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From the Desk of R. Lewis Dark...

THE DARK REPORT

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

Restricted information, see page 3

COMMENTARY & OPINION by...

R. Lewis Dark
Founder & Publisher

Lab Strategies for Population Health Management

EXTRAORDINARY THINGS ARE HAPPENING WITHIN THE HEALTH SYSTEM of this country. Powerful forces of change and transformation are at work in ways that have yet to be fully understood.

The only certainty about the healthcare system we know today is that it will look very different in the next five years. For those of you who lead clinical laboratories and anatomic pathology groups, this presents a high-stakes challenge.

It is essential to prepare your laboratory team for the different ways that physicians and patients will utilize laboratory testing. Similarly, payers and employers will restructure existing health insurance plans to drive utilization of lab testing and all clinical services in new directions. These particular developments will be accompanied by new reimbursement arrangements.

This is why I characterize the upcoming years as "high stakes." Lab leaders need to take time to understand the range of transformative forces now being unleashed by the federal government, by managed care companies, and by employers who fund health benefits for their employees.

In developing such business strategies, lab administrators and pathologists need to be clear about the single most important element that is undergoing change across the entire healthcare system. We are now moving away from an era when "one doctor treated one patient." In its place will be a primary emphasis on "population health management."

In this issue of THE DARK REPORT, we take an important step in helping you understand healthcare's evolution toward the new era of population health management. Last month, *Healthcare Informatics Magazine* published its annual list of "Top Tech Trends for 2012." On pages 10-16, you will read about these 10 trends, along with our analysis.

We think the list of top health technology trends provides a useful mirror for lab leaders. Yes, these are the market trends and informatics needs which have hospital and medical clinical CIOs scrambling. But if these are important to hospitals and medical groups, they are equally important to the clinical labs and pathology groups providing lab testing services to these providers.

As you read our analysis, keep in mind that the unifying theme of healthcare's coming reform is the transition away from the "one doctor/one patient" emphasis and to population health management. TDR

MD Self-Referral Issues Target of Utilization Study

In-clinic histology labs and pathology services operated by urology groups come under scrutiny

CEO SUMMARY: When it comes to the in-office ancillary service (IOAS) exception to physician self-referral, the issue of in-clinic pathology services has become a hot potato. Publication in* Health Affairs *of a study of urologists' self-referral of their patients for anatomic pathology services attracted national media attention. That study was funded by a grant from two national laboratory associations. The Large Urology Group Practice Association was quick to weigh in with its criticisms of the study.

FAULT LINES ARE APPEARING between the pathology profession and the urology profession over the issue of in-clinic histology laboratories operated by as many as 300 urology practices across the United States.

The latest and biggest earthquake triggered along this fault line was publication of a study titled "Urologists' Self-Referral For Pathology Of Biopsy Specimens Linked To Increased Use And Lower Prostate Cancer Detection," by *Health Affairs* in its April issue. This is a peer-reviewed journal.

This study generated national media coverage about its findings. Particularly notable was a detailed story on April 9 published in *The Wall Street Journal* with the headline "Prostate Test Fees Challenged."

Author of the study is Jean M. Mitchell, Ph.D., an economist who is Professor of Public Policy at **Georgetown University**, in Washington, D.C. She has published more than 80 peer-reviewed articles in leading economics, health services research, and medical journals. One particular focus of her work is physician self-referral.

Funding for the study came in the form of grants to Georgetown University. The grants were provided by the **American Clinical Laboratory Association** (ACLA) and the **College of American Pathologists** (CAP).

In a document on its website, the CAP described two major findings of the study as follows (underlines by THE DARK REPORT):

The study found that for each prostate biopsy procedure performed, self-referring urologists on average billed Medicare for 72% more anatomic pathology specimens

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than non self-referring physicians with no increase in cancer detection and no added benefit for the patient.

For those counties included in the study in which physicians self refer, there was a less than 21% cancer detection rate by self-referring urologists vs. a detection rate of 35% by non self-referral urologists. This detection rate is 40% lower for the self referring urologists, on average, despite their billing for nearly twice as many specimens.

The study used Medicare claims data from the years 2005-2007. It was a "targeted-market-area case-study" and looked at pathology services provided to men "who met the selection criteria and resided in a geographically-dispersed set of counties across the United States." A total of 36,261 cases met the criteria and were part of the study.

Urologists Respond

In response to the publication of the study, a press release titled "Urologists Debunk Misleading, Grossly Inaccurate Prostate Cancer Biopsy Study" was issued by the **Large Urology Group Practice Association** (LUGPA). This trade group represents 95 urology groups with 1,800 urologists, representing 20% of the nation's practicing urologists.

"This study simply furthers the political agenda of its sponsors to recapture lost market share and does not deserve credible recognition," stated Deepak A. Kapoor, M.D., in the press release. He is President of LUGPA and Chairman and CEO of **Integrated Medical Professionals, PLLC**.

"To suggest that certain [urology] practices are performing extra and unnecessary pathology work for their own remuneration when they are working within rational clinical guidelines is offensive," he continued. "It shows a total lack of understanding of proper prostate cancer diagnosis."

More information about the study's data sources and the LUGPA rebuttal are in the sidebar on page 5. What is important for pathologists and clinical laboratory administrators to understand is the strategic goals of the lab associations that provided the funding for the study.

This is explained succinctly in a document on the CAP website, which states:

The CAP and ACLA are members of a coalition of organizations whose members are affected by self-referral arrangements. This coalition is focused on educating Congress and government agencies on the impact of self-referral on health costs and patient outcomes.

In fact, most pathologists and lab executives are unaware of the coalition referenced in that statement and to which CAP and ACLA are themselves members. This coalition is called **Alliance for Integrity in Medicare** (AIM).

