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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

Charting Your Lab's Course for 2014

WITHOUT QUESTION, CLINICAL LABS AND PATHOLOGY GROUPS will be confronted with tough challenges during 2014. Across the nation, lab executives and pathologists tell us that it is no longer "business as usual."

What I find most interesting about the feedback pouring into our offices is that the Affordable Care Act is not a factor for labs, at least not yet. We all know that health insurers are narrowing networks as they develop their health insurance exchange products to meet the specifications of the Bronze, Silver, Gold, and Platinum plans. Yet few labs are complaining that they have been excluded from the provider networks associated with these insurance plans.

Rather, the immediate source of pain is financial and is associated with the decline in reimbursement paid by Medicare and private payers. For many independent clinical labs and pathology groups, it is the reduced prices now paid for certain important CPT codes that creates financial pressure.

It is a similar story for hospital laboratories. Nationally, there is a cumulative decline in inpatient admissions. By itself, this is a troublesome trend for these institutions. But the declining inpatient admission problem is compounded by several Medicare initiatives, not the least of which are RAC audits and financial penalties associated with higher readmissions of Medicare patients.

On their own, hospitals are responding to these developments by classifying some incoming patients for observation under the OPPS fee schedule. The net effect is less money per patient bed per year. That directly affects the hospital laboratory because of cuts to the lab's annual operating budget.

Equally troublesome is that 2014 will bring a new set of challenges for laboratories. For example, on pages 3-5 of this issue, you will read our first assessment of the final rules for the 2014 Medicare Fee Update. Medicare officials pulled back the most onerous elements of their proposed changes to pathology and clinical laboratory pricing. That's the good news. But the Medicare program will move forward in ways that will reduce what pathologists and clinical labs get paid for important lab testing services.

That is why it is easy for me to predict that one trend we will see in 2014 in the clinical lab industry is lots of cost-cutting. With less money coming in the door, financial sustainability requires every lab organization to get better at eliminating sources of waste, trimming costs, and boosting productivity. TDR

ACLA, CAP Comment on Final 2014 Medicare Rules

Medicare officials moderated some elements of three proposed rules, but fee cuts will happen

CEO SUMMARY: On November 27, as the nation prepared for the Thanksgiving holiday, the federal Centers for Medicare & Medicaid Services (CMS) announced the long-awaited final rules for 2014. Early analysis of the 1,300 pages of rules CMS released indicates that the agency moderated one of its proposals to cut back what pathologists and clinical labs are paid. At the same time, CMS will continue to move forward with its review and revision of other pathology and clinical lab procedures.

Late afternoon of November 27, the day before Thanksgiving, the federal **Centers for Medicare & Medicaid Services** (CMS) released its final rules for the 2014 Medicare Physician Fee Update. This event was long anticipated by laboratory professionals.

Because the final rules take up 1,300 pages, there was only limited analysis available as The Dark Report went to press. This story provides an initial assessment of the multiple key issues of concern to pathologists and clinical laboratory executives. In the weeks to follow, there will be more detailed analysis about the final rules and their effect on labs in 2014 and beyond.

The final rules associated with three different Medicare fee schedules will bring definite changes. There is moderation of at least one proposed rule, but pathologists and clinical lab managers can expect to see reduced reimbursement in certain key areas.

For anatomic pathology, the CMS final rules contain several significant changes that will become effective in 2014 and beyond. One such change involves restrictions on the number of prostate biopsies for which a pathologist can bill the Medicare program. In its analysis of the rule, the **College of American Pathologists** (CAP) said that CMS imposed restrictions on billing of 10 or more prostate biopsy specimens and will require individuals who bill more than 10 to use a G code for such billing.

CAP also wrote: "CMS halted its plan to cap payment rates in 2014 in the Medicare physician fee schedule at Hospital Outpatient Ambulatory Classification

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(APC) Rates. Additionally, CMS reduced payment for certain anatomic pathology codes and expanded bundling of payments for all clinical laboratory tests (other than molecular pathology tests) performed on hospital outpatients that are currently billed to the Clinical Laboratory fee Schedule (CLFS)."

CAP further wrote that, "As expected, the final rule included payment reductions to the following pathology code families:"

- **Immunohistochemistry: 88342:** CMS reduced the value of both the PC and TC and established a requirement to use new G codes to bill services going forward.
- **Enhanced Cytology Services: 88112:** CMS reduced value for the PC and TC.
- ***In situ* hybridization services: 88365, 88367, and 88368:** CMS deferred action on revaluation of the PC and TC until 2015.
- **88305 TC:** CMS did not reduce valuation for the TC.

One Positive Development

One positive development from the announcement is that CMS will allow pathologists to qualify for incentive payments starting January 1, 2014, under the Physician Quality Reporting System (PQRS) by filing claims or using a registry option for labs that report fewer than nine measures, CAP said.

This rule about PQRS is significant. In 2011, pathologists received an average bonus of $856.50 and—just by participating in PQRS this year—pathologists avoided penalties that begin at 1.5% of their Medicare Part B billing in 2015 and rise to 2% in the following years, CAP said. CMS did not agree to add three new pathology measures that CAP recommended, CAP said.

A major area of concern for clinical laboratories was the draft rule that called for CMS to review the fees for 1,250 clinical lab tests over the next five years. CMS intends to proceed with this initiative.

"Starting in 2014, CMS will review these codes on the Medicare Part B Clinical Laboratory Fee Schedule," stated Alan Mertz, President and CEO of the **American Clinical Laboratory Association** (ACLA.) "However, it appears CMS changed the procedure versus what they had proposed back in July.

