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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

Pathologists Face Unsettling Times

THESE ARE UNSETTLING TIMES FOR PATHOLOGISTS, particularly those who practice in a private pathology group that serves one or more community hospitals. Blame it on healthcare's unfolding transformation and the new aggressiveness of payers to cut the prices they pay for anatomic pathology services.

At the strategic level, healthcare's acceptance of integrated care organizations like ACOs and patient-centered medical homes will cause these entities to want to utilize anatomic pathology services in different ways. At the same time, if ACOs do succeed in keeping people out of hospitals, how do pathology groups serving community hospitals access an adequate volume of inpatient specimens to financially sustain their operations?

At the tactical level, both the Medicare program and private health insurers have demonstrated a willingness to lower the prices they pay for the CPT codes that represent pathology's highest volume procedures. Just the technical component price cuts enacted by Medicare in recent years have eviscerated the profitability of many technical pathology labs owned and operated by private pathology groups.

Simply said, private pathology groups are finding themselves caught in the jaws of a powerful vice. One jaw is the trend toward integrated clinical care. The other jaw is the trend toward value-based reimbursement, including bundled payments and per-member-per-month fees. (Think: no more fee-for-service!)

As the jaws of this vice tighten during the next 24 to 36 months, I expect the financial woes of many pathology groups to become visible. In fact, consultants, attorneys, and other advisors to pathology groups are telling us that they are already engaged in conversations with their pathology group clients on how to restructure or reconfigure their group practices.

One such restructuring step is already happening. It is reported that many pathology groups are taking steps to release their least productive pathologists. This is increasing the number of pathologists re-entering the job market.

All of these developments make it imperative that pathologist business leaders understand how the twin forces of healthcare transformation and the shift away from fee-for-service payment will alter the existing financial stability of their group practices. Now is the time to be responsive to these changes. TDR

New Pricing Formula for Advanced Diagnostic Tests

New law defines ADTs and directs CMS to use HCPCS codes and list prices for these new tests

CEO SUMMARY: One section of the federal H.R. 4302: Protecting Access to Medicare Act of 2014 is getting positive reviews from many lab experts. The law defines advanced diagnostic tests (ADTs) and directs CMS to assign a temporary HCPCS code and use list prices to pay labs for such tests while it is determining reimbursement guidelines. However, because few labs perform ADTs, this section of the law affects only a handful of lab companies performing sole-source lab tests.

PASSAGE OF THE NEW FEDERAL LAW TITLED THE "Protecting Access to Medicare Act of 2014," creates a statutory definition of an advanced diagnostics test (ADT) and requires the federal **Centers for Medicare & Medicaid Services** to set payment rates for those clinical lab tests that are ADTs.

Lab industry groups seem to like this specific section of the new law. However, its benefit is limited to a specific group of laboratories that offer proprietary or sole-source diagnostic tests.

"While the ADT section in the legislation is positive for the lab testing industry, it does not affect many clinical lab companies because few labs offer these single-source tests that are either multi-analyte assays with algorithmic analyses (MAAAs) or FDA-cleared LDTs," said Jacqueline Huang, Senior Associate at **Quorum Consulting Inc.**, a company in San Francisco, California, that specializes in clinical reimbursement issues.

However, for those laboratory companies that do offer tests that meet the definition of an ADT, the language of this law will be highly beneficial. "Overall, this [section of the] law represents a clear win for labs performing complex or esoteric single-source tests as well as for labs that have obtained FDA clearance for their LDTs [that qualify as ADTs]," wrote Quorum in a summary of the new law for its clients. "As the sole providers of such tests, these labs have stronger bargaining power with private payers, which will in turn influence Medicare payment rates as well."

Rina Wolf, Vice President, Strategic Commercialization, Consulting and

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Industry Affairs for **Xifin, Inc.**, in San Diego, agreed with Huang that the number of labs running ADTs was relatively small. "But the issue is important nonetheless because labs are continually introducing new diagnostic tests and many of these tests could fit the definition for an ADT," she explained.

Definition Of An ADT

"On that point, the definition of an ADT is not exactly clear when you consider that the law says an ADT may also be defined as meeting 'other agency criteria,'" observed Wolf. "If you think about it, that definition is rather broad.

"Thus, how will federal regulators define the growing number of diagnostic tests now moving to next-generation sequencing and that neither require algorithms nor are FDA-cleared?" she asked. "This is just one of dozens of questions that the lab industry has about this law and it will take some time to get all the answers."

An advanced diagnostic test must meet the following statutory definition: a clinical diagnostic laboratory test that is offered and furnished by a single laboratory and not sold for use by a laboratory other than the original developing laboratory (or a successor owner). In addition, the test must meet at least one of the following three criteria:

1) It is an analysis of multiple biomarkers of DNA, RNA, or proteins combined with a unique algorithm to yield a single patient-specific result;
2) It is cleared/approved by the FDA; or,
3) It meets other similar criteria that the secretary of HHS will establish.

Through 2016, the current methods of crosswalking or gapfilling will be used to set prices for ADTs. After that, labs offering new ADTs will need to provide the comparative market data after the first three quarters. Further, while establishing a price, the law says CMS should base payment on the laboratory list price of the tests for three quarters after launch.

"Everyone in the lab business will want to pay close attention to the details of how this law is implemented by following the clarifying language that the specialty associations and other stakeholders put forth for consideration by the secretary," advised Katherine Tynan, President of **Tynan Consulting LLC**, of San Francisco, California. "What the lab professional societies and other stakeholders recommend to the federal regulators and what gets accepted from their recommendations will be the key to how this law will work."