Besides ACLA and CAP, this coalition includes the **American Society for Clinical Pathology** (ASCP), **American College of Radiology** (ACR), **American Physical Therapy Association** (APTA), **Association for Quality Imaging** (AQI), and the **American Society for Radiation Oncology** (ASTRO).

In a published statement available on the Web, AIM states "We seek to remove those healthcare services most susceptible to overutilization and abuse from the IOAS [in-office ancillary services] exception [to the Stark Law], while preserving the ability of robust, integrated and collaborative multi-specialty group practices to offer these services through the exception."

Credibility of Peer Review

Thus, the study published in *Health Affairs* is a strategic move by individual members of the AIM coalition to provide the credibility of a peer-reviewed source of information that can be used in discussions with lawmakers as part of an effort to change existing laws.

This conclusion is affirmed by a statement on CAP's website, which reads that "there are legislative and regulatory steps that can be taken to eliminate the financial

incentives to self-refer, principally eliminating anatomic pathology services from the In-Office Ancillary Services [IOAS] Exception currently in effect."

For pathologists wondering what all the fuss is about, the *Health Affairs* study does mention the amount of money involved in in-clinic pathology labs operated by urology group practices. It notes that *Laboratory Economics* estimates that 300 urology groups currently operate an in-office pathology laboratory. These groups represent 2,000 urologists and each urologist generates an average of $150,000 per year in revenue from referring patients for pathology services.

Accept these estimates and simple math indicates that in-clinic pathology services are now a $300 million per year ancillary service for those 300 urology groups. That's an average of $1 million per year per urology group.

Major Dollars Are Involved

THE DARK REPORT observes that these numbers, as presented in the study, give some idea of how much revenue has been lost to **Laboratory Corporation of America**, **Quest Diagnostics Incorporated**, other national pathology companies, and independent pathology group practices.

What is true about this matter is that different interests will look at the same situation with different perspectives. The two big questions to be answered by future developments are about "who gets stuck."

First, are male patients "getting stuck" because of biopsies that are unnecessary? Second, are taxpayers and the Medicare program "getting stuck" due to overutilization of pathology services because of physician self-referral arrangements?

Publication of the *Health Affairs* study funded by the two lab associations should be considered one salvo in this developing battle. The urology profession may weigh in with a peer-reviewed study funded by their associations in the future. Such an event would further stir this pot. TDR

Study of In-Clinic Path Labs Relies on Certain Data Sets

IN CONDUCTING THE STUDY of urologists' self-referral of prostate biopsies, author Jean M. Mitchell, Ph.D., an economist and Professor of Public Policy at Georgetown University, selected claims data from the period 2005–07 for samples of Medicare beneficiaries who resided in a designated county, were continuously enrolled in Medicare fee-for-service, and met the criteria for potential candidates for prostate biopsies.

Mitchell conducted her analysis by pooling data from five sources: carrier standard analytical file, outpatient standard analytical file, beneficiary summary file, Medicare physician identification and eligibility registry file, and national provider identification file.

In its critique of the study of urologists' self-referral of prostate biopsies, the Large Urology Group Practice Association (LUGPA) wrote:

Mitchell hand-selected 11 counties out of more than 3,100 in the United States, reviewing only 9,976 biopsies in urology groups with in-house urology pathology labs. Mitchell claims that positive biopsy rates fell from 27.4% to around 21%, as much as 14% lower than her control group—a claim that is hardly credible given that extended biopsies are reported to increase the detection rate of clinically significant cancer by more than 30%.

To verify this, eight of the largest urology groups from across the United States reviewed their actual positive biopsy rates from their in-house pathology labs. The results were staggering: with between two and seven years of follow-up, an aggregate 42,474 prostate biopsies were performed with 16,990 positives, or 40%. This difference between Mitchell's work, calculated by mathematical manipulation of carefully selected claims data, and actual data derived from real-time tracking of results from a broad cross section of groups can only be explained by a serious flaw in the algorithm Mitchell used to derive her data.

Hospitals Get Bad News Re: TC Grandfather Expire

➤Anatomic pathologists and rural hospitals need to negotiate new payment arrangements by July 1

➤➤CEO SUMMARY: During negotiations to extend the payroll tax cut in February, congressional negotiators agreed to end the technical component (TC) grandfather provision for more than 1,000 rural hospitals. Seeking to save $50 million annually, Congress said anatomic pathologists would no longer be able to bill Medicare for the TC services on surgical specimens. Pathologists now need to negotiate with these rural hospitals over the fee for TC services once the new law becomes effective on July 1, 2012.

ONE LITTLE-KNOWN PROVISION tucked away in the payroll tax cut extension passed by Congress last February is creating disruption at as many as 1,000 rural hospitals and the anatomic pathology laboratories that provide services to these hospitals.

Congress used that bill to not only extend the payroll tax cut, but to implement a 10-month fix to avoid cutting physicians' Medicare reimbursement by 27.4%, as required by the sustainable growth rate (SGR) formula. However, one source of the money Congress used to fix the SGR problem was to eliminate what is commonly called the pathology "TC grandfather provision."

After June 30, independent labs that provide AP services to hospitals covered under the TC grandfather, including rural hospitals, will no longer be able to bill Medicare directly for payment for the technical component (TC) of certain surgical pathology services performed on behalf of Medicare Part A patients. It means that, effective July 1, 2012, pathologists must bill the hospitals for those TC services.

After this law was passed in February, Alan Mertz, President of the **American Clinical Laboratory Association** (ACLA) observed, "This TC provision is bad overall because labs will have trouble collecting from hospitals after June 30."

Since passage of this bill, pathologists have been forced to consider the direct impact the elimination of the TC grandfather clause will have on both their pathology laboratory and those hospitals for which it is contracted to provide technical component services for Medicare Part A patients.

