agreed to acquire three clinical laboratory business units from competitor **Healthscope, Ltd.**, of Melbourne, Australia.

The acquisition was announced on May 16. In three separate transactions, Sonic will pay A$100 million (US$99.4 million) for the Healthscope pathology operations in Queensland, Australian Capital Territory, and Western Australia. These businesses represent annual revenue of about A$105 million.

This deal comes on the heels of an earlier lab transaction between the two companies. In February, Sonic, the largest pathology company in Australia, acquired Healthscope's Tasmanian pathology business. At the time, Colin Goldschmidt, M.D., Sonic's CEO, said he was considering other acquisitions.

Sonic Has Global Reach

Sonic Healthcare is one of the world's largest pathology and clinical laboratory companies. It has operations in Australia, New Zealand, the United States, Germany, and the United Kingdom. Healthscope runs hospitals in Australia and pathology services in Australia, New Zealand, Malaysia, Singapore, and Vietnam.

In recent years, Healthscope has made aggressive efforts to build market share in the pathology business. But, as reported in *The Wall Street Journal*, Healthscope was selling its pathology businesses after it failed to achieve "critical mass."

However, Healthscope does foresee a strong future for its pathology businesses in the states of Victoria, South Australia, and the Northern Territory. Robert Cooke, Healthscope's Managing Director, said his company will retain these operations.

Tough Lab Test Market

The Australian newspaper reported that pathology companies have been under significant pressure since restrictions governing collection centers were lifted two years ago. But in that time, Sonic has reported strong revenue growth and improved profit margins, the newspaper said.

In Australia, the clinical laboratory market has been dominated by three firms: Sonic Healthcare, **Primary Health Care Limited**, and Healthscope. By selling some of its pathology business to Sonic, Healthscope is reducing its market share in Australia, leaving Sonic and Primary as the two major national competitors.

In the United States, Sonic Healthcare has been an opportunistic acquirer of both clinical lab companies and anatomic pathology laboratories. It entered this country in 2005 by paying US$300 million to purchase **Clinical Pathology Laboratories** of Austin, Texas. *(See TDR, September 12, 2005.)* TDR

—By Joseph Burns

In Florida, New Law Bans Certain Lab Sales Practices

Labs can no longer place phlebotomists in doctors' offices nor lease phlebotomy space

CEO SUMMARY: Florida law has long prohibited clinical laboratories from giving kickbacks and other forms of remuneration to physicians to induce specimen referrals. Specifically, state regulations have prevented labs from placing specimen collectors in physicians' offices. Despite these clear prohibitions, labs regularly violated state rules by placing specimen collectors and other lab employees in physicians' offices. Now a new law enacted by the 2012 Florida legislature specifically prohibits these activities.

AS OF APRIL 27, FLORIDA has a new state law that prohibits a number of common lab industry sales practices, including placement of a lab-employed phlebotomist in a doctor's office and the leasing of phlebotomy space in a physician's office by a laboratory.

Recognizing that labs often flout the state's regulations, the Florida legislature passed HB 787, "An Act Relating to Health Care Facilities," in the most recent legislative session. This bill was signed into law last month by Governor Rick Scott.

Ongoing violations of existing state laws and regulations by laboratories were the impetus behind passage of the new legislation. Often, investigators from Florida's **Agency for Health Care Administration** (AHCA) couldn't get a straight answer to a simple question.

Acting on a complaint or a tip, AHCA investigators would arrive at a physician's office and find that a laboratory company had placed personnel in the physician's office. It is against the agency's regulations for labs to place personnel in a physician's office to collect blood or other specimens, stated Craig Smith, the former general counsel for AHCA, which regulates clinical laboratories in the state.

After arriving at the doctor's office, the investigators would ask the laboratory personnel, "What are you doing here?" The investigators almost always got conflicting answers and rarely got the truth, observed Smith, who today is a lawyer in Miami and Tallahassee with **Hogan Lovells**, serving a variety of healthcare clients. Smith has reviewed publicly available documents on AHCA's lab inquiries.

A Trend in Other States?

Florida joins New York and California as states that prohibit the placement of personnel in physicians' offices, said Howard Appel, President of **Millennium Laboratories, Inc.**, in San Diego, California. Pennsylvania also has rules prohibiting the placement of personnel in physicians' offices but they do not go as far as the rules in these other three states.

"Florida's legislators acted decisively in addressing flagrant violations by laboratories that compromise honest and unsuspecting doctors and their patients in the name of profit," declared Appel. "Despite

previous multiple warnings and actions from regulators in Florida, these bad behaviors continued. Now, violators will be forced to either quit their irresponsible conduct or quit the state entirely."