The story behind this section of the law is interesting. It starts in late March, just weeks before Congress passed the law. That was when the **Rare Disease Legislative Advocates** announced that it had suggested language related to the development of diagnostic tests that was included in the legislation. In the announcement, RDLA touted two specific areas of concern in the law.

"First, the bill would establish a temporary HCPCS code for advanced diagnostics so that healthcare providers can quickly begin using new tests, greatly speeding patient access," the RDLA announced. "Second, the bill establishes an expert advisory panel to better determine the payment rates for diagnostic tests. The creation of this panel will be a positive step in demonstrating the value of diagnostics and driving innovation in the field of personalized medicine."

Standardized Rate-Setting

A number of sources interviewed by THE DARK REPORT stated that the special provisions for ADTs were clearly the result of work by the RDLA. In its analysis of the issue, Quorum Consulting wrote that the method of setting payment rates for ADTs will help to standardize how rates are established for advanced molecular diagnostic tests. Labs are likely to prefer this method especially when compared with the gapfilling methodologies that CMS used to set payment rates for Tier 1 and Tier 2 molec-

Rule-Making to Implement New Laws's ADT Section Will Be Key to Developing Appropriate Pricing

AMONG THE KEY ISSUES TO WATCH in the coming months will be the definitions that evolve at CMS as regulators write the rules to implement the Protecting Access to Medicare Act of 2014, said Katherine Tynan, Ph.D., a consultant for diagnostics companies and the Founder and President of Tynan Consulting LLC, in San Francisco, California.

"For example, will next-generation sequencing tests fall under that definition of ADTs?" she asked. "If it does, that could be both good and bad. It would be good in that you could argue for more value-based pricing for these tests. But it would be bad in that we may not have the health economic skills across the healthcare community to communicate effectively the value of many of these tests.

"Everyone in the lab business will want to pay close attention to the details as this law is implemented," she advised. "They can do this by following the clarifying language that the specialty associations and the 'outside advisory panel' (that the secretary must establish by July 1, 2015) put forth. What they recommend and what gets accepted from their recommendations will be the key to how this section of the law will work.

"Another key issue that affects the current molecular testing industry is that, because payment for all these tests is based on the clinical laboratory fee schedule (CLFS), the professional work that goes into developing tests does not usually get built into pricing," she added. "There's a similar problem with LDTs.

"With LDTs, there is the development time, the validation time, and the professional work to interpret the results," said Tynan. "None of that is compensated on the CLFS. That is why careful attention must be paid to the rule-making to ensure these cost components are incorporated into the lab reimbursement paid for molecular tests.

"Clinical labs and professional societies need to influence the rule-making in the most positive manner by educating CMS about the value of molecular diagnostics," said Tynan. "In turn, laboratories must improve the quality systems they use to develop tests. They also must think through how to objectively substantiate claims of clinical utility for tests."

Tynan's message reflects the fact that the laboratory profession, and its various societies and associations, have generally been poor communicators of the value of lab testing. Also, it is seldom that the laboratory profession can speak with one voice about the range of issues that surface during lawmaking and when federal agencies are seeking public comment before issuing rules.

ular pathology codes last year under the MolDx program, Quorum suggested.

The section of the law that addresses ADTs may have another consequence. "Labs may be encouraged to apply for FDA approval for their LDTs because they will have more authority over their Medicare payment rates, at least in the short term," Huang said.

"However, there is a question as to whether this would provide enough incentive for labs to actually go through the regulatory process, since it would be yet one more hurdle for these labs," she noted. "Labs will need to weigh the pros and cons of each pathway and consider what will be the best way to optimize reimbursement in the long run. Either way, more LDT-developers will be interested in going down the FDA approval process. In turn, that could prompt the FDA to establish formal guidelines on FDA regulation over LDTs." TDR

—Joseph Burns

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Pathologists Top Earners In Medicare MD Pay Data

First release of what Medicare pays doctors made headlines in newspapers across the nation

CEO SUMMARY: Never in 50 years had the Medicare program made public the money it pays physicians for Part B services—never until April 9, that is. On that day CMS revealed how it disbursed $77 billion to individual physicians during 2012. Newspapers and television reporters jumped on this story and several pathologists found themselves listed among the highest paid physicians in the nation, rightly or wrongly. Experts predict this data release will trigger changes to physician payments.

When it comes to how Medicare pays physicians, things will never be the same. That's because, for the first time since inception of the Medicare program in 1966, the federal **Centers for Medicare & Medicaid Services** has made public what it pays doctors.

Moreover, pathologists should not overlook the cascade of national and regional news stories that followed the release of the 2012 payment data made to 880,000 U.S. physicians during 2012. It shows that the American public is hungry for this information.

Pathologists Named

Equally noteworthy is the fact that certain pathologists found themselves named in news stories as being among Medicare's highest paid physicians in 2012. In many cases, the number was deceptive, since an entire pathology laboratory had often used one pathologist's billing account number. Nonetheless, news accounts trumpeted that pathologist's name and the amount of money that Medicare had paid.

What will catch the attention of Congress, federal health officials, and managed care executives is the fact that a small number of physicians received a large percentage of the $77 billion paid to physicians by Medicare for Part B services in 2012. In its analysis of the data, *The New York Times* reported that just 2% of physicians received about 25% of the total payments, about $15 billion. That figure excluded the $13.5 billion of the total that went to clinical laboratories and ambulance services.