➤Hospitals Need TC Services

"It will be a complete change for our pathology group and for the hospitals that we serve because it will require that we bill the hospitals for the technical component," stated R. Bruce Williams, M.D., FACP, a pathologist and partner in a 30-member group in Shreveport, Louisiana.

Since February, pathologists in Williams' group have been explaining the issue to administrators at the 29 hospitals in northern Louisiana that operate under the TC grandfather clause and that are served by their practice. The pathology group provides AP services to 50 hospitals in the state,

End of TC Grandfather Rule Comes on July 1

WHEN THE EXISTING TC GRANDFATHER RULE expires on June 30, 2012, pathology laboratories currently providing technical component services covered by this rule need to be prepared to deal with several important issues, advised Peter M. Kazon, an attorney at **Alston Bird** in Washington, DC.

"Even though the rule applies only to anatomic pathology (AP) services and only to specimens from hospital patients (meaning inpatients or outpatients—but not outreach patients), it could be a big deal for some pathology laboratories and for some hospitals," stated Kazon, who has extensive experience representing lab associations and laboratories.

"Certain hospitals, called covered hospitals, had a special exemption for technical component (TC) services when those services have been supplied by outside, independent AP labs," he continued. "That exemption allowed the labs to bill Medicare for TC and professional component (PC) services provided to patients at covered hospitals. Now, effective July 1, 2012, those labs must bill the TC back to the hospital and the PC gets billed to Medicare.

"Independent AP labs will likely face considerable pressure from hospitals when they negotiate on a price for the TC service," he said. "For an inpatient, the TC is included in the DRG payment from Medicare. That means the hospital doesn't get anything additional for inpatient services. The hospital can bill for TC services furnished to outpatients, but that service is paid under the Outpatient Prospective Payment System, which pays the hospital far less than an independent lab is paid for the same service."

"Therefore, when the hospital and the lab negotiate, it will be important for the laboratory to understand how the hospital is being paid," Kazon said. "The hospital will obviously not want to pay more than it believes it is receiving from Medicare for those same services."

"When negotiating, labs and hospitals need to consider another important point," he warned. "There will be a lot of pressure on labs either to give these TC services away for free or offer them at significant discounts.

"There is a potential for a fraud and abuse issue," Kazon noted. "If labs give away the TC services for free or at below market value, this could possibly violate anti-kickback rules. Therefore, a lab needs to charge a fair market rate for these TC services and that rate will be determined when the two sides negotiate."

and 29 of these hospitals are affected by the changes in the TC grandfather provision.

"Some hospitals have agreed to pay Williams' group for the TC services but some cannot afford it," he said. If a hospital can't pay for the TC services, Williams said his group will not be able to continue to provide TC services at that location.

"We would have to walk away because of the legal aspects of the issue," Williams explained. "We can't do the work for free and we do not want either the hospital or our group to be cited for inducement.

"Giving the work away for free or providing TC services at less than fair market rates could be interpreted as an inducement to get other work under applicable federal and state laws," observed Williams. "Therefore, if we can't agree on a fair-market price, our group would have to walk away.

"Over the past few weeks, we talked with these hospitals and many are part of larger chains," he added. "Therefore, they are sending this information to their home offices. We expect they will have their lawyers advise them on the best ways to proceed.

"So far, reaction from hospital administrators has varied," Williams said. "Those who understand the problem are ready to negotiate. With them, we explain that we've been reimbursed at Medicare rates and we want to provide a little dis-

count so that we can get about 95% of the Medicare rate."

Williams estimated that more than 1,000 rural hospitals could be affected. Williams also expressed concern that if a hospital cannot support a medical laboratory, affected patients could be forced to travel longer distances to receive medical care than necessary at present.

New Clause In Contracts

"Several years ago when Congress considered eliminating the TC grandfather clause, we added a new clause to our hospital contracts as they renewed," he said. "The contracts say that we would bill TC services at 90% to 95% of the Medicare rate if Congress eliminated the grandfather clause. We haven't changed all of our contracts, but many of them have this language.

"Now, despite having that language in a number of contracts, some hospitals think they can't pay it," he said. "Others want to negotiate a lower rate because they can't afford to pay for TC services at the Medicare rate.

"And some hospitals are not even aware of this problem—in part because they might have a new administrator," Williams added. "However, most hospitals are familiar with this issue because, at the end of every year, there has been uncertainty about whether the TC grandfather provision would be extended or not.

Help With Lobbying Efforts

"Similarly, over these same years, the **College of American Pathologists** (CAP) has lobbied Congress on this issue and we recruited some rural hospitals to lobby on this issue as well," he explained. Williams has represented CAP on this issue when lobbying Congress.

Tricia Hughey, the CEO of **UniPath, LLC**, in Denver, Colorado, has also started negotiations with the hospitals served by UniPath. UniPath provides AP services to 15 hospitals in Colorado, and three are small rural facilities that will be affected by the elimination of the TC grandfather provision.

"Another issue is that each of these three facilities is a critical access hospital, and thus gets additional money from Medicare for TC services," observed Hughey. "This is a complex issue and troubling in several ways.

"Because it involves a lot of billing complexity. it is not a simple problem," she noted. "Labs will need to send the professional component (PC) bills one way—meaning to Medicare—and TC bills will go another way—meaning to the hospitals. That's something we've done in the past, but every time you establish a new billing procedure, you can expect problems, especially in the beginning.

Preparing for Negotiations

"Since only three of our hospitals are affected by this, it's not a high-volume issue for UniPath," she added. "And it doesn't necessarily involve a high volume service because surgery in small hospitals is typically not a main service line. Plus, surgeries that create AP specimens are maybe about 50% of the total.