CMS Gave Itself Flexibility

"In the proposed rule, CMS was going to review all 1,250 codes over five years, starting with the oldest and working forward," explained Mertz. "In the final rule, it appears from my initial review, that CMS officials gave themselves some flexibility in how they will review the codes.

"It looks as if CMS will not necessarily review the oldest ones first, as was proposed in July," he added. "From reading this final rule, it appears CMS officials wanted more flexibility in how they prioritize the codes for their review.

"The rest of what CMS decided appears to be the same as what was proposed," Mertz said. "CMS has the statutory authority to adjust rates on a code-by-code basis for any technological changes that have been made since the codes were introduced.

"CMS did not alter the definition of technological changes," he said. "A technology change is still defined as any difference in how labs use labor, tools, and machines. Again, this is based on my first review of the rule which came out on Thanksgiving eve, so we may have subsequent interpretations that are different.

Hitting Labs Twice

"One problem CMS does not appear to address is that Congress already put in place an annual 'productivity adjustment' in 2010 that occurs every year going forward that cuts prices for all test codes to account for increased efficiencies such as those from technological changes," Mertz said. "In essence, labs are being hit twice: once by CMS for making improvements in technology and once by law for making improvements in productivity. However,

for a lab, these improvements are what they do and so they are penalized twice."

Mertz did praise CMS for not finalizing a proposal to cut Medicare payments drastically for anatomic pathology services used to diagnose breast, colon, prostate, skin, ovarian, leukemia and other cancers. "Under a proposal in the Physician Fee Schedule published in July, CMS would have capped Medicare payments to independent laboratories at the same rate it pays hospitals under the Hospital Outpatient Prospective Payment System (OPPS)," noted Mertz. "In so doing, CMS would have cut payment for 39 common AP tests by an average of 26% and specific tests by as much as 80%.

"It was good news that this proposal was not made final because it was a big cut and it was coming fast, since it would have gone into effect on January 1," Mertz said. "We appreciate that CMS recognized our comments and also heard the concerns of labs, pathologists, manufacturers, patients, and members of Congress who had expressed strong opposition to the OPPS proposal as well."

Bundled Payment Rule

Neither Mertz nor CAP commented on the CMS decision regarding bundling payment under Medicare's Hospital Outpatient Prospective Payment System (HOPPS). CAP explained that "beginning January 1, 2014, payment for all clinical diagnostic laboratory tests (other than molecular pathology tests) performed on hospital outpatients that are currently billed under the CLFS will be bundled into payment for primary hospital outpatient procedures."

CAP further wrote that "the expanded bundling payment would apply for services that are provided on the same date of service as the primary service and ordered by the same practitioner who ordered the primary service." TDR

—Joseph Burns

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Financial Analyst Assesses Final Medicare 2014 Rules

IN ASSESSING THE FINAL RULES published November 27, by the federal Centers for Medicare & Medicaid Services (CMS), one financial analyst characterized some of the modifications made by CMS as a "meaningful positive" for pathology groups and clinical labs.

In her first notes about the announcement, Amanda Murphy, CFA, of **William Blair & Co.**, in Chicago, noted that CMS will take additional time to consider capping payments on the physician fee schedule for services provided in nonfacility settings. This proposal deals with tests that are performed in independent labs and would set the price cap at the same rates paid in the hospital outpatient prospective payment system (HOPPS).

"We view this as a meaningful positive," wrote Blair. "Based on the proposed rule published in mid-July, these caps would have resulted in meaningful cuts to 39 anatomic pathology services and could have had outsized implications on reimbursement rates for a number of key anatomic pathology procedures, including fluorescence *in situ* hybridization (FISH) testing (cut by 62% globally) and flow cytometry (technical component of add-on markers cut by 76%). Both of these tests are frequently leveraged to diagnose cancer and are particularly important in diagnosing hematological malignancies (such as leukemia and lymphoma).

"CMS also appeared to back off of its original proposal to formally reevaluate payment rates for all 1,250 codes on the Medicare clinical lab fee schedule (CLFS) over a five-year period," Murphy wrote. "However, the 2014 rule indicates that CMS intends to explore an existing statutory provision that would allow CMS to review and update the CLFS based on changes in technology."

Lab Companies' IPOs Go Two-for-Three in November

It's been a busy IPO season for companies with proprietary molecular and/or genetic tests

CEO SUMMARY: This fall, a parade of molecular and genetic test companies moved forward with initial public offerings (IPOs) of their stock. In September, Foundation Medicine raised $106 million from its IPO. Encouraged by this success, three different companies proceeded with IPOs during November. The IPOs of Veracyte and Oxford Immunotec raised $58 million and $64 million respectively. Meanwhile, CardioDx, which had hoped to raise up to $92 million, pulled its IPO.

DESPITE DIFFICULT FINANCIAL TIMES for the clinical lab testing industry, companies with proprietary molecular diagnostics tests have been willing to offer initial public offerings (IPOs) this fall.

Last month, three companies decided to test the waters and attempt to sell stock to the public. Two of the IPOs were successful and the third IPO was pulled from the market.

First up was **Veracyte, Inc.**, of South San Francisco, California. Investors liked the stock and on November 4, Veracyte announced that the IPO had raised net proceeds of $58 million. The company's stock now trades on NASDAQ under the symbol: VCYT.

Veracyte's Proprietary Test

Veracyte markets the Afirma Thyroid FNA Analysis. This proprietary assay is used to test thyroid nodules previously diagnosed by cytopathology as indeterminate. Studies show that the assay can reclassify a significant number of these cases as benign, thus giving patients a more definitive treatment option.

For third quarter 2013, Veracyte performed 12,417 tests. The retail price of the Afirma Thyroid FNA Analysis is $4,275.

The second lab test company to complete an IPO during November was **Oxford Immunotec**. This company is based in Oxford, United Kingdom, and its offices in the United States are located in Marlborough, Massachusetts.