The Times also reported that 100 physicians were paid a total of $610 million. Of this group, the highest total was $21 million paid to a Florida ophthalmologist, along with "dozens of doctors, eye and cancer specialists chief among them, who received more than $4 million each" during 2012.

The data released April 9 allow consumers to compare doctors and treatments in a way they have never had until now, stated *The Times*, adding that it built a searchable database to allow consumers to search payments by physician name, specialty and zip code.

The release of the physician payment data this year follows the CMS release last year of what approximately 3,000 U.S. hospitals charge for the 100 most frequently billed discharges.

Among those physicians receiving the most in Medicare payments were two pathologists. According to a report from *CNBC.com*, one pathologist was Michael McGinnis, M.D., medical director for **PLUS Diagnostics** in Union, New Jersey. McGinnis received $12.6 million in reimbursements, *CNBC* reported.

"I was actually stunned," McGinnis told *CNBC* of the amount before explaining that more than two dozen other pathologists at PLUS Diagnostics bill under the same National Provider Identifier.

In its analysis of the data, T*he New York Times* reported that just 2% of physicians received about 25% of the total payments, about $15 billion.

PLUS Diagnostics used McGinnis' ID number for all billing and then paid other pathologists, McGinnis told *Becker's Hospital Review*. "The money doesn't come to me. It goes to the company. It goes to PLUS Diagnostics," he said.

During a conference call with CMS officials, reporters asked about the practice of how a physician will use another's NPI to bill Medicare. Niall Brennan, acting director of the CMS Offices of Enterprise Management, responded, saying, "We believe, in general, providers should not be using another provider's number to bill. We'd like to encourage providers to use their own NPI number."

A similar story was reported in Minnesota when the *Pioneer Press* in St. Paul wrote that Franklin Cockerill, M.D., chairman of the pathology department at the **Mayo Clinic,** was the highest-paid Medicare physician in Minnesota. He received $11.6 million in 2012, the newspaper said.

$11.6 Million To Pathologist

A clinic spokesman explained that Cockerill's situation was similar to that of McGinnis in that the $11.6 million represented total fees for all patient specimens tested at Mayo laboratories during the year, the *Pioneer Press* reported. As the supervising physician for the clinical laboratory, Cockerill's name appears on all claims from Mayo laboratories, a Mayo spokesman said.

"Like all Mayo Clinic physicians, Dr. Cockerill receives a salary. He doesn't receive commissions on tests performed by Mayo laboratories," the spokesman told the newspaper.

In Massachusetts, *Boston Business Journal* reported **Quest Diagnostics** received $22.2 million in 2012, making it the highest paid provider in the state. Second was **American Medical Response**, an ambulance services company that got $19.4 million. Third was **Boston Heart Diagnostics Corp.,** a company in Framingham that got $13.1 million to provide outsourced clinical lab services, and **Cohen Dermatopathology** in Newton that was paid $9.9 million from Medicare in 2012, the journal reported.

Release Of Payment Data

Release of this data has been controversial and many physician associations had multiple reasons to oppose the release. *CNBC* made the significant point that fraud investigators, health insurers, and researchers will likely go through this Medicare Part B payment data to physicians to see how many tests each physician ordered and how many procedures they performed. The result is likely to be some downward adjustments in payment to physicians from Congress, CMS, and commercial payers. **TDR**

—By Joseph Burns

ACA Update

Labs Face Bad Debt Exposure From New Patients in ACA Plans

ACA's 90-day grace period rule exposes physicians and clinical labs to risk of non-payment for services

LABS MAY BE AT RISK for the total cost of lab testing performed for patients who enroll in a subsidized insurance plan through the ACA's health insurance exchanges (now called the marketplaces), but never pay their premiums during the 90-grace period.

The federal **Centers for Medicare & Medicaid Services** (CMS) allows individuals who buy subsidized coverage through the marketplaces a grace period of 90 days before their coverage is cancelled for non-payment. In a notice to its members, the **American Medical Association** warned that providers could have significant financial exposure each time they provide health care services to patients who are enrolled but not fully covered.

Labs should be aware that the last day for initial enrollment into a subsidized health plan in the marketplaces was March 31, 2014. Therefore, those patients have until the end of June to pay their premiums.

"Clinical labs typically use insurers' online verification systems to verify patients' enrollment in the health plan," said Charles C. Dunham, IV, an attorney with **Bond Schoeneck & King**, in Albany, New York, "but these systems may not be updated in a timely fashion with information regarding premium payments."

Dunham called attention to the fact that, because many patients are likely to have high-deductibles under the plans offered on the exchanges, this makes them responsible for the first $1,000 or more of healthcare services. "These high deductibles are the reason why patients may be responsible for the entire cost of laboratory testing," he added.

Among the four ACA plan levels (bronze, silver, gold, and platinum), bronze plans cover only 60% of covered medical expenses for a typical patient. Silver plans cover 70%, gold plans 80%, and platinum plans 90%, according to a report by **HealthPocket**, a health plan rating service.

This year, the deductible for an individual in a bronze plan is $5,081, which is 42% higher than the average deductible of $3,589 last year, noted HealthPocket. It also said that the deductible for a family with a bronze plan is $10,386.

Labs Should Contact Payers

"Given that health plans participating in the marketplaces are required to continue enrollment for 90 days—even without payment of the premium—a lab will confirm the patient information with the health plan through the online verification program prior to performing the test if possible," said Dunham. "But in addition, labs should call the health plan to verify that patients have paid their premiums if that information is not available online."