"My first step was to send explanatory letters and I have a new agreement written for each facility," Hughey said. "We are meeting with these administrators now to assist them with their change of protocol.

"Because of inducement and anti-kickback rules, we recognize that TC services cannot be given away for free" she explained. "Because our negotiations are not complete, we are uncertain of the true financial impact this will have on our pathology group and the hospitals where we provide TC services." TDR

—By Joseph Burns

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Form 5010 Update

Medicare Extends 5010 Implementation For a Second Time, Effective July 1, 2012

FACED WITH THE FACT that many payers were not ready to implement the 5010 standard under the Health Insurance Portability and Affordability Act (HIPAA), on March 15, the federal **Centers for Medicare & Medicaid Services** (CMS) announced a second delay in enforcement of the standard. The extension is until June 30.

As of March 15, CMS stated that Medicare payers were successfully processing about 70% of all Part A claims and 90% of all Part B claims in the 5010 format. But that meant 30% of Part A claims and 10% of Part B claims were going unpaid.

Cash Flow Problems

"5010 implementation is a significant development," noted Matt Warner, Associate Vice President, Operations, at **XIFIN, Inc.**, a San Diego-based provider of SaaS billing and revenue cycle management solutions. "This second extension makes it more complicated for labs.

"Some payers now have an excuse to delay accepting 5010 claims," said Warner. "However, the enforcement delay doesn't necessarily change the 5010 transition date for a given payer. Several payers are proceeding forward with their own timelines, independent of the delay, partly because they see no value in further delay.

"We see the 5010 as a much-needed improvement in the industry because it greatly reduces the number of conflicting interpretations of the specs governing the formats," he continued. "That translates into reduced complexity and labor savings by reducing per-payer, one-off variations. Providers are much closer to the time when they can send the exact same format to every payer.

"From a practical viewpoint, the extension means labs must continue to simultaneously handle two formats for a longer period of time: one for payers using 5010 and one for those payers still using the legacy 4010 format," he added. "Worse, some payer's backend systems are already implementing 5010-related changes even as they continue to accept 4010."

Issues with the 5010 format caused problems for clinical laboratories and pathology groups. **PSA, LLC–A MED3000 Company** is a billing service provider in Florence, South Carolina. It saw that many pathology labs experienced revenue declines due to payment delays from January through February. In most cases, problems associated with 5010 implementation were resolved by the end of March and income returned to normal levels.

"In January and February, things were brutal because so many 5010 claims became lost at the payers," noted Vandy Tibbets, Vice President, Implementation, Billing Support at PSA. "We would get an acceptance notification of the 5010 claim, but then the labs weren't paid. We'd call the payers and all they could tell us was to refile the claim."

Both Warner and Tibbetts recommend that labs diligently review every claim filed to ensure that each one is paid in full. In researching this situation, THE DARK REPORT learned that most private health insurance plans were ready to accept claims submitted on the 5010 forms. That was not the case with many carriers handling claims for the different state Medicaid programs. TDR

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CEO SUMMARY: Healthcare's shift away from fee-for-service medicine and toward integrated clinical care is widely recognized. However, few lab administrators and pathologists are aware of the even faster transformation underway in healthcare informatics. Presented here are the "Top 10 Tech Trends" identified last month by* Healthcare Informatics*. A common theme is the need for information technology and healthcare informatics to serve patient care organizations, a new term that describes care models such as accountable care organizations (ACO) and medical homes. In similar ways, clinical labs and pathology groups will need to deploy robust informatics capabilities to serve providers.

Fast-Moving Developments in Health Informatics

Top 10 IT Trends Send Message For Labs & Pathology Groups

EVERY CLINICAL LABORATORY and anatomic pathology group in the world produces the same end product: information. Yet many lab organizations fail to stay up-to-date with their use of information technology (IT).

Bad news is coming to those laggard laboratories. In the United States, healthcare is poised for a deep transformation of existing care delivery models. Gone will be the solo practitioners and the many self-standing specialist providers of recent decades.

In their place will be wholly-integrated provider organizations. This integration will be visible in two ways. First, clinical care will be thoroughly integrated within the self-contained organization. Think **Kaiser Permanente**, **Mayo Clinic**, and **Geisinger Health** as useful examples.

Second, the coming generation of integrated provider organizations will fully consolidate all the operational and service functions required to deliver integrated clinical care. In particular, these providers will establish a seamless and all-digital informatics backbone to support both operations and the delivery of clinical care to patients.

Because clinical laboratories and pathology groups are essentially "information factories," these major healthcare trends put all labs at risk—if they fail to advance their use of information technology in parallel with the organizational and clinical integration of the physicians and providers they serve.

Lab administrators and pathologists have fair warning of this about-to-unfold transformation of the American healthcare system. Time remains for every lab organization to develop a robust IT strategy that anticipates these developments and positions their laboratory to be an essential, added-value resource to physicians, patients, and payers.

Last month, *Healthcare Informatics Magazine* published its annual list of the "Top Tech Trends for 2012." This list of trends turns out to be chock-full of valuable insights on how hospitals, health systems, and major physician groups are prioritizing their information technology projects.

The list developed by *Healthcare Informatics* (*HI*) will surprise many lab administrators and pathologists. Of the 10 trends it deems most significant, none involve adoption of a specific type of information technology, such as offering wireless access or moving to cloud-based solutions.

To the contrary, each of the 10 health technology trends presented by *HI* represents a clinical or operational strategy of hospitals and health systems that must be supported by a different IT structure and capability. This is a significant development. Among other things, it is evidence that deeply-transformative forces are already in play.

To help lab directors and pathologists come up to speed on these important trends, THE DARK REPORT offers its insights about *HI's* "Top Tech Trends for 2012." Sprinkled throughout *HI's* description of these trends is the use of a new term: "patient care organization." This term recognizes that the range of integrated clinical care organizations will not be limited to hospitals and health systems, but will include multi-provider arrangements owned and operated by physicians, by health insurers, by employers, and by not-for-profit organizations.