On November 22, the company announced that its IPO in the United States had raised $64 million. Its stock trades on NASDAQ under the symbol: OXFD.

The proprietary molecular test sold by Oxford Immunotec is the T-SPOT.TB test. This assay is designed to detect latent tuberculosis (TB). Experts estimate that one-third of the world's population has latent TB. About half of immigrants arriving in the United States have latent TB.

Oxford Immunotec reported revenue of $28.6 million for the first nine months of 2013. It says that about 50% of its sales come from the United States. The company also noted in public documents that its T-SPOT.TB test is covered under CPT 86481 and Medicare's national limitation amount for 86481 is currently $103.

Buoyed by the success of Veracyte's IPO, another Silicon Valley lab testing company was prepared to initiate an IPO during November. **CardioDx, Inc.**, of Palo Alto, California, wanted to sell as much as $92 million worth of stock. However, on November 14, CardioDx said that had pulled the offering. Company officials stated that the market conditions for an IPO were poor.

Test For Atherosclerosis

The proprietary test sold by CardioDx is Corus CAD. From a blood specimen, it looks at 23 distinct messenger RNA sequences associated with atherosclerosis. The company says that "CardioDx's Corus CAD test is the... only commercially available blood-based gene expression test that provides a current-state assessment for non-diabetic patients with symptoms that are suggestive of obstructive CAD. Corus CAD helps clinicians rule out obstructive CAD as the cause of these symptoms."

For the first nine months of 2013, CardioDx performed approximately 14,100 tests and generated revenue of $5.1 million. Retail price for this test is approximately $1,200.

Earlier this fall, **Foundation Medicine** of Cambridge, Massachusetts, successfully completed its IPO. The offering closed on September 24 and raised about $106 million. The company trades on NASDAQ under the symbol: FMI.

Proprietary Molecular Assay

The company offers a proprietary molecular assay called FoundationOne. It is described as "a fully informative genomic profile to identify a patient's individual molecular alterations and match them with relevant targeted therapies and clinical trials."

The list price for the FoundationOne test is $5,800. During the third quarter of 2013, Foundation Medicine performed 2,577 FoundationOne tests.

It is significant that four lab testing companies with proprietary molecular diagnostic assays or genetic tests were willing to test the IPO waters in recent months to gauge investor interest. It is also significant that three of the four IPOs were successfully funded.

After all, in the realm of molecular and genetic testing, the year 2013 has not been kind to many laboratories, not the least because of Medicare's snafu on how it handled implementation of the 114 new molecular CPT codes that became effective on January 1, 2013. Similarly, private health insurers have been equally tough on coverage guidelines and pricing for proprietary molecular diagnostic assays this year. *(See TDRs, April 15, 2013, and June 17, 2013.)*

Thus, investor willingness to buy up the stock of three different companies with proprietary assays shows that some investors still see opportunity in molecular and genetic testing.

Arguing Clinical Value

In fact, each lab company that tested the IPO waters this fall would argue that its proprietary test delivers clinical value and informs the physician in a way that can positively alter the course of treatment for the patient. At the same time, each company is expanding the number of physicians who are willing to order these tests when it is appropriate.

This success is in contrast to the financial struggles seen at many other laboratory organizations. Throughout the course of 2013, a number of lab testing companies closed their doors for good or were sold. *(See TDR, November 12, 2103.)*

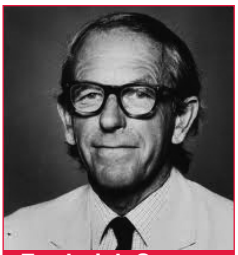
Clearly the market trends in clinical laboratory testing are mixed at this time. The American healthcare system and the lab test marketplace are both in the midst of sorting out winners from losers. Thus, pathologists and laboratory executives need to stay nimble and refocus their lab's services to better meet the changing needs of their referring physicians. TDR

Notable People

Frederick Sanger Dies at Age 95, Hailed as Father of Genomics

Double Nobel Laureate in chemistry determined chemical structure of proteins and sequenced DNA

EVERY DAY, ACROSS THE GLOBE, labs perform testing using Sanger sequencing and other fundamental techniques of proteomics and genomics pioneered and developed by Frederick Sanger, who died last month at the age of 95.



Frederick Sanger
1918-2013

Sanger is considered one of the giants in biochemistry. He was one of only three people awarded two Nobel prizes in science. Both of his Nobel prizes were for chemistry, in 1958 and 1980. The other dual awardees were Marie Curie (physics and chemistry) and John Bardeen (twice in physics). Linus Pauling's two Nobel prizes were for chemistry and peace.

In the 1950's, working at the **University of Cambridge** in the United Kingdom, Sanger was the first to unravel the structure of a protein. That was insulin. Among other things, Sanger proved that the ordering of amino acids was crucial to the actual function of a protein. His work led to the laboratory synthesis of insulin and major advances in treating the disease.

Developed Sanger's Reagent

To accomplish this feat, Sanger developed a technique that used a marking agent—now called Sanger's reagent—that took long chains of amino acids in protein molecules and broke them down into short fragments. Over a ten-year period, in his study of insulin, he analyzed these short fragments to understand their composition.

By 1953, Sanger was able to accurately specify the exact sequence of amino acids for bovine insulin. He also demonstrated that precise and very small differences existed among the insulins from various types of mammals. For these accomplishments, Sanger was awarded the 1958 Nobel Prize for chemistry.

In the early 1960s, Sanger became part of a new molecular laboratory at Cambridge. This lab was led by Max Perutz. Other members of the team included James Watson and Francis Crick, who had identified the structure of DNA just a few years earlier.