"Making that call may be the only way to verify that the patient and the service in question are covered," he cautioned. "After all, the health plans will place the onus on the providers to be sure that patients getting treatment have paid their premiums."

In its notice to physicians, the AMA explained that, "Under the CMS rule, insur-

ers in health exchanges are required to pay any claims incurred during the first 30-days of the grace period, *but insurers are not required to pay claims incurred during the last 60 days for any patient whose coverage is terminated*. Patients are considered to be covered for care during the entire grace period, but insurers are allowed to place all the claims during the last two-thirds of the period in a pending status and *retroactively deny them when coverage is terminated at the end of the grace period*." (Italics by THE DARK REPORT.)

Key Point For Lab Managers

These statements apply to clinical laboratory testing services provided to a patient covered by health insurance purchased from a health insurance exchange. The key point for lab administrators is this: if the patient does not pay his or her health insurance premiums in full before the end of the grace period, the health insurer will not extend coverage for the second or third months of the grace period and will deny claims for services provided during that time. In this case, a patient is then responsible for paying the entire bill for services rendered during the second and third months.

Dunham pointed out that one important change every lab can make is, whenever possible, to determine the deductible payments and collect this amount upfront as a deposit. Collecting some money up front and making an agreement with the patient to pay some amount over time—whether those payments are made weekly or monthly—will help ensure that the lab gets paid. However, unlike most providers who see patients face to face, labs may not interact with their patients if the specimens were collected by a member of a physician's office staff.

Clinical laboratories and anatomic pathology groups would be smart to put in place policies and procedures that can help them collect more money from patients who have enrolled in health plans offered through the health insurance exchanges. Some innovative labs are developing systems that allow staff at patient service centers to see billing information and collect payments from patients at time of service.

This is true not just because of the financial exposure triggered by ACA's 90-day grace rule, but the simple fact that a growing proportion of patients now have very high deductible and copay requirements. It is smart business for all labs to get ahead of this specific trend. TDR

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AMA Recommends Steps Providers Should Take

WHEN PHYSICIANS ARE CONCERNED about providing healthcare services to patients and not being paid for those services, then it is likely that clinical laboratories are exposed to the same risk of non-payment for lab tests they perform on these same patients.

The concern centers around the 90-day grace-period rule in the Affordable Care Act. In a recent statement about this issue, AMA President Ardis Dee Hoven, M.D., wrote, "The grace period rule imposes a risk for uncompensated care on physicians... Managing risk is typically a role for insurers, but the grace period rule transfers two-thirds of that risk from the insurers to physicians and health care providers. The AMA is helping physicians take proactive steps to minimize these risks."

To minimize the financial damage that could be caused by any non-payments from health insurers as a result of cancellations of coverage, the AMA recommended physicians and providers take such steps as:

- Collect a copayment from the patient at time of service.
- Make agreements with patients to pay the balance of the deductible and copayment over time.

➤➤ ***CEO SUMMARY: For decades, pathologists have pointed out that their expertise in laboratory medicine can be tapped by physicians to improve utilization of lab tests, contribute to improved patient outcomes, and reduce the overall cost of care. Exactly that is now happening at Atrius Health, where new value-based reimbursement models and integration of clinical care have created an opportunity for pathologists and lab experts to develop care pathways and help physicians order the right laboratory test at the right time.***

Under capitated payment, focus is on delivering high quality care at low cost

Lab Serving Large MD Group Manages Quality and Costs

NEW PAYMENT MODELS are already changing the behavior of physicians and motivating them to order and utilize lab tests more efficiently.

This is a significant development and has major implications for all clinical laboratories and pathology groups. On the negative side—and in the short term—it can mean a decline in test volume from referring physicians, generating less fee-for-service reimbursement for clinical lab organizations.

On the positive side—and over the longer term—it can mean that referring physicians will want to engage pathologists and laboratory scientists for more consultations. These physicians will request expert help in determining the right lab tests to order, how to use the lab test results to determine best therapies for the patient, and for ongoing involvement in monitoring a patient's progress.

One example of a large physician organization now using lab tests differently is Massachusetts-based **Atrius Health**. It is transitioning away from pure fee-for-service reimbursement because a growing proportion of its revenue is shifting to value-based payments, including capitation.

"Atrius Health is a nonprofit multispecialty group of 1,138 physicians that gets more than 70% of its income and 50% of its patient volume from capitated contracts," stated Beth Honan, Vice President of Contracting for Atrius Health. "As a consequence, while delivering high quality care, capitated payment requires our physicians to carefully manage costs and laboratory test volume."

Formed in 2004, Atrius Health is an alliance of six medical groups and a home health care and hospice agency. Atrius Health serves approximately 1,044,000 patients in Eastern and Central Massachusetts. The group contracts with **Blue Cross Blue Shield of Massachusetts** under a capitated contract and has fee-for-service and at-risk contracts with **Aetna** and other health plans.

It is also a Pioneer Accountable Care Organization and 37 of its physician groups have earned the Level 3 designation as patient-centered medical homes from the **National Committee for Quality Assurance**.

To control costs and laboratory test volume, Atrius Health conducts educational sessions with physicians who tend to order more laboratory tests than others. In this way, it helps to ensure that patients get the best healthcare without overusing health care services.