Healthcare Informatics Top Tech Trend #1

PERFORMANCE IMPROVEMENT IMPERATIVES

The editors of *Healthcare Informatics* place this trend at the top of their list for 2012. It recognizes the essential role that Lean, Six Sigma, and similar process improvement methods will play in healthcare moving forward.

Mark Hagland, Editor-in-Chief at *HI*, wrote "...More patient care organization leaders now recognize that deep process change will be required to prepare their organizations for healthcare-reform related mandates."

More specifically, Hagland identifies Lean, Six Sigma, and similar continuous performance improvement methodologies as cornerstones of this trend. It means hospital CIOs are recognizing that, to support this culture of deep process change, their organization's information technology must deliver accurate, complete data in real time.

Mark Van Kooy, M.D., is Director of Clinical Informatics at **Aspen Advisors**, in Pittsburgh, Pennsylvania. He minced no words in his advice to CIOs and CMIOs when he stated "Learn process improvement methodologies, and become fluent in the subject." Only in this way, observed Van Kooy, can healthcare IT leaders understand care delivery processes at a deep level so as to help their parent organization leverage its informatics capabilities in support of continuous process change.

As *HI's* number one tech trend, the recognition of the essential role of Lean, Six Sigma, and performance improvement methods should be an equally powerful statement to lab administrators and pathologists. It is time to fully engage your own laboratories in ongoing process improvement at a deep level.

Healthcare Informatics — *Top Tech Trend #2*

POPULATION HEALTH MANAGEMENT & RE-ADMISSIONS

AT THE MOMENT, this trend is rooted in new health initiatives designed to reduce and prevent hospital re-admissions. But it is wrong to characterize this trend as simply aimed at re-admissions.

Rather, reducing hospital re-admissions is the spear point for the overriding goal of lifting the health of the entire population being managed by a patient care organization.

In the short term, hospitals and health systems will be under direct pressure to measurably reduce hospital re-admissions. Medicare and private payers are instituting programs designed to focus patient care organizations and hospitals to reduce re-admissions in order to maximize their reimbursement as participants in these programs.

Jane Metzger, Principal Researcher at the **Global Institute for Emerging Healthcare Practices** at **CSC** in Falls Church, Virginia, told *HI* that "reducing avoidable re-admissions has become one of the most pressing issues for hospitals as they look to become accountable care organizations (ACOs)."

Further, Metzger noted that hospitals and health systems are scrambling to improve quality metrics and their publicly-available rates of re-admissions because there are now "first time, high financial stakes" to reward them for success in this effort. Of course, lab administrators and pathologists understand that laboratory testing has an essential role in reducing hospital re-admissions.

What *HI* emphasized about this top tech trend is that providers are actively taking steps to improve real-time access to population health analytics. This information is required to guide physicians when providing care.

Similarly, access to this same information is essential for care team members who regularly contact individual patients to implement the proactive care management protocols. These medical professionals also need real-time access to laboratory test data to fulfill these types of care initiatives.

Healthcare Informatics — *Top Tech Trend #3*

PRIVATE HIES ON THE UPSWING

ONE PHENOMENON that gets little public attention is the steady increase in the number of private health information exchanges (HIEs).

This is a response to the American Reinvestment and Recovery and Health Information Technology for Economic and Clinical Health (ARRA, HITECH) Acts. *Healthcare Informatics* noted that "hospi-

tals and health systems, as well as payers, are fueling HIE growth as they build the information backbones necessary to support care coordination and accountable care organization (ACO) development."

Health plans and managed care companies are building HIEs as an extension of their patient portals and as a way to deliver additional services to both patients and physicians. It is also a way that insurers can help in coordinating patient care.

This trend has direct consequences for clinical laboratories and pathology groups. To remain a viable provider of lab testing services in a region, labs will need to participate in these HIEs.

Further, it seems that the emergence of private HIEs alongside public HIEs would create market competition between these organizations. Whether such competition might benefit local laboratories remains to be seen.

Healthcare Informatics — Top Tech Trend #4

TURNING HEALTHCARE'S BUSINESS MODEL INSIDE OUT

IT IS LOGICAL that the fourth tech trend on *Healthcare Informatics*' list centers upon the use of information technology as a necessary tool for accountable care organizations (ACOs) and similar patient care organizations.

This goes beyond the central data warehouse containing patients' electronic health records (EHR). It is a trend that describes how hospitals and providers are developing the capability to analyze healthcare data, then guide the activities of care givers.

HI illustrated how this trend is unfolding by using an example provided by Jim Adams, who is Managing Director, Research and Insights, at the **Advisory Board Company** in Washington, DC. Adams identifies three phases in his "IT maturity model for accountable care."

Phase one incorporates 12 foundational elements. These range from establishing ambulatory EHRs and health information exchanges (HIE), to disease registries, physician and patient engagement, and components focused on quality improvement (such as Lean and Six Sigma).

Phase two for Adams happens when reimbursement models incorporate performance risk and bundled payments for end-to-end acute care episodes (i.e. surgeries) and for ambulatory episodes (i.e. chronic diseases).

In phase three, Adams says that patient care organizations will accept utilization risk for a population of patients. Providers will achieve this by employing preventative medicine to reduce unnecessary utilization and improve patient outcomes.

One expert told *HI* that the purely technological challenge for patient care organizations will be to harness "discreet data across the continuum of care, coming from various care settings and various IT systems, to really understand the health of the population."

Clinical laboratories and pathology groups will also be feeding data to these same patient care organizations. The patient lab test data they produce needs to flow seamlessly into the data repositories of these patient care organizations.

