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INSIDE *NIR*

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Lab Institute Tackles Tough Issues Facing Lab Industry

From ongoing reimbursement threats to new business models for laboratories, G2 Intelligence's annual Lab Institute, held in Arlington, Va., Oct. 16-18, addressed key concerns for the lab industry and offered solutions for surviving and thriving in a tough market.

The 31st annual Institute drew record attendance from across the laboratory and diagnostic sectors. Dozens of speakers addressed a wide range of topics, including the state of the lab industry, how data analysis and technology are transforming health care, raising the value of diagnostics in the era of personalized medicine, and much more.

For a discussion of issues tackled during the Institute, please see *Inside the Laboratory Industry* beginning on page 5.

Government Recovers $20 for Every Dollar Spent on Health Care FCA Cases

The federal government gets $20 back for every dollar invested in False Claims Act (FCA) health care fraud cases, a higher rate than indicated by the Department of Justice's reporting on FCA settlements, according to a report from the Taxpayers Against Fraud (TAF) Education Fund released Oct. 22.

The report, "Fighting Medicare & Medicaid Fraud: The Return on Investment from False Claims Act Partnerships," said that the DOJ's reporting doesn't include criminal fines associated with FCA cases or state recoveries associated with federal FCA cases, which together accounted for $9 billion in recoveries from fiscal year 2008 through FY 2012.

As a result, the DOJ's return on investment of 16-to-1 for FCA health care fraud cases "is an understatement of the full 'rate of return' from the federal government's anti-fraud activities," the report said.

Overall Recoveries

Overall civil, criminal, and state recoveries associated with federal FCA health care fraud cases totaled $18 billion between FY 2008 and FY 2012, the report said.

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Government Recovers $20 for Every Dollar Spent, *from p. 1*

During the same time frame, the three agencies that investigate and prosecute health care fraud FCA cases (the U.S. Attorney's Offices, the Department of Health and Human Services Office of Inspector General, and the DOJ's Civil Division) received a total of $575 million from the Medicare trust fund for health care fraud enforcement, the report said.

"While it is difficult to quantify federal and state costs associated with recovering these federal criminal and state civil dollars, we are confident that if all costs and benefits are accounted for, the benefit to cost ratio of False Claims Act law enforcement now exceeds 20:1," the report said.

Whistleblower Cases

FCA cases involving health care fraud whistleblowers have increased dramatically since 1986, when penalties under the FCA were strengthened.

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> *—Taxpayers Against Fraud*

For example, from 1986 to 1992, there were 62 new health care fraud whistleblower referrals, investigations, or actions. In comparison, there were 417 in 2011 and 412 in 2012.

In 2012, whistleblowers received $284 million out of $2.5 billion in health care fraud whistleblower settlements.

The TAF report also said that criminal FCA cases are becoming increasingly important to the federal government. "Not only do they bring in additional recoveries, but also they create the possibility of criminal conviction, which serves as a deterrent to committing fraud against the government," the report said.

Criminal FCA cases also often are linked with civil FCA cases, the report said, as a civil investigation can lead to criminal charges.

Sen. Charles E. Grassley (R-Iowa), who wrote the 1986 amendments to the FCA, said the TAF report indicates the value of the FCA. "The law has empowered whistleblowers to come forward, risk their careers and root out the shady characters looking to give the taxpayer a bad deal," Grassley said in a statement released Oct. 22.

Although the focus in 1986 was on defense contractors, the FCA is "the most effective tool against health care fraud, as evidenced by the report released today," he said.

Grassley said any attempts to weaken the FCA "should be met with skepticism by the courts and Congress."

Takeaway: Given that the government gets such a great return on investment for money spent pursuing fraud, health care providers should ensure that they are in full compliance with all federal laws.

Date-of-Service Changes Affect AP Billing in J5

Recent changes to the date-of-service policy implemented by the Medicare contractor for Jurisdiction 5 (Iowa, Kansas, Missouri, and Nebraska) is having an impact on how anatomic pathology (AP) services are billed.