Florida's new law prohibits clinical laboratories from providing personnel to perform functions or duties in a physician's office unless the laboratory and the physician's office are owned and operated by the same entity. *(See sidebar on this page.)* The new law also prohibits clinical laboratories from leasing space in a physician's office and requires the agency to investigate complaints, impose fines, and deny an application for a license or license renewal under certain circumstances.

New Florida Law Aims To Eliminate Ambiguity

FLORIDA LAW **HB 787,** titled "An Act Relating to Health Care Facilities," defines precisely what labs cannot do regarding the placement of personnel in doctors' offices. The law states:

A clinical laboratory is prohibited from, directly or indirectly, providing through employees, contractors, an independent staffing company, lease agreement, or otherwise, personnel to perform any functions or duties in a physician's office, or any part of a physician's office, for any purpose whatsoever, including for the collection or handling of specimens, unless the laboratory and the physician's office are wholly owned and operated by the same entity.

A clinical lab is prohibited from leasing space within any part of a physician's office for any purpose, including for the purpose of establishing a collection station.

The agency shall promptly investigate all complaints of noncompliance with subsection (1). The agency shall impose a fine of $5,000 for each separate violation of subsection (1). In addition, the agency shall deny an application for a license or license renewal if the applicant, or any other entity with one or more common controlling interests in the applicant, demonstrates a pattern of violating subsection (1). A pattern may be demonstrated by a showing of at least two such violations.

Violations Were Common

It was ongoing violations of existing Florida statutes by laboratories that triggered passage of the new law. "There already were a number of Florida laws—including a provision in the clinical laboratory licensure chapter—that prohibit any person from giving a physician kickbacks or any form of remuneration in return for referrals," explained Smith. "Broad anti-kickback laws already exist in Florida and in federal law.

"When you read Florida's statutes and regulations prior to this new legislative amendment, you can see that a laboratory is prohibited from giving remuneration to physicians to induce their referrals, including by placing a person in a physician's office to collect specimens," he said. "This was one activity that was specifically called out in the regulations as a kickback.

"But there were a number of lab companies attempting to circumvent that prohibition in different ways," continued Smith. "One way was for the laboratory to enter a so-called 'space lease' in a doctor's office, then place their own employee in that leased space.

"In so doing, the labs still were subject to regulatory scrutiny," he said. "But those labs often argued, 'I haven't placed a collector in a doctor's office. That's my leased space.'

Flawed Argument

"However, that argument has an obvious flaw: if it is an unlawful kickback to place a specimen collector in a physician's office, how can it be okay to place the collector there and give the physician lease payments?" added Smith.

"Also, when investigating licensure complaints, AHCA staff would learn that a lab had placed a person in the physician's

office but would hear very conflicting statements about what the person was doing," he noted. "The individuals involved would deny that any specimen collection was going on, which would lead to the question of why they were working within the doctor's office. Unfortunately, investigators rarely got a straight answer.

"The agency's rule says a lab cannot place its personnel inside physicians' offices to collect specimens, but in truth, there's a bigger issue," Smith said. "The overarching statute essentially says you can't give a physician remuneration of any kind to induce referrals to your lab.

"So now the legislature has decided to make it crystal clear in statute: labs cannot place personnel in physicians' offices to perform any function whatsoever," he explained. "There were a lot of arrangements that appeared to be suspect, and the legislature enacted this provision to make it very clear in the law that those types of arrangements are specifically unlawful. The new legislation also makes clear that labs are prohibited from using independent staffing companies or other indirect means to circumvent the prohibition.

Advisory Committee Created

"Since 2010, the agency has been looking into this issue," noted Smith. "AHCA had convened a technical advisory committee that included representatives from the clinical laboratory industry to advise the agency on the need for more specific regulations or laws.

"When you have personnel from a lab in the doctor's office to perform functions that the doctor's office staff should be performing, it could open the door to many unscrupulous practices," he observed.

"The federal **Office of Inspector General (OIG)** also has expressed concern about labs placing phlebotomists in physician's offices," observed Smith. "However, to date, the OIG has not announced a bright-line rule that the practice is unlawful.

Level Playing Field Good for All Labs

ONE LAB INDUSTRY EXECUTIVE with extensive experience in lab sales and marketing for large health systems and public laboratory companies points out that compliance with both federal and state laws should help small labs in Florida compete more effectively.