Healthcare Informatics — Top Tech Trend #5

BRIDGING THE CARE TRANSITION GAP

HEALTH INFORMATICS has an important role in managing the problem of transitioning patient care from one provider to another. IT collaboration tools are being developed to meet these needs.

Health professionals will use information technology to help coordinate care teams, identify the responsibilities of providers, and avoid duplication of care while backstopping providers to ensure that nothing needed by the patient is dropped or overlooked by a caregiver.

Further, these are new uses for healthcare IT. "In the past, discharge summaries were focused on what happened, as opposed

to here are the goals, here is what needs to be done and this is what has been done so far, and what information needs to be handed off to make the transition successful," stated Harry Greenspun, M.D., Senior Adviser for Healthcare Transformation and Technology at the **Deloitte Center for Health Solutions** in Washington, D.C

Consistent with this need, Pat Rutherford, R.N., Vice President of the **Institute for Healthcare Improvement**, in Cambridge, Massachusetts, told *HI* that she sees "the hospital's role as a 'pay it forward' dynamic of providing the information that the next provider of care needs, and what it can do to make that transfer of information successful."

This affirms the need for real-time access to lab test results, such as when the patient is about to be discharged. Transmitting the patient's lab test data generated during the hospital stay as part of the transition to the next care setting will be important if that next team of care givers is to be effective at reducing or preventing a re-admission of this patient.

Using informatics to support the transition of patient care is likely to involve both clinical laboratories and pathology groups in new ways. It will create different interactions between laboratories and providers.

Healthcare Informatics — Top Tech Trend #6

PRIVACY AND SECURITY DURING THE YEAR OF THE CSIO

HERE'S A HEALTH IT TREND that has yet to be recognized by most lab administrators and pathologists. *Healthcare Informatics* believes that 2012 is the year of the Chief Information Security Officer (CISO).

In other words, healthcare organizations across the United States are giving more attention and funding to patient privacy and IT security than at any time in the past. Current developments explain part of this heightened interest.

For one thing, this year will see the release of the final rules for the privacy and security regulations specified by the Health Information Technology for Economic and Clinical Health (HITECH) Act. These are modifications to the Health Insurance Portability and Accountability Act (HIPAA).

The second factor is increased provider audits by the HHS Office for Civil Rights (OCR). OCR contractors will conduct as many as 150 provider audits between May and December this year.

At the same time, provider IT departments are working to minimize the risk of data breaches from unsecured mobile devices, like smart phones and iPads. More than 60% of respondents to one survey said that their institutions had increased the portion of the IT budget devoted to security.

The appearance of this trend in the tech top 10 list is a timely reminder to laboratories that more attention should be devoted to beefing up IT security and creating employee awareness about the risk of privacy breaches involving sensitive patient information.

Healthcare Informatics — Top Tech Trend #7

SECOND-GENERATION CLINICAL DECISION SUPPORT

IT IS WIDELY-ACCEPTED that the first generation of clinical decision support (CDS) systems have not performed to expectations. For that reason, considerable investment is flowing into the development of second-generation CDS.

HI described the existing deficiencies in CDS as follows: "what has become clear in the past few years is that the first generation of CDS tools, as embedded in commercial healthcare IT vendors' core EHR systems, has not lived up to expectations; and indeed, has required continuous customization work on the part of healthcare IT leaders seeking to avert alert fatigue and truly optimize the workflow of physicians and other clinicians. So, what's next?"

Healthcare Informatics answered its own question by quoting Jerry Osheroff, M.D., Principal at **TMIT Consulting** in Cherry Hill, New Jersey, who said, "'...there are care delivery organizations and others who are drawn very strongly to this notion of measurably improving high-priority outcomes through the use of second-generation clinical decision support."

"Major learning number two," noted Osheroff, "is that there is a relatively small handful of relatively high targets [for broad performance improvement] of interest to care organizations. That's why folks have locked onto issues such as optimizing VTE [venous thromboembolism] prophylaxis and hemoglobin A1C management; and the next big target will be re-admissions."

HI noted that Osheroff believes that success with implementing second-generation clinical decision support "will require creating consensus around concrete performance improvement targets the physicians can embrace."

Of course, developing care algorithms and evidenced-based medicine (EBM) guidelines that incorporate laboratory tests is a core competency of pathologists, clinical chemists, and laboratory scientists. THE DARK REPORT sees this as an opportunity for local clinical labs and pathology groups to engage early with patient care organizations and participate in developing the protocols that will be built into the second-generation clinical decision support systems now actively under development.

Healthcare Informatics — Healthcare IT Leadership, Vision & Strategy

Top Tech Trend #8

IMAGING INFORMATICS AND THE ENTERPRISE

HOSPITALS ARE DEALING with an explosion of digital images across a variety of medical specialties. These images are produced in medical specialties ranging from radiology and cardiology to dermatology, gastroenterology, and pathology.

With physicians often needing to access three or four different viewers to see images, hospitals are seeking a way to handle digital images with a single enterprise solution. In this sense, these institutions are outgrowing the capabilities offered by PACS (picture archiving and communications system).

The additional complication is that many electronic medical record (EMR) systems are not able to handle the variety of image types that are produced by different medical specialties.

According to *HI*, digital archiving solutions "must address the workflow and management issues that typically do not match up across departments." Vendor-neutral archive (VNA) systems have yet to gain favor with providers. One expert observed that "VNA solutions ignore the need for standards-based visualization tools that can be applied to an archive."

Another issue is that existing standards for managing and accessing digital images exist. However, there are no mandates by government. Nor is there consensus by industry on how providers should adopt and use these standards.