According to the College of American Pathologists (CAP), Wisconsin Physician Services (WPS) has instructed providers billing Medicare part B that the billing date for professional component services should be the date that the pathologist actually provides the interpretation. When the technical and professional components are performed on different days, each component should reflect the actual date performed. WPS says this shift in policy is based on their interpretation of Medicare guidelines.

Currently, most labs that perform both the technical component and professional component (PC) for AP specimens submit a global charge to their Centers for Medicare and Medicaid Services (CMS) contractor with the same date of service for both components.

The Kansas Medical Society disagrees with WPS's interpretation and has asked the CMS for clarification of the date-of-service rule for PC billing of diagnostic tests. But according to CAP, a senior staff person at CMS stated the agency "does not currently have a date-of-service policy and that it is up to the local MACs to establish policy for their respective jurisdictions."

Takeaway: Until CMS offers further clarification on date-of-billing issues, labs should check with their Medicare contractors regarding billing rules.

Medicare Payment Rules Likely to Be Delayed

The Centers for Medicare and Medicaid Services (CMS) said Oct. 23 that four 2014 Medicare rules, including the physician payment rule, will be delayed, possibly until Nov. 27.

In a memorandum to providers, Robert Fritter, director of CMS's Division of Provider Relations and Outreach, said that although the agency still is assessing the impact of the partial government shutdown on regulatory work, the final rules will be issued by Nov. 27, "generally to be effective on Jan. 1, 2014."

The four rules that were due out around Nov. 1 are:

- Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2014 Final Rule with Comment Period (CMS-1600-FC);
- CY 2014 Home Health Prospective Payment System Final Rule (CMS-1450-F);
- CY 2014 Changes to the Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System (CMS-1601-FC); and
- Medicare Program; End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (CMS-1526-F).

The prospect of the late publication of the physician rule concerned at least one group. The Medical Group Management Association "will urge CMS to do everything in its power to release the physician payment rule earlier than the 27th," said Anders M. Gilberg, MGMA's senior vice president for government affairs.

Takeaway: Labs and pathologists may have only about a month to prepare for new payment policies scheduled to take effect Jan. 1, 2014.

focus on: Lab Institute

Laboratories Facing Serious Challenges, But There's Light at the End of the Tunnel

The tone at the 31st annual Lab Institute, held Oct. 16-18, 2013, was somber but not without hope as more than 500 people from clinical and anatomic pathology laboratories and related industries confronted the serious challenges currently facing the diagnostic community.

With Medicare and private payer reimbursement for lab tests constantly under attack, many speakers and attendees acknowledged that not all laboratories will survive continued cuts and the fluid dynamics of today's health care marketplace. To survive, labs will need to be nimble, willing to consider different business models, and open to serving as consultants in patient care.

"I hate to be a downer, but our industry is in for really tough times. Most independent laboratories won't continue to be here," said Robert Babkowski, M.D., the laboratory medical director for Stamford Hospital in Connecticut. "With more high-deductible insurance, patients will price shop. Mrs. Smith will call around to see who has the lowest price for the panel she needs. . . . At the end of the day there will be extreme consolidation and a race to the bottom."

Dave King, chief executive officer of LabCorp, agreed that labs are in "the most challenging environment we have ever been in," which makes it ever-more imperative for labs to be more aggressive and specific about conveying critical messaging to lawmakers.

"Congress needs to understand us better, and it is incumbent on us as an industry that we [do a better job of teaching them]," said King during a conversation with Dennis Weissman, founder and executive editor of G2 Intelligence. Laboratory executives must reach out to their local senators and congressmen and invite them to tour their labs so they can understand the true value of what labs offer. This is especially true of the small, community labs that feel disproportionate effects of payment cuts.

The sad truth is that not all labs will survive as payment for lab tests continues to decline.

King noted that small labs need to survive because they serve lines of business that national labs may not always pursue, such as serving nursing homes. "The community labs and services they provide are fundamental to health care," he stressed.