"By eliminating the ability to put phlebotomists in doctor's offices, this new Florida law will help to level the playing field," stated Julie Pantalone, who is Vice President of Sales at **Atlas Medical** in Calabasas, California.

"Smaller labs—with a proportionally higher cost structure—often feel they are at a disadvantage against larger labs because it's hard to justify the added financial impact of putting a phlebotomist in a doctor's office," explained Pantalone. "Physicians—especially high-volume specialists—ask labs to put phlebotomists in their offices.

"Many labs, when signing agreements for these arrangements, spell out what the phlebotomists can and can't do," she said. "But just because the lab has a piece of paper signed by the doctor and the lab, that doesn't mean the phlebotomists will follow those guidelines. Plus, how does a small lab justify putting an employee in place to draw 20 patients a day when that phlebotomist could do 40+ patients a day in a patient service center?"

"The core question in this context—under all types of anti-kickback laws—is this: 'Does the lab intend to induce a referral by offering the physician something of value?' Those prohibitions can apply," he said, "whether that value appears in the form of cash payments or free personnel to perform services." TDR

—Joseph Burns

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Initiatives May Reduce Lab Test Reimbursement

Health Insurers Now Finding Ways to Cut Costs and Shed Risks

CEO SUMMARY: Both employers and health insurers are taking aggressive steps to rein in healthcare costs. Several strategies to control spending and create powerful new incentives for providers are gaining favor. At this year's Executive War College, Paul Mango of McKinsey & Company, explained these strategies and emphasized that new models for handling health risk are changing the status quo. More employers are self-insuring and putting their employees into high-deductible health plans. One consequence of these trends is more downward pressure on lab test reimbursement.

In today's healthcare system, almost every health insurer is overwhelmed with information. And it's a problem that will get worse, asserts Paul Mango, who is a Director with **McKinsey & Company** in Pittsburgh, Pennsylvania.

"The fact is that many payers are overloaded with information," observed Mango, who spoke last month in New Orleans at the *Executive War College on Laboratory and Pathology Management*. "This overload of data means that most payers are unable to use this information in a meaningful way.

"Payers recognize this situation," he continued. "For example, when asked if their laboratory providers give them both the CPT codes and the full lab test results, most health insurers will answer 'yes.'

"But ask them if they use the lab test data for other purposes, and the answer is most interesting," he continued. "They will say, 'we don't integrate this lab test data with the rest of our data. It's too overwhelming.'

"Here is where lab administrators and pathologists can step up and add value to payers in their region," Mango stated. "It centers around helping health insurers extract insight from all the data and information that they collect. This is equally true for hospitals and health systems.

"Along with payers, hospitals and health systems are just as overwhelmed by the overabundance of health data—including lab test results," he said. "And this problem will get worse as the health insurance exchanges authorized by the Accountable Care Act (ACA) create another deluge of information.

"This point is actually quite important: It's not about raw information," he said. "The issue is who can deliver the insight and delivering insight will be much more important than having information.

"That's the point I want to stress for laboratory professionals: It is not about information; it is about insight," declared Mango. "Pathologists and laboratory scientists are positioned to be able to offer useful insight, since they daily review patient lab results in the context of other clinical data," he stated. "These core skills can be leveraged at a higher level to support how health insurers utilize the information that they collect."

Mango identified another significant problem for the health insurance industry that will eventually put pressure on reimbursement for lab tests. It is the means by which payers underwrite medical risk.

"As a result of health reform, there is a fairly dramatic shift occurring in what we call financial accountability for medical risk," he said. "The Accountable Care Act further inhibits payers' ability to manage this risk rather than resolving it."

The problem is that, under health reform, insurers are being asked to provide insurance to all Americans: 1) without traditional underwriting; 2) with guaranteed issue; 3) with higher minimum medical loss ratios; and, 4) with elevated standard benefits. Taken together, these factors make the risk of doing so too great, asserted Mango.

Medical Risk

"In response to this situation, health insurers are moving away from the risk business at a very fast pace," stated Mango. "Payers do not want the financial accountability for medical risk because—from their perspective—a very large proportion of the population in this country is now considered uninsurable in the traditional sense.

"Here's why insurers are getting out of underwriting major-risk health insurance," he said. "In today's market, payers can rate the risk of individual patients. It is why, for example, that a 63-year old female smoker with diabetes may pay an insurance premium that is 20 times greater than the premium paid by an 18-year-old, healthy, non-smoker.

"At $1,600 per month, the older person's premium is 20 times more expensive than the younger person's premium of approximately $80 a month," noted Mango. "In today's medically underwritten individual health insurance market, you easily find a 20-times difference in premiums because of how health insurers underwrite risk.