Informed by the insight that a single, precise sequence of amino acids was essential to the function of the protein, Sanger next set out to understand how the information contained within DNA is used to make the proteins that do the work inside living cells. As described by *The Guardian* newspaper:

Once Crick and Watson had produced an explanation for how the genetic code was inherited through DNA, it was inevitable that Sanger should apply his flair in amino acid sequencing to deciphering the detailed construction of individual genes. Sanger said in his Nobel lecture in 1980 that it was the coded amino acid sequences within specific sec-

tions of the strands of DNA that conveyed the genetic information. Those sequences were as much the stuff of genes as the DNA helix.

In Sanger's group at this time were Bart Barrell, Alan Coulson, and George Brownlee. Together, they worked to develop methods to sequence both DNA and RNA. Their work produced techniques such as chain terminators, very thin gel systems, and cloning methods to produce strands of DNA.

First To Map A Genome

The breakthrough achieved by Sanger and his team was to be first in the world to map the entire genome of a living organism. This was accomplished in 1977 and their target was the virus Phi X 174, which consisted of 5,400 base pairs of DNA. Next, the team sequenced the DNA of a human mitochondrian, which is the structure that generates energy in human cells.

The 1980 Nobel Prize was awarded to three individuals. Sanger shared the prize with Walter Gilbert of **Harvard University** and Paul Berg at **Stanford University**. Sanger and Berg were recognized for their work in determining the base sequences of nucleic acids. Berg was recognized for demonstrating a method to recombine segments of DNA in ways that made genetic engineering possible.

Frederick Sanger was recognized as a modest man by those who knew him. He was born in 1918 and attended **St. John's College** in Cambridge on a scholarship. One influence on Sanger during this time was Frederick Gowland Hopkins, a Nobel Laureate who had discovered vitamins.

Interest in Proteomics

Upon graduation in 1939, Sanger pursued his Ph.D. in protein metabolism. As a Quaker, he was a conscientious objector during World War II. During this time, he was close to the work of British biochemists Archer Marting and Richard Synge. These two scientists had initiated a revolution in analytical chemistry because they had developed the technique of partition chromatography.

Partition chromatography allowed scientists to separate and purify very large molecules, including proteins and nucleic acids. Sanger's first grant supported his research into the structure of proteins, with insulin being the primary subject.

Sanger retired in 1983. In *The Guardian's* obituary covering his life, Sanger was characterized as "almost absurdly self-effacing, describing himself as someone who had merely 'messed about in his lab.'"

One anecdote about his life confirms this trait. He declined to accept a knighthood, saying that he preferred not to be called "sir."

Sanger was made a fellow in the Royal Society in 1954 and a Commander of the Order of the British Empire in 1963. In 1986, he earned the Order of Merit.

UK's Sanger Institute

In recognition of his lifetime of accomplishments in proteomics and genomics, the **National Health Service** named its molecular and genomics research organization the **Sanger Institute**.

Today, Sanger sequencing is still the most widely-used technique for genetic sequencing. It is considered the gold standard for most clinical gene sequencing applications.

Independently, biotech companies and other research teams are developing different techniques for sequencing DNA. But even these research and development efforts are building upon the body of work left by Frederick Sanger.

Sanger's passing at the age of 95 might be seen as one more door closing on the first era of proteomic and genomic research. At the same time, Frederick Sanger will be long-remembered as an essential pioneer in proteomics and genomics who brought the science to a point where humankind was able to benefit from this knowledge. TDR

ENTERPRISE-WIDE MASTER PATIENT INDEX IS ESSENTIAL TOOL

Lab's Patient-Centric Approach Collects Overdue Money in PSCs

➤➤ CEO SUMMARY: At Sonora Quest Laboratories (SQL), the 'Voice of the Customer' is guiding the organization's evolution from physician-centric to patient-centric. It was quickly recognized that an effective enterprise master patient index (EMPI) was essential. One patient-centric service that SQL is in the midst of deploying is the capability to collect overdue money owed it by patients at the time of service.

For decades, the traditional approach of clinical laboratories has been physician-centric. After all, typically it was the physician who selected his or her choice of laboratory provider and interacted daily with the lab.

But in healthcare today, the move is toward patient-centric services. Provider organizations ranging from hospitals and health systems to health insurers and physicians are developing patient-centric models of care.

Clinical laboratories and anatomic pathology groups face many challenges as they shift from today's physician-centric emphasis to tomorrow's patient-centric model of healthcare. One lab organization already moving down that path is **Sonora Quest Laboratories/Laboratory Sciences of Arizona** (SQL), based in Phoenix.

One of its earliest patient-centric initiatives is to improve how it collects overdue money patients owe when they arrive at patient service centers to have their specimens collected. Once fully deployed, SQL expects to collect several million dollars per year in overdue payments directly from these patients.

This strategy is one response to the increased number of patients who are covered by health plans requiring higher deductibles and larger copays. SQL recognized the need to be better at collecting the money owed to it by patients with these types of health plans.

"In our service region, there are already accountable care organizations (ACOs) and patient-centered medical homes (PCMHs) established and delivering services to patients," commented David N. Moore, Chief Information Officer for Senora Quest Laboratories. "To be an added-value provider, our laboratory is developing and offering services that specifically address the needs of patients served by these types of integrated clinical care organizations.

"Of equal importance is the fact that patient satisfaction is an important consideration when hospitals, physicians, and laboratories are evaluated for the quality of care they deliver," noted Moore. "This is consistent with the fact that these new integrated care delivery models directly engage patients in a more personal way than was done in the past.

"Therefore, to be successful going forward, clinical labs need two capabilities," he continued. "First, labs must understand the needs and expectations that patients have as customers of the laboratory. These patient expectations must be communicated to the lab staff, who also need the right tools to serve patients in new and better ways.