The sad truth, however, is that not all labs will survive as payment for lab tests continues to decline. A test that was reimbursed by Medicare at $10 in 1984 when the Clinical Laboratory Fee Schedule (CLFS) was implemented today is reimbursed at only $8.33 today, according to G2 calculations. Based on inflation, that test should be paid at more than $22. Medicare has cut payment to clinical labs by almost 12 percent since 2010 and more cuts are expected. Many labs have already cut costs as much as they can to cope with continued cuts, noted Alan Mertz, president of the American Clinical Laboratory Association (ACLA). "Now we're cutting into bone," he said.

Clinical laboratories could face additional Medicare reimbursement cuts of 14 percent over the next 10 years if Congress decides to adopt President Obama's proposal to extend the 1.75 percent cut to the CLFS for eight more years.

Labs were already facing Medicare cuts of 23 percent over the next 10 years from reductions enacted in the Affordable Care Act, a 2 percent rebasing, and sequestration, according to Mertz. The 1.75 percent cut, enacted in 2010, is currently due to expire in 2015, but the president has proposed extending it to 2023. Lawmakers looking for a way to pay for a fix to the sustainable growth rate used to set Medicare payment for physicians could potentially adopt the proposal, which would reduce test reimbursement by an additional $9.46 billion over 10 years.

"We are clearly on the table for another cut," said Mertz, adding that a lab copay and competitive bidding are also possibilities but are less likely to be approved this year. "I'm most worried about the cut to the fee schedule."

ACLA is actively fighting further reduction to reimbursement for laboratories and pathologists and recently helped get support from lawmakers in stopping cuts proposed by the Centers for Medicare and Medicaid Services (CMS) as part of its Physician Fee Schedule rule. A total of 115 representatives and more than 40 senators signed on to a letter sent to CMS administrator Marilyn Tavenner opposing the cuts. The letter notes that the proposal to cap payments for anatomic pathology services at the Hospital Outpatient Prospective Payment System levels would result in cuts of 26 percent to independent laboratories.

While he is hopeful that CMS will respond to lawmakers' concerns, John Scott, vice president of the division of advocacy at the College of American Pathologists, notes that labs and pathologists should prepare for the worst.

"We have to plan for the end game because CMS does not have to listen," he said. "We have to be ready."

Bruce Friedman, M.D., Receives G2 Intelligence 2013 Laboratory Public Service National Leadership Award

Bruce Friedman, M.D., and Scott Liff, Kellison & Co.

Bruce Friedman, M.D., active emeritus professor, Department of Pathology, University of Michigan Medical School, and president of the Pathology Education Consortium, is the 2013 recipient of the G2 Intelligence Laboratory Public Service National Leadership Award.

Sponsored by Kellison & Co. (Cleveland), the award was announced at this year's Lab Institute on Oct. 17. Scott Liff, Kellison's president for business development, presented the award, which recognizes singular accomplishments that directly enhance patient care and the laboratory profession in one or more specific areas: basic and applied research, business creativity and innovations, public policy, and lifetime achievement.

A thought leader known for his Lab Soft News blog (*www.labsoftnews.typepad.com*) and a pathology informatics conference that he co-sponsors, Friedman has a long and distinguished career in the field of pathology education.

After graduating from the University of Michigan Medical School (UMMS) in 1966, Friedman served his internship at Yale-New Haven Hospital and his residency at UMMS. He served as a pathologist from 1971 to 1973 before returning to UMMS as an assistant professor of pathology. He was promoted to the rank of associate professor in 1976 and professor in 1980. From 1973 until 1983, he served as the associate director of the blood bank at the University of Michigan Hospitals. His research during these years revolved around the study of blood utilization in the United States and systems for reducing the use of unnecessary hospital blood bank services.

In 1982, Friedman was appointed the director of pathology data systems at UM Hospitals, the computing support unit of the Department of Pathology, and he continued in this role until his retirement in 2006.

From 1996 to 2001 he served as director of ancillary information systems for the University of Michigan Hospitals. He currently serves in a consultative role with Medical Center Information Technology.