"But under health reform, this type of medical underwriting is no longer allowed and insurers must provide coverage to all who apply under an ACA rule called 'guaranteed issue'," Mango added. "Some states already have guaranteed issue rules, such as New Jersey and New York. In these states, guaranteed issue compresses the premium difference between the young and healthy and the old and sickly.

"Essentially, the top premium comes down and the bottom premium goes up," he stated. "The socialization of medical risk means the healthier, younger people will pay more premium dollars and the sicker, older people will pay less premium dollars.

"That is the beginning of what we would call the socialization of medical risk," Mango added. "It drives good risk (such as individuals who are young and in good health) out of the market. We have evidence for this trend in every state that has guaranteed issue. As a result, you can predict it will happen.

Socialization Of Risk

"Here is where the ACA will directly influence and contribute to the socialization of risk," he noted. "ACA mandates that the maximum health premium spread between the 18-year-old healthy nonsmoker and the 63-year-old diabetic smoker to be 4½-times, but 1.5-times of this is attached to whether one smokes or not. For non-smokers, the maximum spread is 3-times.

"Given that the maximum premium difference in these health plans is 3-times, if you thought guaranteed issue drove good risk out of the market, you're about to see a lot of other good risk driven out of the health insurance market under ObamaCare," he emphasized. "This is where the individual mandate of ACA comes into play. The controversial individual mandate in ACA states that the penalty for not having health insurance will be a maximum penalty in 2016 of $695."

In the example given earlier by Mango, a traditional underwriting of the risk of a healthy young non-smoker results in a health insurance premium of $80 per month, or $960 per year. The older individual, a diabetic and smoker in her 60s, would pay a premium of $1,600 per month, or $19,200 per year.

Shifts To Premium Costs

Together, these two individuals would pay $20,560 per year in health premiums in a market that allows the health insurer to underwrite the full risk. Under Obamacare, dividing this total by the maximum spread of 4.5-times generates a premium for the younger subscriber of $380 per month, or $4,568 per year and for the 63 year old of $1,333 per month, or just under $16,000 per year."

Obviously, the 63-year-old diabetic smoker would be most happy to have her health premium reduced by 17%. But the healthy young 18-year-old individual has every motivation to drop health coverage that would cost him $4,568 per year and pay the ACA-mandated penalty of $695. Additionally, Mango says even the individual mandate penalty has a flaw.

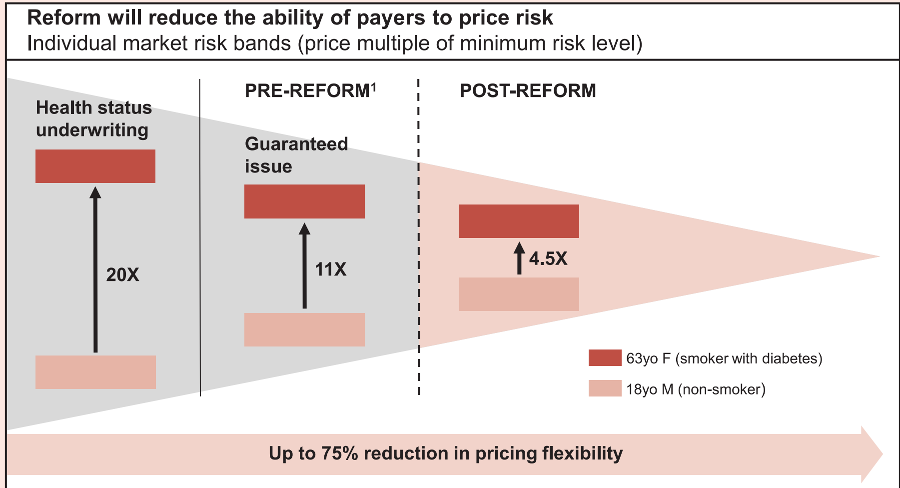
"Something very interesting happens if an individual fails to pay that penalty," said Mango. "There is no penalty for not paying the penalty! The government has only one way to get that money: If the individual overpays his or her taxes, the federal government can take the penalty out of the refund."

Growth Of HDHPs

Having explained why the ACA will encourage further socialization in the underwriting risk of health insurance, Mango next discussed how the health insurance industry is responding to these developments. "To give you an example of how insurers are getting out of the health insurance business, look at the growth in high-deductible health plans (HDHPs)," he stated.