Healthcare Informatics Picks Top IT Trends

PRESENTED BELOW are the "Top Tech Trends for 2012" that were identified by the editors of *Healthcare Informatics* magazine in the March 2012 issue. Each of these 10 health IT trends has a component that involves clinical laboratory test data.

- Performance Measurement
- Population Health Management & Re-Admissions
- Private HIEs on the Upswing
- Healthcare's New Business Model
- Bridging the Care Transition Gap
- Privacy and Security During Year of CSIO
- Clinical Decision Support
- Imaging Informatics and the Enterprise
- Mobile Health, or BYOD—"Bring Your Own Device!"
- Personalized Medicine: Game Changer

All of this confusion may be a benefit to anatomic pathology groups. It provides them time to acquire and use digital pathology systems during that window of time when hospitals and health systems have yet to settle on universal solutions for storing and accessing the multiple types and formats of digital images that are part of a single patient health record.

Healthcare Informatics *Top Tech Trend #9*

MOBILE HEALTH, OR BYOD—"BRING YOUR OWN DEVICE!"

PROBABLY NO SINGLE ELEMENT of healthcare informatics has evolved as rapidly as the acceptance of mobile devices by physicians, nurses, and other clinicians. This might be called the smartphone/tablet revolution because of its speed and scale.

Not surprisingly, *Healthcare Informatics* reports that a study of healthcare CIOs conducted by **Health Information and Management Society** (HIMSS) determined that "while approximately 75% of those surveyed said their organization allows clinicians to access clinical data via a mobile device, only 38% have a policy in place that regulates the use of mobile devices and outlines a mobile strategy."

Essentially, this is a health informatics trend that has outrun the ability of health CIOs to establish policies and provide robust support for the mobile devices in use by their clinicians. Furthermore, this may be a mobile device cat that is already be out of the bag! One CIO declared, "If I told physicians they couldn't bring their own mobile devices, I'd be shot."

Clinical labs report that they are already fielding many requests from referring physicians to establish capabilities which allow the physicians to order lab tests and view lab test results via a mobile device. This creates the opportunity for first-mover and early adopter lab organizations to meet this need of their referring physicians and gain competitive advantage in their regional markets.

Healthcare Informatics *Top Tech Trend #10*

PERSONALIZED MEDICINE: THE GAME CHANGER

PERSONALIZED MEDICINE was selected as one of the top 10 tech trends—not because health IT departments are spending money today on solutions—but because they should be!

It was the opinion of the editors at *Healthcare Informatics* that "the convergence of emerging genetic medicine and electronic health records" is a development that requires immediate attention by hospital and healthcare CIOs.

The common element in this advice and warning was the need for electronic medical record (EMR) systems to handle genetic data. A number of health systems already provide services that incorporate genetic medicine.

For example, the **Coriell Institute for Medical Research**, Camden, New Jersey, and the **Ohio State University Medical Center** in Columbus, Ohio, are collaborating on a clinical study. It involves 1,800 patients diagnosed with congestive heart failure or hypertension who are under the care of OSU cardiologists and primary care physicians.

At this time, the electronic health record system has no fields ready to be populated by genetic data. As a workaround, Coriell and OSU put the genetic risk reports in PDF files. These files are then attached to the patients' records in the same fashion that imaging files are currently attached.

➤Hospitals Need TC Services

As presented above, the 10 top tech trends identified by *Healthcare Informatics* magazine offer an invaluable window into the key issues that dominate spending by hospitals, health systems, and other providers on information technology. Lab leaders will find great value in using THE DARK REPORT's assessment of these trends as part of their strategic planning process. TDR

Lab Briefs

HOSPITAL LAB CLOSED, STAFF EVACUATED AFTER LAB SPECIMEN SPILL

IT'S NOT OFTEN THAT A HOSPITAL LABORATORY needs to be closed and decontaminated following a lab accident. Yet that is what happened on April 2 at 495-bed **Grand River Hospital** in Kitchner, Ontario.

The problem was caused by the release of the soil fungus *coccidioides* when a specimen container broke in the laboratory during disposal. The spores of this fungus can cause a flu- or pneumonia-like illness when inhaled.

The problem was discovered within hours of the contamination. Workers in the laboratory were immediately evacuated and the facility was closed. Because the incident took place within the laboratory, no patients were exposed to the fungus.

The consequences of this contamination event were significant. Both the microbiology lab and the core lab were closed and sealed on April 2. The hospital decided to cancel elective surgeries for as many as 70 patients on the day following the accident in the laboratory.

The *Waterloo Record* newspaper reported that lab testing was switched to nearby St. **Mary's General Hospital**. Lab specimens from Grand River Hospital were also being sent to **Cambridge Memorial Hospital**, **Guelph General Hospital**, and hospitals in Hamilton and London, Ontario.

Any laboratory equipment that could not be decontaminated is being replaced. Areas needing decontamination included the core laboratory. New ceiling panels, lights, and heat detectors were installed and, last week, parts of the lab reopened, including anatomic pathology for cancer testing, the newspaper said.

Another issue is the need to calibrate the new lab testing instruments and validate the tests to be run on these analyzers. For that reason, the Grand River Hospital laboratory has yet to return to normal operation with its full menu of lab tests.

The contamination of a large clinical laboratory by the accidental release of an infectious agent during the disposal of specimens is a rare event. This episode demonstrates how such a lab accident can disrupt normal operations of a large hospital and require substantial money to deal with the contamination, including replacing expensive lab analyzers and instrument systems.

SELF-SAMPLE HPV TEST KIT ALLOWS WOMEN TO COLLECT THEIR OWN SPECIMEN

SELF-SAMPLING FOR HPV TESTING is a concept that is becoming reality. Already, in the United Kingdom, one company sells an HPV test kit to consumers that allows a woman to collect her own specimen and send it away to a lab to be tested.