These strategies to manage the use of clinical laboratory testing more efficiently were described in an earlier issue of THE DARK REPORT. Richard Lopez, M.D., Chief Medical Officer at Atrius Health, discussed how the medical group had produced savings of about $1 million per year through three programs designed to encourage physicians to use lab tests more appropriately. *(See TDR, February 24, 2014.)*

The first initiative involved showing physicians how much a lab test cost at time of order. As reported in the *Journal of General Internal Medicine*, researchers determined a potential savings on lab testing of $45.45 per 1,000 visits per month. For Atrius Health and its 3.5 million patient visits per year, the projected savings were about $157,000 annually.

The second initiative involved setting guidelines for pre-visit lab tests and was designed to address the variation from one physician to the next in the number and types of lab tests ordered. The key change was to introduce evidence-based guidelines based on each patient's age, which medications the patient was taking, and which diagnoses the patient had in the past.

When booking appointments with patients, medical assistants now use the guidelines to order only the lab tests that are appropriate. The reduction in unnecessary tests saved Atrius Health about $500,000 per year.

The third initiative centered upon reducing the number of liver function tests performed for patients on cholesterol-lowering drugs. The updated FDA guideline means that fewer patients on statins need an annual liver function test. Among the 1 million

patients Atrius Health serves, a reduction of such testing produced savings of several hundred thousands of dollars annually.

Harvard Vanguard Medical Associates is the largest of the Atrius Health groups. It has a clinical laboratory with a core lab, an anatomic pathology lab, and 18 regional labs that also provide some testing to other Atrius Health groups. The lab does about 2 million tests annually for Harvard Vanguard and some of the Atrius Health physicians who practice in 58 locations across the state.

Physician-Owned Clinic Labs

Pathologist Juliana Szakacs, M.D., is the Director of Pathology and Laboratory Medicine for the Harvard Vanguard Medical Associates. "The way we operate is not much different from the way many other large physician-owned clinics operate, such as **Kaiser Permanente**," she said.

"Large clinic groups in the United States usually have their own laboratories because a lab is an important part of delivering care to patients," observed Szakacs. "It is a resource that contributes to a higher quality of care, since our pathologists are close at hand to provide consulting as needed to our physicians.

"Equally important is that our in-house laboratory team can develop specific tests that our physicians need for their patients," she added. "Another advantage of having a lab in this system is that we can transmit our test results directly into the **Epic** medical record system."

In addition to sending data to the EHR, Atrius Health also stores patients' lab test results in a data warehouse. The Atrius Health data warehouse contains information from EHRs, medical claims, lab test data, and pharmacy data for hundreds of thousands of patients.

Szakacs noted that the lab team has collaborated in the efforts at Atrius Health to reduce variation in how physicians utilize lab tests. "Our lab staff regularly develops educational initiatives to help physicians standardize ordering for certain tests," stated Szakacs. "One program was designed to improve ordering for vitamin D tests.

"Like most labs, a few years back we saw big increases in vitamin D testing in response to media stories," she continued. "Our first step was to bring that test in-house to bring the cost down.

"Our second step was to work with endocrinologists and internal medicine physicians," said Szakacs. "We presented information about appropriate testing at educational meetings. Also our data told us who was ordering vitamin D and how often.

"Among other things, we could also tell whether they were ordering as part of well-visit screening or for a specific diagnosis," she noted. "Having that data allowed us to be very specific in our training from one department to the next.

"In the Internal Medicine Department, for example, physicians were doing physicals and screening for vitamin D insufficiency," recalled Szakacs. "In this case, we told them they did not need to screen for vitamin D levels in Massachusetts because most patients will have low levels routinely. We added that if their patients had any of a specific list of comorbidities, then they should check their vitamin D levels.

Tremendous Results

"The results were tremendous," stated Szakacs. "In the first 24 months, utilization of vitamin D tests fell by 50%, to a more appropriate level. As a result of these changes, we now spend 80% less for vitamin D testing, compared with spending at the start of our educational program.

"We followed a similar procedure for pre-visit lab testing," she continued. "When patients have a physical, the physician may normally consider a CBC, urine, chemistry, thyroid, and a few other tests depending on the age of the patient and gender and what conditions the patient has had in the past.

"However, the evidence says that, generally, there is no need to order all these

Laboratory Team at Atrius Health Engaged In Projects to Support Improved Patient Care

ONE DISTINGUISHING CHARACTERISTIC of the laboratory at Harvard Vanguard Medical Associates is that it includes a full anatomic pathology laboratory and professional services in addition to its clinical laboratory testing services.

"This makes us a bit different from how other physician groups operate," observed Juliana Szakacs, M.D., Director of Pathology and Laboratory Medicine for Harvard Vanguard, an affiliate of Atrius Health. "Our pathology department does tissue specimens, including breast and other biopsies, because we have a complete breast service and other subspecialist pathologists.

"If a patient has a mammogram during the day and then needs a biopsy we can refer that specimen to pathology," she said. "That patient's test results will be sent to the physician within 24 hours. Our patients love that fast turnaround time.

"For patients with cancer, our pathologists participate on tumor boards with the oncologists, the surgeons, and the radiologists," added Szakacs. "Our clinical integration allows us to schedule surgery within a couple of days if necessary. That speed is rare, even from the best-known health care systems.

"Our subspecialists include gastrointestinal pathologists, dermatopathologists, gynecological pathologists, breast specialists, and cytopathologists," she stated. "Our lab has nine pathologists, including some who are part-time. There are 202 full-time equivalent employees, including technicians who work in our rapid response labs in 18 physician clinics.