"With these plans, insurers and employers are shifting medical risk to consumers," said Mango. "This shift is the biggest stealth issue of the last four or five

"Price Bands Imposed by the ACA Will Further Narrow and Socialize Medical Risk"–Paul Mango



[1] *Illustrative example for health status underwriting in states with no rating regulations and with rate banding regulations.*

SOURCE: E-health insurance coverage search; Senate Finance Committee Policy Option Papers; McKinsey analysis

IN HIS PRESENTATION AT THE *EXECUTIVE WAR COLLEGE* LAST MONTH, Paul Mango, Director, McKinsey & Company, presented this slide to illustrate how medical risk will be socialized. He offered the example of the health insurance premiums that would be paid by a 63-year-old female smoker with diabetes and an 18-year-old healthy, non-smoking male.

With traditional underwriting, the older woman would pay premiums of $19,200 per year and the younger male would pay $960 per year, which is a 20-times difference. Under Obamacare (the third medical risk band showed above at far right), dividing this total by the mandated maximum spread of 4.5-times would mean that the younger subscriber's premium increases to $4,568 per year and 63-year-old woman's premium declines to just under $16,000 per year.

As Mango noted, the younger subscriber would see nearly a five-fold increase in his health premiums and would be financially-motivated to drop insurance coverage and simply pay the penalty of $695 per year mandated by the Acountable Care Act (ACA).

years because it has resulted in a dramatic increase in HDHP enrollment. Despite this nation's credit crisis and a long-lasting recession, the market for HDHPs has tripled to the point where there are almost 30 million people enrolled in these products. It means that one of five individuals with private health insurance is now enrolled in an HDHP.

"With HDHPs, consumers pay for everything out of pocket, until an annual deductible requirement of $5,000 or more is met," detailed Mango. "These consumers are very price conscious about buying any service related to healthcare. That is why individuals with HDHPs place great importance on value.

"Health insurers have two other ways they can use to exit the traditional health insurance business," noted Mango. "First, health companies can serve self-insured employers in contract arrangements

known as administrative services only (ASO).

"That's a viable strategy because ever larger numbers of employers are becoming self-insured," he commented. "This means that employers assume the financial risk of delivering healthcare to their workers. As a self-insured employer's ASO, the health plan will evaluate and administer claims on behalf of the insurer's health benefits plan.

Employers Opt To Self-Insure

"It is useful to understand what motivates these employers to transition to self-insurance," Mango said. "It is a response to the fact that state legislatures have layered many coverage requirements and regulations on top of health insurance plans. In a state such as New Jersey, these added regulations represent 70% of the cost of the typical health insurance premium!

"However, the health benefits programs offered by self-insured employers are exempt from the state-based requirements," added Mango. "This means they don't have to include all the additional coverage requirements that the state typically requires for health insurance plans.

"Today at least one insurer, **Cigna**, offers a stop-loss program that allows self-insured employers to limit their risk of loss to a certain amount," he commented. "Such offerings by health insurance companies make self-insurance that much more attractive to employers.

"Thus, the use of ASOs to serve self-insured employers and their HDHPs represents the first way that health insurers are exiting the traditional health insurance business," noted Mango. "The second way is a more passive strategy. But it has the same effect and is linked to the federal government's evolving role in assuming healthcare risk.

"Currently, the federal government is on a legislatively-mandated path to take on the financial risk of delivering healthcare," he explained. "This path will make it one of the biggest owners of financial accountability for medical risk,

"This is because of the substantial number of people covered under the Medicare and Medicaid programs," noted Mango. "Enrollment in these programs is expected to increase significantly in coming years.

"At the same time, another element is poised to shift more risk to the federal government," continued Mango. "Under ACA, the federal government will subsidize the cost of premiums for people who enroll in the new health insurance exchanges. These federal premium subsidies will be linked to wages for those who are employed and to the federal poverty level for others.

"For individuals in this second group who are at 150% of the federal poverty level, 85% of their insurance premium will be paid by the federal government," he noted. "For individuals with income at 350% of the federal poverty level, the federal government will pay 25%. Collectively, this puts the federal government on the hook for a substantial amount of health insurance subsidies.

"But that is not the whole story," stated Mango. "The formula spelled out in the Accountable Care Act will increase the risk the federal government bears. It has to do with the spread between the rate of growth of wages and the rate of growth in health spending.

Negative Spread

"Let's assume that health premiums go up at 6% to 8% per year, which is similar to the annual rate of increase that has been true over the past two decades," said Mango. "During this same period, expectations are that wages might go up 2% to 3% per year. The problem for the government is that, under the ACA, it will forever own the negative spread between wage increases and premium increases.