"Second, every lab is going to need additional informatics capabilities that enable the delivery of personalized services to individual patients," Moore said. "Most labs today lack this capability. That must change if a lab organization is to succeed in delivering patient-centric services."

Moore pointed out that almost all clinical laboratories in the United States have a laboratory information system (LIS) that is physician-centric and not patient-centric. "It is common for a lab's LIS to be keyed around the physician that ordered the test," commented Moore. "During the past four decades, labs were organized to serve a physician's office and the physicians within that office. In the era of physician-centric healthcare, it made sense that the LIS was designed to make it easy for the labs to meet the needs of client physicians.

"As originally designed, a typical LIS was never meant to extend to the patient," he said. "The lab would enter the information on the paper lab test requisition. The LIS would produce results and report those results to the physician clients.

➤ Voice Of The Customer

"Today, Sonora Quest Laboratories is engaged in a company-wide project that is called 'Enhancing the Patient Experience'," explained Moore. "The 'Voice of the Customer' is what tells us how to identify patient-centric services that have value to our patients, providers, and payers."

Guided by the customer's definition of quality, SQL quickly ran up against the limitations of today's generation of laboratory information systems. That caused it to

engage outside informatics experts to create the real-time capabilities required in today's healthcare marketplace.

"Because most of today's LIS products are optimized to serve a physician-centric healthcare practice, nearly all clinical laboratories lack the information technology required to support patient-centric services," explained Moore. "At SQL, our strategy is to add additional layers of information technology on top of our LIS to enable us to serve individual patients in personalized ways. To acquire these capabilities, we decided to engage selected informatics vendors."

SQL is using this layered informatics strategy to support its newest patient-centric service. This strategy has the important goal of improving how SQL collects overdue balances from patients as they show up at patient service centers to have their specimens collected. This project reflects the fact that more patients now have health insurance with larger co-payment amounts or higher deductibles—often $5,000 to $10,000 per year for a family.

Collecting At Time Of Service

"Here in Arizona, many of our patients are being asked to pay more of their share of the cost of care than they have in the past," observed Moore. "For this reason, we are deploying a service that allows us to collect past due balances now with a view to soon being able to collect copayments, and deductibles at the time of care.

"Our goal is to collect money directly from the patient that, under the physician-centric lab system, would have been written off as uncollectable," he said. "We are still in the midst of this rollout, but the early results confirm that patients are cooperative and the amount of overdue money that we now collect directly from patients is substantial."

In order to provide a patient-centric account management service within its patient service centers (PSCs), SQL found it necessary to combine several new layers of informatics capabilities to supplement its LIS. As noted earlier, outside vendors were engaged by SQL and form an integral part of the past due collection program which must function in real time.

Master Patient Index

The foundation for this entire effort is an enterprise-wide master patient index (EMPI). It is a solution that every lab organization must implement in order to support any and all patient-centric services.

Every clinical laboratory and pathology group is familiar with this common problem: How can a lab be sure it has a positive patient identification and, using that patient ID, how can the lab's staff view all the clinical and billing information it has on that patient in real time?

SQL is devoting much time and energy to solve this problem. "Remember that, by design, the typical LIS is physician-centric," observed Moore. "Early this year we began transitioning our laboratory information system so that it could manage an enterprise-wide master patient index.

"In real-time, our EMPI allows us to know everything we need to know about each patient who comes to the lab or makes an appointment online," stated Moore. "Once we know who the patient is, there are many side benefits that help us improve care and manage the patient's interaction with the lab."

SQL is using the EMPI to underpin two separate patient-centric collection services. One is to collect from cash-paying, uninsured patients at time of service. The second is to collect overdue balances owed the labs by patients whenever they show up at a patient service center to have their specimen collected.

"We started to deploy this system into our PSCs in May," commented Moore. "Currently it is up and running in about 30 of our 55 PSCs across Greater Phoenix.

"Ongoing results indicate that we will be collecting several million dollars per

Labs that Interface to an HIE Gain Capability To Be Better at Filling in Missing Patient Data

WITH HEALTHCARE MOVING TOWARD AN INTEGRATED CARE MODEL, it becomes essential for clinical laboratories to have a full and complete patient record. One way labs can solve the problem of finding missing patient data is to interface with the health information exchanges (HIEs) in their service regions.

"HIEs can usually provide much of the missing information from previous patient encounters with the healthcare system," stated David N. Moore, Chief Information Officer for SQL. "This is particularly important today because of the need to have accurate patient identification on every encounter.

"Take the example of a patient who is covered by an accountable care organization (ACO)," he said. "Over time, the lab is likely to see lab test orders involving the same patient come from office-based physicians, from hospitals, and from skilled nursing facilities. To have an accurate and complete data record on that patient, the laboratory must be able to make positive identification with each test request.

Solving Common Problem

"This is where the ability for a laboratory information system (LIS) or electronic health record (EHR) to get data from an HIE helps solve a common laboratory problem," stated Moore. "It provides access to information on patient encounters that is not usually available in the patient's record. In our case, our interface with the HIE allows our LIS to match patients' names with other names in our enterprise-wide patient index (EMPI) that are similar.

"We worked with an outside vendor, **Atlas Development** of Calabasas, California, to develop our EMPI," he said. "What happens is impressive. Using a series of algorithms, our system matches the earlier data on a specific patient in the HIE with the current patient's data in our LIS."

Lab managers and pathologists everywhere recognize the challenge of identifying patients accurately when providers spell the same name differently on lab test orders. Moore has an extreme example of this phenomenon and how his laboratory's EMPI is programmed to resolve the patient identification problem.