"Among the approximately 2 million tests we run every year in our core lab in Needham, about 40,000 are surgical specimens and 60,000 are Pap smears and cytology cases," commented Szakacs. "Our rapid response labs perform stat testing and the test menu includes such tests as CBCs, basic chemistry, PT/INR, urinalysis, pregnancy, and strep testing.

"Our lab team also oversees a huge point-of-care testing operation," she explained. "Our nurses perform such tests as urine analysis, flu, and HIV testing while patients are in the office seeing the physician. For these tests, a patient gets the results immediately during the same appointment with the doctor."

Lean Program In The Lab

The lab's Lean management program has been another source of significant cost reduction and productivity improvement. The Lean program was started when Szakacs joined Harvard Vanguard in 2005.

"All our laboratory staff have been trained in Lean," stated Szakacs. "They are empowered to bring up anything they think needs to be improved. We encourage staff to become involved in implementing quality and efficiency improvements that they identify.

"In addition, as part of our process improvement efforts, all testing has been standardized," she continued. "All lab locations have the same instrumentation, the same orders and methodology, and labeling.

"One example is the automation and new instrumentation we acquired to track all blood products via bar code as they move through the system," noted Szakacs. "That system has helped us get as close to zero errors as possible with blood management."

tests on healthy individuals," Szakacs noted. "Together with the quality assurance staff and some internal medicine physicians, our lab team developed guidelines for which testing should be done at what ages as part of well visits.

"The team also identified which tests to order for patients with certain comorbidities such as diabetes or enlarged prostate," she said. "Guidelines were then developed that would allow the physicians to order tests specific for each patient."

This initiative produced significant results by improving patient care while reducing the cost of lab testing associated with these specific office visits. "Our data shows that, over the years, the trend was for clinicians to order more and more tests," recalled Szakacs. "This data showed the number of tests ordered had climbed to 1.51 tests per patient visit.

"After we launched our educational initiative in 2010, we tracked the number of tests per visit," she explained. "It initially declined to 1.35 tests per visit and is now down to 1.28! When you run 2 million tests a year, that 16% decrease in average tests-per-patient-visit represents significant savings."

Physician Compensation

At Atrius Health, the physicians have a variety of compensation systems. Some, such as the pathologists, are on salary, and some are paid per procedure.

To compensate pathologists for exceptional work, the department instituted a bonus pool taken from the department's salary budget. Money from this pool is distributed based on participation in what Szakacs called good citizenship projects.

"Citizenship behaviors involve helping with conferences or working to improve quality, for instance," noted Szakacs. "In the recent past, we installed a computer system to track pathology specimens via barcode from the time we receive them until we issued a report. With this system, we can track every piece of tissue and every jar, block, or slide all the way to the pathologists' desks.

"We decided a certain amount of our department salary pool would be divided among those who worked on that project," she explained. "Now, with our barcode system in place and fully implemented, we have reduced our error rate down to zero for four months in a row." TDR

—Joseph Burns

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New Reimbursement Models Require a Different Response

Changes in reimbursement models are reshaping how the physicians at Atrius Health maintain high quality while addressing the need to rein in unnecessary costs.

"While we have a variety of payment terms, it's important to emphasize that we focus on delivering population-based healthcare and being accountable for the care we provide, regardless of whether it's capitated or fee-for-service," stated Beth Honan, Vice President of Contracting for Atrius Health. "The laboratory and the clinicians are not asked and don't need to know about reimbursement or how our contracts work. Their primary focus is on providing appropriate care and delivering the right services to patients at the right time.

"In addition, our laboratory does not do any managed care contracting because Atrius Health does the contracting for each of the six affiliated groups," explained Honan. "When we contract with a health plan, we negotiate for all of the services that the groups provide, including the laboratory at Harvard Vanguard Medical Associates."

The largest of Atrius Health's six physician groups, Harvard Vanguard Medical Associates runs a clinical laboratory that does about 2 million tests annually for its physicians who practice in 58 locations.

"Our contracts are not specific to lab services," noted Honan. "For that reason, you won't hear us talk about whether we are at risk or capitated or not. You'll just hear us talk about providing the best and most cost-effective care to our patients.

"We are unlike other physician practices and delivery systems that look at the clinical laboratory as a revenue-generating center," commented Honan. "Instead, we look at all of our services as cost centers. That includes the laboratory."

International Update

UCLA Pathologists to Open Joint Venture Lab in Shanghai

PATHOLOGISTS at the **University of California Los Angeles** Department of Pathology will participate in a unique commercial laboratory company that will be based in Shanghai, China.

On April 8, UCLA announced a partnership agreement with **Centre Testing International Corp.**, in Shanghai, to operate a new clinical laboratory company. CTI is a public company that provides services in product testing, inspection, certification, and consulting. Much like **Underwriters Laboratories** here in the United States, CTI helps companies in many industries to ensure quality and sell products worldwide.

The partnership is the first between a Chinese company and a U.S. academic medical center to create a specialized laboratory company in China. Scheduled to open in September, the 25,000-square-foot lab will offer genetic and molecular diagnostics and other tests that exceed the scope of the average lab in China, stated Scott Binder, M.D., Senior Vice Chair, Pathology and Laboratory Medicine at UCLA's Geffen School of Medicine and Director of Pathology Laboratory Services for the UCLA Health System.