"Therefore, if there is a 6% spread in any given year, we could have a doubling

As Employers Self-Insure, They Adopt HDHPs And Encourage Employees to Shop for Providers

CONSUMERS ENROLLED in high-deductible health plans (HDHP) are poised to exert significant change to healthcare in the United States. Clinical labs and pathology groups will experience these changes as consumers in HDHPs select their healthcare providers.

"Back in 2006, there were just 6 million consumers enrolled in HDHPs," stated Paul Mango, Director at McKinsey & Company. "Today, about 30 million people are covered by HDHPs.

"McKinsey has predicted that when HDHP enrollment reaches approximately 15% of the insured population, it will represent a critical mass of value-driven consumers and these individuals will be at the forefront of some dramatic changes in how healthcare is delivered," he noted. "With annual deductibles of $5,000 or more, these consumers are assuming substantial financial risk for their healthcare.

"HDHP members need transparency and access to specific information about providers," said Mango. "As they go to buy healthcare services, HDHP consumers want information about quality and price in order to choose the hospitals, physicians, clinical labs, and other providers who offer the most value.

"This surge in HDHP enrollment has not gone unnoticed," he added. "To serve these 30 million HDHP members, intermediary companies are springing up to offer information to those consumers and help them better manage their financial risk when they make decisions about where they go to seek care.

"As part of broader trends, surveys conducted by McKinsey analysts determined that managed care companies recognize that the reimbursement they pay to a hospital laboratory for a CBC or any routine lab test typically can be 2½ times higher than what is charged by **Laboratory Corporation of America** and **Quest Diagnostics Incorporated**," observed Mango. "In turn, this 2.5 times higher price for hospital lab testing versus other lab testing sources gives payers a real incentive to provide that transparency information to individuals in HDHPs.

Difference In Lab Test Costs

"By the way, it was not the 'big bad payers' who were the first group to call attention to this dramatic difference in the cost of lab testing services," revealed Mango. "It was the employers who saw that there was a difference of about 2.5 times what they were paying for lab tests versus what they could pay if they were self-insured."

Mango believes that market fundamentals in favor of continued growth in HDHP enrollment are well established. "Keep in mind that another big trend is for employers to drop the full-risk health plans of insurance companies and move to self-insurance," he pointed out. "Numbers show this trend is happening at a rapid pace. We expect it to continue because employers are taking on more risk by becoming self-insured. But at the same time, they are handing off that risk to their employees in the form of HDHPs."

of the federal government's obligations over 10 to 12 years just to fund the healthcare subsidies that are not attached to wages," Mango commented. "That will make the federal government the big new owner of medical risk.

"This mandate does not begin until 2014," added Mango. "In the meantime, to keep their costs under control, health insurers are focusing most of their efforts on a combination of benefit design and payment innovations.

"These two payer strategies go hand-in-hand," he continued. "Benefit design involves establishing tiered provider networks which establish financial consequences for consumers. Beneficiaries will be free to go to any provider, but going to

certain providers will cost them more than going to in-network providers." *(See TDR's coverage of the New Hampshire Blue Cross Blue Shield "point of service" health plan in the April 23, 2012 issue.)*

"Payment innovation is similar except that it affects the provider rather than the consumer," he added. "Physicians can refer patients wherever they'd like, but the physicians' reimbursement amount will vary based on where they send patients for services—including lab testing or medical imaging. Physicians can give up that variable part of their compensation if they send patients to the most expensive ancillary service providers.

Implications Of This Strategy

"Lab managers and pathologists need to understand the implications of these strategies," said Mango. "It definitely affects choice in the market by signaling to the consumer and to the doctor that—for the first time—there are real economic consequences for referring consumers to certain providers.

"More to the point, because clinical labs and pathology groups may not recognize this strategy as it unfolds, they are likely to suffer financially," continued Mango. "These dynamics will be hard to detect because it is difficult to recognize the volume of case referrals that do not come to your lab.

"Certainly labs can see the volume that's coming in the door," he said. "But it is not easy to track the volumes of specimens going to other providers. The point to emphasize here is that there is a hidden effect triggered by the tiered networks [different incentives to visit in-network providers] now being established by many health insurance companies.

"The jury is out, however, on how the strategy of narrow networks succeeds for payers," observed Mango. "A number of health plans have established narrow networks, but found they can be very complicated to administer.

"For example, look at the complications for a multi-line payer when it has both narrow and broad networks in the same community," offered Mango. "That would mean that some hospitals are in the broad networksome hospitals are in the narrow network, and other hospitals are left out entirely.