Friedman is a director of a continuing education symposium on automated information management in the clinical laboratory that is devoted to the topic of laboratory information systems and automated information management in the clinical laboratories.

Light at the End of the Tunnel

It's clear that the reimbursement outlook is troubling and the current market dynamics are being disrupted by loss of payer contracts, the growth of accountable care organizations, and care delivery models moving from fee-for-service tied to volume to payment for value. However, speakers at Lab Institute were quick to point out that there are still many opportunities for laboratories, from developing new business lines, to leveraging the data that they collect and payers want, to becoming a partner in cost control and patient care.

A value market means providers have a new set of needs, ranging from population management to cost management to care coordination, explained L. Eleanor Herriman, M.D., MBA, director of advisory services for G2 Intelligence. Labs must position themselves as partners in health care if they are to be viewed as valued players in the marketplace. This means working with clinicians on test interpretations, testing plans and interventions, prevention of complications, and better quality metrics. By capturing that value, labs have a hand up in negotiating with payers and within new payment structures.

"Labs can prosper from current market turbulence by leveraging new technologies and traditional expertise and delivering information services that advance clinical decisionmaking, thereby generating clinical value far beyond the 3 to 5 percent of health care spending that testing comprises," said Herriman.

For example, labs can contribute to a 36 percent decrease in care costs by conducting rapid molecular testing to identify pathogens and working with the pharmacy to recommend antibiotics to clinicians. Other areas where labs can have a concrete impact on costs: reducing costs from acute renal failure by implementing new biomarker testing for earlier diagnosis and nephrologist intervention to stop progression to later stages; reducing costs from hyponatremia by consulting with clinicians on test ordering, interpretation, and management decisions; and reducing costs from pneumonia readmissions through rapid molecular testing.

"Labs can prosper from current market turbulence by leveraging new technologies and traditional expertise and delivering information services that advance clinical decisionmaking, thereby generating clinical value far beyond the 3 to 5 percent of health care spending that testing comprises."
— Eleanor Herriman, G2 Intelligence

Herriman gave several examples of laboratories that partnered with other health care providers to create value and save money. One large regional reference lab—PathGroup (Brentwood, Tenn.)—partnered with the largest oncology contract research organization (CRO) to create a new model for recruiting patients from community oncologists. PathGroup created a next-generation sequencing tumor profiling panel to identify patients eligible for clinical trials based on their tumor mutations/pathways. This created value for the CRO through faster and more accurate recruitment and provided a new source of revenues for PathGroup.

Another lab, Health Diagnostic Laboratories (HDL; Richmond, Va.) has developed a business model that helps primary care physicians detect cardiometabolic disease earlier, treat appropriately, and manage patients' adherence to treatment plans. A study published in the September 2013 issue of *Population Health Management* found that advanced cardiometabolic testing paired with follow-up health management from HDL resulted in a 23 percent decrease in patients' overall health care costs in two years when compared to a control group.

HDL has also developed a partnership with the Washington Redskins to screen players, with opportunities for game sponsorships, fan fitness challenges, military veteran screenings, and a fitness expo. All of these activities help promote brand

awareness for the lab and seem to be helping HDL's bottom line. According to Tonya Mallory, CEO of HDL, the company is growing at an astounding 5 percent per week.

Advantages of Smaller Labs

While most labs will find it hard to compete with the national labs on price, smaller labs do have some advantages when it comes to community relationships and name and location recognition, says Richard Nicholson, CEO of West Pacific Medical Laboratory (Sante Fe Springs, Calif.), which has grown from revenues of $2.5 million in September 2010 to more than $25 million today.

Nicholson recommends that community labs comarket with a specialty provider to find ways to differentiate themselves from the big labs. Smaller labs also sometimes have the edge when it comes to customer service, since they are integral parts of the communities in which they operate. Nicholson advises recruiting "small-company people," those who want to feel valued and involved. Since community labs can't compete with the large labs on salary and benefits, they will need to offer different kinds of incentives and benefits—such as allowing all employees to have a say in the company and to feel valued.