"There was a patient we were serving who lives in a long-term care setting in the Phoenix area," recalled Moore. "Her name came through on lab test requisitions 36 times over two years.

Variations Of Same Name

"On those 36 requisitions, 30 came from her nursing homes, several came from a Banner Healthcare facility here in Phoenix, and others came from her doctor," he said. "All requisitions were hand-written.

"When we examined these 36 requisitions, we saw 18 variations in the spelling of her name," Moore stated. "Her last name was hyphenated as—let's say—Mary Smith-Jones. About half of the time, it was correct but the other half it was Mary Jones-Smith. There were other problems too.

"By running the algorithms in our enterprise-wide master patient index application and by working closely with our vendor, Atlas Development, we found each of the variants and matched them properly for accurate patient identification," commented Moore. "Our automated system has eliminated the manual process that most laboratories use to resolve this particular problem involving patient identification.

"With the manual process, lab staff often spend weeks searching for each error and correcting it," commented Moore. "Now, our lab has an automated EMPI capability, along with experts whom we can call upon. Here at Sonora Quest Laboratories, the turnaround time for correcting these types of errors has gone from weeks to minutes!"

year from patients at full deployment," he said. "Until now, this is money that has been written off. We plan to also deploy this system into our PSCs in Tucson, Flagstaff, and other areas of Arizona.

"This patient collection effort is operated as a hub-and-spoke model within our PSCs," stated Moore. "Within each hub PSC, we staff a billing businessperson. There are typically three to five PSCs associated with that hub. When patients visit those PSCs, they will be served by the billing representative in the hub PSC, usually by telephone.

Building Confidence

"When the patient presents at a hub PSC, the phlebotomist takes the patient right away, but first hands the registration slip to the billing person," he said. "That billing rep enters the patient's name and date of birth into our new patient-centric billing application.

"A similar procedure happens in the spoke PSCs," he continued. "The patient's records are checked in our system. Once the information is verified, the phlebotomist at that PSC can put the patient on the telephone with the billing representative at the hub PSC if necessary.

"The billing person can immediately view all records from earlier encounters with this patient," Moore explained. "The application also retrieves outstanding invoices and notifies our billing person if those invoices are in accounts receivable or have been sent to collection.

"Should the patient owe a significant balance, we have adopted certain rules," said Moore. "The patient will be asked to submit to a payment plan, for example, and also to pay as much as possible that day. This is also our policy for patients who have no insurance and are paying cash.

"Sometimes a patient will have a balance from a previous encounter," noted Moore. "When that happens, the patient may say, 'I thought the insurance company paid that.' Our billing representative can immediately pull up the explanation of benefits (EOB) and show them what the insurer paid previously and what the patient paid. Most patients accept that information and will work with our billing representative on a payment arrangement to bring their account current with us.

Comfortable With Process

"In general, patients are comfortable with this process," he said. "After all, it is exactly what happens to them when they go to their doctor or the hospital. Today, patients expect to be asked to pay at the time of the service.

"However, we have noted that there are examples of a patient who will go outside and call the insurer to double check the information our billing person showed to him or her," continued Moore. "Almost every time, those patients return to the PSC and pay something toward the amount owed. This all happens in real time while the patient is still in our PSC.

Confirming New Insurance

"Occasionally we will have a patient with an overdue balance who has changed from one insurer to another," he recalled. "In those situations, our billing person can confirm the new insurance and update our system while the patient is in the PSC. We can then refile the claim with the correct insurer. Our system also allows the billing representative to see if there is secondary coverage and confirm that information with the patient during these conversations.

"In the past, we couldn't access that information in our billing system," said Moore. "We addressed this problem by adding a layer of informatics capability involving our billing and collections that is provided by **XIFIN, Inc.**, of San Diego, California.

"Now we have real-time access to any patient's payment history from the XIFIN system," he explained. "It shows our billing representatives all payments made by the

health plan and the patient. Having that information immediately available makes the conversation between our billing person and the patient standing in our PSC much easier and less confrontational."

Uncommon Lab Capability

It is still uncommon for a clinical laboratory to have the capability to collect money from patients when they show up to have specimens collected. That puts Sonora Quest Laboratories in the vanguard of innovative laboratories that are doing today what every lab will need to do in the near future.

Moore has some insights for other laboratory organizations that would like to move down this path. "The system is simple in execution, but requires a sophisticated blend of real-time informatics resources behind the scenes to work properly," emphasized Moore. "Also, we believe it is smart to build these capabilities in a layered fashion, in a manner that does not disrupt the existing LIS.

"Another key is to draw upon the expertise of outside informatics vendors," he concluded. "Why re-invent the wheel when someone else already has a robust solution? Further, cloud-based computing services make it easier, cheaper, and faster to tap these outside capabilities than to build them in-house."

Sonora Quest Laboratories' pioneering use of an EMPI and layered informatics as a way to deliver patient-centric services demonstrates one path that other clinical laboratories can follow to better meet the clinical and operational needs of ACOs and similar integrated care organizations more eficiently.

To share more lessons learned by SQL about the development and use of its EMPI, there will be another interview with David Moore on this topic in an upcoming issue of THE DARK REPORT. TDR

—Joseph Burns

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How Sonora Quest Delivers Value to Different ACOs

ONE WAY THAT CLINICAL LABORATORIES CAN deliver value to accountable care organizations (ACOs) is by creating an enterprise-wide master patient index (EMPI) and using the EMPI to assemble a longitudinal record of individual patient's lab test data.

"Ideally, a well-run EMPI will be scrubbed of all unmatched and incorrect data," said David N. Moore, Chief Information Officer for Sonora Quest Laboratories. "Once a lab has an EMPI with all the patient data in one place, it allows that laboratory organization to shift its focus from one that is physician-centric to one that is patient-centric.