Narrow And Broad Networks

"I expect that the intricacies of operating these networks will discourage health plans from developing many narrow networks," he continued. "They are complex and difficult to administer.

"There is another reason why narrow networks are failing, added Mango. "Again, health insurers are learning this lesson the hard way. It centers on the issue of non-par emergency room charges. This refers to the higher charges that come from non-participating providers.

"Health plans have a contract rate for in-network providers," continued Mango. "The out-of-network rate is often four to five times higher than the contract rate.

"Each time a patient goes to an emergency room (ER) of an out-of-network hospital, it is very expensive," he stated. "Those higher charges from the ER visit typically offset any savings that accrue to the health plan because it traded lower price for volume within the network."

Financial Changes Ahead

Mango's analysis of how healthcare reforms will trigger specific consequences provides lab executives with essential insights they can use to better prepare their labs for the significant financial changes that are approaching. Further, Mango has explained why both employers and health insurers now seek ways to avoid paying prices for lab testing from hospital labs that can be as much as 2.5 times higher than the lowest discounted lab test prices of the national laboratory companies. TDR

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Employers, Payers, and Physicians Joining Together to Create New Care Delivery Models

IN ADDITION TO 'NARROW NETWORKS' with a limited number of contract providers, health insurers are pursuing several other strategies to control healthcare costs, noted Paul Mango, Director, McKinsey & Company.

"These strategies fall into two broad categories: payment bundling and integration," he said. "In payment bundling are: capitation, accountable care organizations (ACOs), episodes of care, patient-centered medical homes (PCMH), and pay-for-performance. Integration involves the development of integrated delivery networks.

CAPITATION: "Full capitation is one of the many experiments that health plans are developing nationwide," Mango added. "In some markets several of these strategies may be visible. In other markets, not so many. Full capitation will be relatively rare, but examples exist. In New York, it is reported that **Montefiore Medical Center** and insurer **EmblemHealth** are in talks to develop a full capitation plan.

ACOs: "Of course, ACOs are a hot concept now," he noted. "In California, **CalPERS**, **Catholic Healthcare West** (now **Dignity Health**), and **Hill Physicians** developed an ACO. This is a risk-bearing product, in which doctors, hospitals, and ancillary service providers work together to manage risk more effectively than they would by working separately. There are reports that this group has lowered health costs by 10%, which is a good start."

EPISODES OF CARE: "**Geisinger Health** in Pennsylvania and **Horizon HealthCare** in New Jersey are examples of this strategy," explained Mango. "Under an episode of care arrangement, the health system can control much of the risk. This strategy can extend to a lot of different conditions, ranging from hip and knee replacements to spinal surgeries."

PATIENT-CENTERED MEDICAL HOMES: "Patient-centered medical homes have been in use for many years and **Humana** is one of the best in the business," he said. "It's extraordinary how they have reduced both admissions and readmissions as well as unnecessary utilization. Even with the decreases in Medicare Advantage reimbursement in the last couple of years, Humana has been very profitable by reducing utilization costs in the range of 15% to 20%."

PAY-FOR-PERFORMANCE: "Pay-for-performance could be a popular mechanism for reimbursement because health insurers are discussing the possibility of not raising providers' reimbursement rates," he noted. "Instead, they will give them an opportunity to increase their total income by 50% if they adhere to certain parameters. Health plans know that the range in prices for certain services, such as lab tests, medical imaging, and ambulatory surgery, can be as wide as 2.5 times the lowest price. That means the doctor has to change where he or she sends patients for these services. It's relatively easy to do so and it can have a huge effect on the physician's income."

INTEGRATED DELIVERY NETWORKS. "In my hometown, Pittsburgh, we're experiencing a lot of market turbulence over how much formal integration we will have in the delivery network," he said. "There are three types of integrated networks. The one most relevant to 95% of the country is called "bilateral open." In this arrangement, a health system would have to open up its network to other providers unless it's a dominant player with 40% or more of the market. If that network is opened up to other providers, the health system may have to contract with other health insurers. As you can imagine, this is strategically very complex.

"The other end of the spectrum is bilateral exclusive, which is what **Kaiser Permanente** does," he added. "Kaiser contracts only with itself as a provider and the providers within Kaiser only contract with one payer. That is strategically very simple but it is economically volatile. In other words, the game is won or lost on January 1 every year depending on what Kaiser wins in enrollment. And if they don't win a lot in enrollment, they still have the fixed costs of being a fully-integrated provider."