For small labs, it's all about personal relationships and flexibility, according to Nicholson. Those that can find a market niche and learn to adapt to market changes will survive. Those that don't may not survive.

"There definitely will be more consolidation, but there is still a need for community labs," said Nicholson. "It's all in how you position yourself."

Takeaway: Despite the serious challenges facing the laboratory industry, opportunities abound. Labs that are nimble and can adapt will survive, while those tied to old ways of doing business will not. G2

UMD Senior Georgina Nicolo Receives G2 Intelligence Scholarship Award

Brian Kemp from McKesson presents Georgina Nicolo a $2,500 scholarship award.

Georgina Nicolo, a senior in the Medical Laboratory Science (MLS) Department at the University of Massachusetts Dartmouth (UMD), is the 2013 recipient of G2 Intelligence's Scholarship Award for Excellence in the Clinical Laboratory Sciences (sponsored by McKesson).

Brian Kemp, executive director, McKesson Business Performance Solutions (Alpharetta, Ga.), presented Nicolo the $2,500 award at G2 Intelligence's 31st annual Lab Institute on Oct. 17.

Nicolo, who has excelled academically, is the student president for the New England chapter of the American Society for Clinical Laboratory Science, an admissions ambassador, and an orientation leader. Nicolo is also involved in campus life as demonstrated by the fact that she plays women's rugby, is a member of the UMD chapter of the National Society of Leadership and Success, and is a member of the UMD Medical Laboratory Science Student Association.

According to Frank Scarano, Ph.D., a professor at UMD who nominated her, Nicolo has been on the dean's list four of the six semesters she has studied at the university and has a cumulative GPA of 3.356. "This is truly an amazing feat for a student studying in the sciences," wrote Scarano in nominating Nicolo. "At a recent academic advising session, Georgina indicated that she also has an interest in an education and/or chemistry minor. The average student finds the MLS major more than enough of a challenge, but to have the drive to want even more demonstrates her superior work ethic and determination."

Salary Outlook for Lab Professionals Looking Up

Lab professionals on average are making more money than they were two years ago, concludes a new report from the American Society for Clinical Pathology (ASCP).

"Overall, the salary outlook for the laboratory professional appears to be thriving," concludes the report, published in the fall edition of *Lab Medicine* (*www.labmedicine.com*).

The ASCP survey is conducted every two years to determine the extent and distribution of workforce shortages in the nation's clinical laboratories. The survey was conducted between March and April, 2013. A total of 13,108 responses were received. Most laboratory professionals who responded to the survey have full-time permanent positions (87.3 percent) followed by part-time (8.8 percent). On call, per diem, and temporary contract made up the remaining positions. More than 73 percent of those responding were medical technologists (MT), clinical laboratory scientists (CLS), medical laboratory technicians (MLT), and clinical laboratory technicians (CLT).

Overall, wages for lab personnel are higher than reported in the last survey. Lab assistants and phlebotomists continue to have lower salaries and cytotechnologists and physician assistants have higher salaries than the rest of the laboratory professions surveyed.

The average age of laboratory personnel is 44.3 years, and the average wage for staff-level MTs and CLSs is $56,430, according to the survey. MLTs and CLTs earn an average of $42,619 although supervisors earn more than $47,000 on average.

Total compensation by occupational title is highest in reference and independent laboratories and hospitals, except for phlebotomists, who get paid the most at physician office laboratories. Where data allowed for comparisons between certification status, wages tend to be higher for certified laboratory personnel.

"Although salaries appear to have increased over time for the overall profession, there is not a considerable difference between the average hourly wages of laboratory professionals working in their current occupational title for one to five years compared with those working for longer than 30 years," says the report. "Results from the survey also show that higher-level laboratory personnel work an average of 31 to 50 hours per week and that a typical laboratory professional holds more than one job in the laboratory."

Takeaway: While lab personnel are making more money, the fact that many hold more than one job is consistent with a shortage of qualified personnel.

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