In the joint venture, UCLA pathologists will train Chinese lab specialists to operate the analyzers and interpret tests accurately. "China has a shortage of pathologists because pathology has a history of being undervalued in that country," commented Binder. "That is one reason China has so few pathologists trained to diagnose and interpret complex test results in specialized fields of medicine. Now, CTI and UCLA have the opportunity to save lives by changing that situation."

In addition to running clinical and molecular tests for patients with cancer and other diseases, the lab will perform routine testing to support clinical trials.

"This new lab resulted from a process begun back in 2005 when we made the first of several visits to China," said Binder, who conceived the idea. He worked closely with Jianyu Rao, M.D., Professor of Pathology and Laboratory Medicine, whose knowledge of pathology services in China helped move the project forward.

Teaching Exchanges

"Since then, we've had teaching exchanges where UCLA has hosted Chinese pathologists and technologists for training in specialized diagnostics for skin, blood, brain tissue, and other diagnostic areas," explained Binder. "In turn, UCLA pathologists are traveling to China to learn about diseases that are common there but rare in the United States."

Called **CTI-Pathology/UCLA Health**, the new company is jointly owned by CTI and the **University of California**. Under the agreement signed at the **Ronald Reagan UCLA Medical Center** in a ceremony broadcast in China, UCLA will oversee management of the laboratory. University staff will ensure that the operations meet international quality standards and seek CAP accreditation. CTI will provide capital funding and marketing expertise. TDR

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New Skills Needed for Difficult Lab Job Market

As job market for pathologists and lab execs tightens, some are developing promotional skills

CEO SUMMARY: Across the nation, a small but growing number of pathologists and lab directors has begun to engage career coaches and management recruiters specifically to sharpen their interviewing and career development skills, even though they are still employed. One expert says this trend reflects today's tougher job market and recognition that career advancement requires supplementing scientific expertise with polished skills in management and personal development.

THERE'S AN INTERESTING PHENOMENON surfacing that involves a small but growing number of pathologists and clinical laboratory directors. They are seeking out career development consultants to help them sharpen their interviewing and promotional skills.

"What is different today than in past years is that a larger proportion of our new clients are pathologists and medical directors with solid jobs, but who have decided that it is smart to acquire these skills in order to improve their prospects for advancement in their existing lab organization," observed Peggy McKee, a career coach specializing in healthcare and clinical lab workers.

"Each of our new clients share the same problem: They have spent so much time becoming good at their jobs and understanding modern clinical laboratory medicine that they have had no time for self promotion," explained McKee, who is Founder and CEO of **PHC Consulting** and **Career Confidential** in Celina, Texas. "Today, these individuals are watching their hospitals and labs squeeze down costs, including the number of physicians and staff. These changes motivate them to learn and master the skills used by effective leaders, which include effective self promotion."

McKee was careful to define what she meant by self promotion. "One thing that is common in the careers of all successful physicians, managers, and executives is the talent for working within the organization in such a manner that co-workers recognize the consistency of their contributions toward meeting organizational goals, taking initiative to move projects forward, and fostering a positive working environment," she noted.

Examples of Key Producers

"We all know who these individuals are within our own companies and healthcare organizations," continued McKee. "At the same time, each of us also has examples of key producers who work off the radar screen of senior leadership. The primary difference between those who are recognized and those who are not is that the former apply specific skills and techniques that anyone can learn and use."

Career Coach Lays Out Three Essential Steps to Make Career Contributions More Visible

AS A CAREER COACH and management recruiter, Peggy McKee has 15 years of experience in working with professionals in a variety of fields, with a particular focus on the clinical laboratory industry. She has coached everyone from entry-level staff to chief executives about how to package themselves for what's next in their careers. Usually her clients are applying for jobs or are facing some career crisis such as a layoff.

McKee, Founder and CEO of PHC Consulting and Career Confidential, recommends that any professional wanting to support their career growth by developing more visibility for their expertise and accomplishments needs to take three steps.

"Step number one is to create a strong online presence," said McKee. "This is the foundation that enables your career to advance in today's networked business environment.

"Whether it is a website your company puts up for you or a website you build for yourself, a strong online presence is essential to your career growth," she added. "You have the option to build your own website or use sites like LinkedIn, FaceBook, Google Plus, and even YouTube that make it simple for you to create your own site to which you can easily add information and content.

"At the very least, you need your photo and a list of the articles you've published to go onto your site," said McKee. "Pathologists and Ph.D.s have curriculum vitae and this document is a good resource from which to pull information when building your website.

"Step two is to always have an up-to-date resume on hand in case someone asks for it immediately," said McKee. "One common trait for people whose careers move forward at a steady pace is that, if some company unexpectedly pops up with an attractive job offer, they are prepared.

"The third step is to be able to define yourself succinctly," she noted. "This step may be the most difficult of the three because professionals generally don't know where to start. Often, they talk about what they've done rather than who they are.

Describe What You Will Do

"You need to develop the ability to describe what you will do for the lab you want to work for," she continued. "Know and describe the specific steps you would take to bring this lab from what it is to where you believe it should be. And you need to describe how your background—whatever that may be—has enabled you to be uniquely suited to do the job.

"Keep in mind that you are not a list of accomplishments and you are not a list of job titles," advised McKee. "Instead, you are a capable, professional, results-driven manager who knows how to get done what lab owners want and need. If the hiring person needs someone to steer a foundering ship through troubled waters, you should be able to describe yourself confidently as that very person."