"Patient-centric labs will provide better service to patients," he continued, "This is true both when the patient moves around the service area and when the patient travels around the country.

"Of equal importance, an EMPI can help clinical labs manage patient data for ACOs," advised Moore. "When a patient gets care within his or her ACO, that care would be provided in-network.

"But once an ACO patient goes outside of the ACO for care, then the ACO will have no record of that patient encounter," he explained. "That is where a larger lab organization serving multiple ACOs in a region has the opportunity to add value.

"By using its EMPI to search for all the lab test data on a single patient—regardless of the provider or the location where the service was accessed, the lab has the ability to provide a full longitudinal report of that patient's lab test data to the ACO.

"In Arizona, SQL is a provider to multiple ACOs," concluded Moore. "We already see how, when a patient uses different providers, that our EMPI allows us to accurately identify that patient and compile a more complete record of his or her lab test data. It is one way we can deliver more value to the ACOs that we serve."

Georgia Lab Pays Docs For Urine Test Referrals

➤Veritas Laboratory has legal opinion showing such payments are legal, but will feds agree?

➤➤CEO SUMMARY: Physicians could make $400 or more per sample, according to one physician. But under the federal Stark Law, the federal Anti-kickback Law, and under Florida state law, physicians and other healthcare providers are prohibited from referring patients or doing work for kickbacks and from splitting fees with other healthcare providers, according to one attorney for a national law firm. An attorney for Veritas, however, issued an opinion that the arrangement complies with state and federal law.

WHEN IT COMES TO COMPLIANCE with Medicare and Medicaid law, probably the single most important guiding principle for pathologists and lab executives is "Thou Shalt Not Pay Inducement to Referring Physicians!"

This has been true since the birth of these federal health programs in 1966. Thus, veteran lab executives will be astonished to learn that a laboratory in Tifton, Georgia, openly pays physicians who order urine drug screening tests for their patients, according to **Health News Florida** (HNF), a news service in Gainesville.

Last month, HNF reported that **Veritas, LLC**—a lab company that conducts complex urine drug screening tests—collects hundreds of dollars from health insurers for each patient tested, but keeps only $100 of each patient's reimbursement amount. It sends the remaining amount of each patient's reimbursement to the referring physicians, HNF reported. The news service said that it had seen internal documents that described this arrangement.

The number of physicians who had received such payments from Veritas was not known, HNF reported. But one physician said in an email message to other physicians that payments from Veritas amounted to "fantastic revenue," wrote HNF.

HNF quoted Jonathan Daitch, M.D., a pain specialist in Fort Myers, as saying, "You can make $400 or more per sample. Our practice has been using this arrangement VERY profitably for the past eight months!"

➤Questions About Referrals

Assuming that the news story by Health News Florida about Veritas LLC is true, the situation raises troubling questions. How can Veritas engage in a practice that is viewed by the vast majority of the nation's clinical laboratory organizations as a violation of federal and state law?

What legal opinion underpins this policy of Veritas? And why haven't federal or state prosecutors taken up this case, if this practice of a lab paying physicians is done in the open, as reported by HNF?

For insight and advice, THE DARK REPORT turned to attorney Richard Cooper, who leads the National

Healthcare Practice Group of **MacDonald Hopkins** in Cleveland, Ohio. Cooper had strong words of warning.

"Under the federal Stark Law, the federal Anti-kickback Law, and under Florida law, physicians and other healthcare providers are prohibited from splitting fees with other healthcare providers and from receiving kickbacks or remuneration for referring patients to any other healthcare provider or facility," declared Cooper.

For his clients, Cooper does not recommend an arrangement such as the one between Veritas and its physicians. "We would not issue an opinion to any of our clients suggesting that this arrangement is appropriate," he said. "Looking at the facts and circumstances of the arrangement as it was reported, we don't feel comfortable that it is a compliant arrangement. We would not recommend that any of our lab clients or physician clients enter into an arrangement like the one that has been reported."

Legal Issues Examined

The appropriateness of the arrangement hinges on whether Veritas receives a referral for work from its physician clients, noted Cooper. However, as reported by Health News Florida, two Florida attorneys and a health policy expert in Florida all claimed the arrangement between Veritas and its physician clients does *not* violate state or federal law.

In its reporting of this story, HNF wrote that the wording of the legal opinion Veritas follows indicates that the reason the arrangement does not violate federal law is that the contract between Veritas and its client physicians is worded carefully so that the cash-back payments to physicians come only from tests for patients covered by private health insurers.

HNF reported that the payments from Veritas to referring physicians do not come from Medicare, Medicaid, or Tricare. The applicable federal statutes are known as the Stark Law and the Anti-kickback law. Many states have similar laws, but in its news story, HNF said that some Florida legal experts said Florida law allows such arrangements.

HNF wrote that Veritas has an eight-page legal opinion from attorney Mark S. Thomas of Gainesville. Notably, Thomas was previously Chief of Staff for the **Florida Agency for Health Care Administration** as well as Chief Assistant Attorney General in the Florida Attorney General's Medicaid Fraud Control Unit.

In his opinion, Thomas explained that no work is being referred to Veritas. "Instead, he [Thomas] said, the doctor is merely outsourcing the high-tech part of the lab work," HNF reported. "The high-tech part of the work is the technical component of reviewing urine screening drug test results."

The arrangement Veritas has with its physicians "is not a kickback, self-referral or fee-splitting arrangement, which would be a violation of Florida law, but is instead a so-called 'safe harbor' from liability," HNF reported, citing Thomas' legal opinion as the source.