World Lab Watch

Lab Restructuring Moves Ahead In United Kingdom and Ireland

Need to reduce cost of laboratory testing is one motive behind more aggressive steps to consolidate lab services

IT IS TOUGH TIMES FINANCIALLY for pathology and clinical laboratories in the British Isles. In both the nations of the United Kingdom and Ireland, the budget woes of the respective national governments are driving major changes in the organization and delivery of laboratory testing services.

In the United Kingdom, efforts by the government dating back to 2010 to reduce annual health spending by the **National Health Service** (NHS) by a target of 20% have met strong resistance from a wide range of vested interests. That resistance is no surprise.

In the UK and Ireland, pathology laboratory describes what is typically called clinical laboratory in the United States. Histopathology in the UK refers to the services of anatomic pathology as they are known in the United States. Efforts are underway in the UK and Ireland to consolidate pathology labs as a way to achieve cost savings and meet other operational goals.

Lab Joint Ventures In The UK

One interesting aspect of laboratory restructuring in the United Kingdom is use of joint ventures (JV) with commercial partners. To that end, just last month the NHS issued a tender for two potential pathology laboratory joint ventures.

One JV tender requests a proposal to bring the pathology labs of **University College London Hospitals** and **Royal Free London Hospital** together with a commercial partner. A second tender names **Royal Free London**, **University College London Hospitals**, and **North Middlesex University Hospital** as the pathology labs to be included in a possible joint venture.

At the same time, there is regional consolidation taking place in different regions across the United Kingdom. An example of this is an announcement last month by the four CEOs of **Croydon Health Services**, **Kingston Hospital, Epsom and St. Helier's NHS Trusts** and **St. George's Healthcare Trust** of their intent to develop a plan to consolidate their pathology testing services and base it at St. George's Hospital.

Pathology Network In Ireland

Meanwhile, similar initiatives are proposed for pathology testing in the Republic of Ireland. However, the significant financial problems of the government have slowed down plans to create one or more central laboratories to handle "cold testing" in the nation of 4.4 million people.

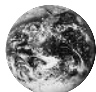
In April, the Board of the Health Services Executive (HSE) endorsed a proposal to establish a national pathology network, as well as to appoint a director to oversee implementing the "new service configuration."

In both countries, these initiatives to create regionalized, consolidated medical laboratory networks are designed to help control the cost of lab testing without compromising patient service. TDR

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report



It's a milestone on the path to personalized medicine and an example of how integrated health informatics will give clinicians real-time access to unlimited amounts of medical data. The **1000 Genomes Project** announced in recent months that "the world's largest set of data on human variation" is now available on the **Amazon Web Services** cloud for public access. Founded in 2008, the public/private collaboration of the 1000 Genomes Project is creating a detailed map of human genetic variation. It intends to sequence the genomes of more than 2,600 people from 26 populations around the world. The data now available on the cloud is comprised of sequencing information for 1,700 people. Plans are to sequence the other 900 people during 2012.

MORE ON: *Genomes*

Laboratory professionals, researchers, and the public can access this genome data at: *www.1000genomes.org*. The volume of data is substantial. Currently at 200 terabytes, that volume of data represents 30,000 standard DVDs. Pathologists involved in molecular research can access this data. Project organizers stated that "cloud access also enables users to analyze the data much more quickly, as it eliminates the time-consuming download of data and because users can run their analyses over many servers at once."

TRANSITIONS

- **Atlas Development Corporation**, of Calabasas, California, appointed Aron Seidman as Vice President of Product Management. In his career, Seidman has served at **MedPlus**, the informatics business of **Quest Diagnostics Incorporated**, **CGS Systems International**, **Alcatel-Lucent**, and **AT&T Bell Laboratories**.

- **Vermillion, Inc.**, of Austin, Texas, nominated Paul R. Sohmer, M.D., for election to its board of directors at an upcoming shareholder meeting. Sohmer is currently President and CEO of **Viracor-IBT Laboratories, Inc.** He has held executive positions with **TriPath Imaging**, **Neuromedical Systems**, **Genetrix**, **Nichols Institute**, **Pathology Institute**, and **Chiron Reference Laboratory**.

DARK DAILY UPDATE

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...a $900 genetic sequencing system that plugs into a USB port of a computer and can sequence up to 5,000 base pairs without the need for DNA amplification and expensive reagents. **Oxford Nanopore Technologies** developed the system and hopes to bring it to market within 12 months.

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That's all the insider intelligence for this report. Look for the next briefing on Monday, June 25, 2012.

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