Another trend is driving pathologists to learn how to make their accomplishments more visible to those inside and outside their hospitals, laboratories, or pathology groups. "Gen Y and Gen X physicians are online constantly interacting for professional purposes," said McKee. "Just as they use **Facebook.com** to stay engaged socially, they use **LinkedIn.com**, **GooglePlus.com**, and the websites of their professional societies to interact professionally.

"So much professional activity now takes place on the Internet that companies looking to hire—and management recruiters looking for candidates to offer their clients—regularly cruise the Internet when seeking to fill executive positions

and management jobs," she continued. "Consider this fact in tandem with the trend I mentioned earlier—about the downsizing happening with many healthcare providers—and it is only natural that some pathologists and lab directors recognize the value of raising their visibility and accomplishments, both inside and outside their organization."

Professional Expertise

McKee believes that it is essential to elevate the visibility of one's professional expertise and accomplishments. "In an increasingly competitive environment where it is very difficult to be heard above the noise, medical doctors, PhDs, senior executives, managers, and med techs in clinical laboratories all need to spend at least some percentage of their time—even if it's just 1% to 2% of every week or month—making sure they are packaging themselves for the benefit of their own companies and for themselves long term," she recommended.

"This is a small investment that pays big dividends," added McKee. "After all, so many executives and physicians at all levels in all fields spent thousands of dollars and untold hours earning advanced degrees and certifications. But, until now, they haven't put time or money into the one product they sell regularly: themselves!"

Advice for All Professionals

McKee's advice also applies to those who are not necessarily looking to change jobs. Any clinical laboratory professional could benefit in two ways. "First, it is always helpful to have a more substantial presence in the laboratory testing industry," commented McKee. "Outside recognition of an individual's skills and accomplishments is often a factor in annual performance reviews, as well as those times when that person is a candidate for an internal promotion.

"Second, a lab professional who is comfortable and competent at talking about his or her skills gains recognition as an effective clinical team leader and manager," she added.

"However, by the time most of our new clients get to us, they have already tried and failed to find a job because they had no idea about how to promote themselves," observed McKee. "Or, they are worried about their present job and want to find something that pays more or is more stable, but again have no idea how to proceed.

"There is one more reason why clients come to us: They have failed to move beyond where they are despite months or years of trying," explained McKee. "That's because, when it comes time to find their next job internally or externally, most clinicians and laboratory management professionals have not realized that their approach is almost always wrong.

Three Recommended Steps

"We tell our clients they need to do these three steps and if they do them well, they will find a more satisfying job that also pays better," noted McKee. "The secret is that each of these three steps involves self promotion. If you can't promote yourself, you may be stuck in your current position for a long while. *(See sidebar on page 17.)*

"That's not to say that you won't get lucky and be promoted from within tomorrow," she said. "Anything is possible. But it is most unlikely that an employer looking to fill a position that requires the same skills that you possess is likely to find you if you are not promoting yourself in a professional way. If the company looking to fill your dream job can't find you, then you are likely to stay right where you are."

McKee's observations about the job market involving clinical labs and pathology groups are significant. She describes a trend where the job market is tightening. This is useful early evidence that many labs are seeking to reduce staff in order to cut costs. Pathologists planning a career move will want to stay ahead of this trend. TDR

—Joseph Burns

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INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

In recent years, a series of decisions involving molecular diagnostics tests made by Medicare officials and the Medicare Administrative Contractors (MACs) have caused much disruption in the clinical laboratory industry. In response to these developments, on April 16, the **California Clinical Laboratory Association** (CCLA) and a Medicare beneficiary filed a lawsuit against the **U.S. Department of Health & Human Services**. Plaintiffs charge that MACs "continue to develop and apply Local Coverage Determinations (LCDs) that result in policies depriving Medicare beneficiaries throughout the country of critical clinical laboratory tests."

MORE ON: *CCLA Suit*

The lawsuit was filed in the federal district court of the District of Columbia. Counsel for the plaintiffs is **Hooper, Lundy, & Bookman, PC**. The action was taken because of how MACs have "virtually ignored" the input on molecular tests provided by the clinical laboratory industry.

MOLECULAR LABS HIRING MEDICAL DIRECTORS

In the past month, a number of lab companies offering molecular and genetic tests announced the hiring of new medical directors:

- **Bio-Reference Laboratories, Inc.**, of Elmwood Park, New Jersey, said that Robert Daber, Ph.D. will have the dual role as Director of Research and Development and Director of Cancer Genetics at its main laboratory. Draper was formerly at the **University of Pennsylvania**.

- **Vermillion Inc.** of Austin, Texas, appointed Herbert Fritsche, Jr., Ph.D., as the Medical Director of the new CLIA laboratory facility that is now under construction. Fritsche was formerly at **Health Discovery Corporation** and the **University of Texas, M.D. Anderson Cancer Center**.

- **23andMe** of Mountain View, California, announced the hiring of pathologist Jill Hagenkord, M.D., as Chief Medical Officer. She has previously held excutive positions at **Invitae**, **Complete Genomics**, **iKaryos Diagnostics**, and **Creighton University School of Medicine**.

TRANSITIONS

- **med fusion** of Lewisville, Texas, appointed Jon L. Hart as its new CEO. Hart previously held executive positions with **Aurora Diagnostics**, **Genzyme Genetics**, **Quest Diagnostics Incorporated**, **SmithKline Beecham Clinical Laboratories**, and **International Clinical Laboratories**.

That's all the insider intelligence for this report. Look for the next briefing on Monday, May 19, 2014.