It was last fall when **Home Test Direct Pty Limited** introduced its TAMPAP test for detecting the HPV virus, which is associated with cervical cancer. The test is marketed on the company's website (*www.tampap.com*). It costs £19.95, plus £9.95 for postage (a total of US$47.79).

After purchasing the HPV test, the woman is sent a collection kit. She is told "You just take a sample of your cervical cells in the comfort of your own home (using an ordinary tampon) then dispatch it to our state-of-the-art laboratory in a specially supplied container."

In February, 2011, the *British Journal of Cancer* published a study about the use of self-sample HPV test kits by consumers. In this study, 3,000 women were selected who

had not responded to invitations to visit their physician for a cervical cancer screen.

Study authors wrote that "The women were randomised on a 1:1 basis to either receive an HPV self-sampling kit or a further invitation to attend for cervical cytology." It was found that the HPV self-screening group responded at a rate of 10.2%. This was statistically higher than the 4.5% response rate by those women who visited their physician in response to a notice inviting them to come in for a cervical cancer screen.

Self-sampling for HPV testing has been the subject of several studies in Mexico. In November, 2011, the medical journal *Lancet* published a study conducted in "540 medically underserved, predominantly rural communities in Morelos, Guerrero, and the state of Mexico." Researchers wrote that the goal was "to establish the relative sensitivity and positive predictive value for HPV screening of vaginal samples self-collected at home as compared with clinic-based cervical cytology."

Approximately 12,000 women participated in the HPV self-sample group and 11,000 women participated in the cervical cytology group. The researchers determined that self-sampled HPV tests would be a useful option in "low-resource settings where restricted infrastructure reduces the effectiveness of cytology screening programs."

Collectively, these examples provide evidence that advances in lab test technology make it feasible to involve the patient in self-sampling, at least for HPV testing. However, THE DARK REPORT is unaware of any laboratory in the United States that currently offers consumers an HPV test that utilizes a self-sampled specimen.

PSYCHE SYSTEMS, SIEMENS ENTER ALLIANCE TO INTEGRATE LIS AND PATHOLOGY LIS

ON APRIL 10, 2012, IT WAS ANNOUNCED that **Psyche Systems Corporation** had inked a strategic alliance with **Siemens Healthcare**. The two companies intend to more closely integrate their respective laboratory information products.

Siemens' flagship laboratory information system (LIS) is NOVIUS Lab. As part of the strategic alliance, WindoPath, the anatomic pathology information system sold by Psyche, will be offered "as the anatomic pathology component of NOVIUS Lab."

This alliance of a laboratory information system (LIS) company with a pathology LIS company is a sign that laboratories recognize the need to deploy informatics solutions which offer more integration between the clinical lab's LIS and the pathology information system used by the anatomic pathologists.

That goal was described in the press release about the strategic alliance. The two companies stated "By integrating Siemens' Soarian, INVISION, and MedSeries4 health information systems with Psyche's WindoPath AP system, the companies will provide AP capability for laboratories with bi-directional data, results, and demographic sharing and reporting to enhance laboratory workflow."

BIO-RAD MAY BE ACQUISITION TARGET AFTER DEATH OF FOUNDER

BIG CHANGES MAY BE AHEAD for **Bio-Rad Laboratories Inc.,** of Hercules, California. Following the death of its founder and Chairman, Howard Schwartz, on April 1, the business press is speculating that the company may be offered for sale.

Business Week magazine declared that Bio-Rad "is presenting potential buyers with the most affordable acquisition in the U.S. life-science equipment industry as investors bet the family-run company will now be open to a sale."

Bio-Rad had sales of $2.1 billion last year. It is a respected provider of life science research and clinical diagnostic products test kits. The company was founded in 1952. TDR

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

"Innovator of the Year" honors were recently bestowed on Robin Felder, Ph.D., who is Professor of Pathology and Associate Director of Clinical Chemistry at the **University of Virginia School of Medicine** in Charlottesville. Felder was selected as the winner of the 2012 Edlich-Henderson Innovator of the Year Award, the highest honor bestowed by the University of Virginia. Across the lab industry, Felder is recognized for his ongoing work in the field of laboratory automation. He calls himself a serial entrepreneur and has played a role in launching nine companies in the past 20 years.

MORE ON: *Felder*

Felder's colleagues complimented him on his continuing enthusiasm for identifying new technologies and bringing them to market. "He is the poster child for how innovation can become a key part of faculty members' academic pursuits," observed Mark Crowell, Executive Director of **UVa Innovation** and Associate Vice President for Research. "He has taken the extra step of looking for opportunities to translate discoveries in the lab into a new service, product, or company to benefit society and generate economic value."

MAYO PICKS FIRM TO DO WHOLE GENOME SEQUENCING

For its whole human genome sequencing needs, **Mayo Clinic**, of Rochester, Minnesota, will use the services of **Complete Genomics, Inc.**, of Mountain View, California. The outsourcing arrrangement will support and expedite Mayo's translational genomics-based programs.

TRANSITIONS

• John J. Krolewski, M.D., Ph.D., was named Chair of Pathology and Laboratory Medicine at the **University of Rochester Medical Center** in Rochester, New York. Most recently, Krolewski was Professor of Pathology and Laboratory Medicine at the **University of California, Irvine** (UCI). He established molecular diagnostics labs at both UCI and **Columbia University**.

• **CombiMatrix Corporation**, of Irvine, California, announced that Richard Hockett, M.D., will be the company's new Medical Director, effective May 1. Hockett was formerly Chief Medical Officer at **Affymetrix, Inc.**, and has held positions with **Eli Lilly and Company**, and with the Department of Pathology and Laboratory Medicine at the **University of Alabama, Birmingham**.

That's all the insider intelligence for this report. Look for the next briefing on Monday, May 14, 2012.