Cooper, however, was very clear on this point. "We would not issue an opinion with that interpretation of federal and state law," he explained. "In regards to Medicare, Medicaid, and Tricare, the attorney who wrote the opinion for Veritas is attempting to avoid issues under federal law by limiting the tests to those performed only for patients covered by private commercial payers—but not for patients covered by Medicare, Medicaid, or Tricare.

Risk in Screening Patients

"There is risk in believing that a lab can be 100% successful in screening out patients who have Medicare, Medicaid, or Tricare coverage—even if it is the lab's intent to do so," Cooper explained. "First, the physician might not catch all the traditional Medicare and Medicaid patients, or patients covered by Medicare Advantage or when Medicare is a secondary payer.

Second, patients may not accurately report their coverage to the physician or the laboratory may not detect such coverage due to automated crossover of billing data.

"It is possible that some patients will slip through the screen despite a lab's best efforts to keep them out," he added.

Violation Without Intent

"Even if it is the intent of the lab to screen out certain patients, the Stark Law is not an intent-based statute," observed Cooper. "The lab could violate the Stark Law if there is a referral for a service for a patient covered by Medicare or other government program—even if there was no intent to have the arrangement apply to such patients.

"Mr. Thomas is entitled to his opinion," Cooper continued. "But his opinion appears to hinge on a belief that a referral has not occurred. From what has been reported, it appears that he is saying that the ordering of lab tests by the physicians for the physicians' patients does not constitute a referral under federal or state law.

"We believe, in fact, that the ordering of lab tests as described is arguably a referral as 'referral' is discussed in a variety of government statements that the federal Office of Inspector General has issued in advisory opinions and in other communications," Cooper said. "Mr. Thomas appears to be saying that the remitting of reimbursement from the clinical lab to the physician is, in essence, a standard clinical lab service arrangement for the provision of medication monitoring services."

Service Provided By Doctor

On this point, does urine drug testing involve medication monitoring? This is a service provided by an attending physician who: 1) reviews the medications prescribed for the patient; 2) assesses the patient's adherence to the medication protocols; and 3) reviews the result of the clinical lab testing performed by an independent laboratory service.

"Generally, the provision of medication monitoring services is part of the physician's evaluation and management (E&M) services," Cooper said. "The AMA's descriptions for the clinical laboratory CPT codes billed by laboratories for this type of testing do not include medication monitoring services. We have never heard of a third party payer including a component for medication monitoring of lab services in its payment for services billed with these codes.

"The testing being done by the clinical laboratory under the CPT code doesn't contain any component for medication monitoring services," he stated. "Therefore, when the lab bills for the clinical lab testing, it is billing only for the laboratory testing, and not for the medication monitoring services.

"Therefore, I would not be comfortable saying that the lab is compensating the physician for medication monitoring services," added Cooper, "because the lab is not billing or being paid for such medication monitoring services.

"We are concerned that enforcement agencies would consider the ordering of the testing by the physicians to be a referral that is not covered under any exception or safe harbor under federal or state law," noted Cooper.

M.D., J.D.'s Opinion

In its reporting of this story, HNF interviewed Adam Levine, M.D., J.D., a Law Professor at **Stetson University Law School**. He stated that "I think a prosecutor might have a fairly easy time convincing a jury that's a self-referral, you're getting paid for it. I would not advise my clients to set up this sort of arrangement."

HNF wrote that, "Wolfson said he disapproves, even if the deal is technically legal. The payment acts as an inducement to order more tests, even if they are not medically necessary, he said." TDR

—Joseph Burns

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INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Despite the continuing cutbacks in reimbursement for lab testing, some professional investors still see opportunity in this market sector. On November 13, **Genova Diagnostics, Inc.**, of Asheville, North Carolina, was acquired by **Levine Leichtman Capital Partners** and "members of management." The sellers were **Nautic Partners** and **Ferrer Freeman & Company, LLC**. Genova's CEO is Ted Hull, who has been at the company since 2000. The sales price was not disclosed.

ADD TO: *Investors*

Investors also supported three different initial public offerings (IPOs) by emerging lab test companies. As reported on pages 6-7 of this issue, **Foundation Medicine**. **Veracyte, Inc.**, and **Oxford Immunotec** each completed their IPO. They raised $106 million, $58 million, and $64 million, respectively

MAGNAMOTION INKS DEAL WITH SIEMENS

MagnaMotion, Inc., of Devens, Massachusetts, has entered into a strategic partnership with **Siemens Healthcare Solutions**. Siemens gains an "exclusive license for the use of MagneMotion's advanced linear synchronous motor (LSM) products and technologies in the field of *in vitro* diagnostics (IVD)." MagneMotion's LSM technology uses a system based on magnets to propel things, including lab specimens, down an automated line without the noise associated with other types of automated lines. MagneMotion has exhibited in recent years at the **American Association for Clinical Chemistry's** annual meeting.

TRANSITIONS

- Pierre G. Cassigneul was appointed President and CEO of **NMS Labs** in Willow Grove, Pennsylvania. He previously served at **Predictive Biosciences**, **XDx, Inc.**, **Becton Dickinson**, **Bayer**, **Ortho-Clinical Diagnostics**, and **Abbott Diagnostics**.

- Robert Thompson was named as CEO of **Emerge Diagnostics**, a company in Tulsa, Oklahoma, focusing on products for the diagnosis and treatment of soft tissue injuries. Thompson was formerly the CEO at **eScreen, Inc.**, and **Orasure Technologies**. He also held executive positions at **LabOne**.

- **Pathway Genomics Corporation** of San Diego, California, appointed Robert C. Verfurth as its new Vice President of Sales. Verfurth has held positions at lab industry companies that include **Becton Dickinson**, **Prometheus Laboratories**, and **Dianon Systems**.

That's all the insider intelligence for this report. Look for the next briefing on Monday, December 23, 2013.