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LABORATORY INDUSTRY REPORT™

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Upcoming Events

Lab Leadership Summit:
Designing, Implementing & Managing a High-Profit Lab Outreach Program
May 11, 2017 – 8 a.m.-5 p.m.
Holiday Inn Airport South, Atlanta, GA
www.lableadershipsummit.com

Lab Institute 2017
October 25-27
Hyatt Regency Washington on Capitol Hill, Washington, DC
www.labinstitute.com

Abbott and Alere Resolve to Move Forward with Deal on New Terms

Abbott's deal to acquire Alere is back on. Both companies announced Friday, April 14, 2017, that they will move forward with the deal and have revised its terms. Abbott, a global health care company with a significant diagnostics business, had originally announced a plan to acquire Alere in February 2016. The parties were embroiled in lawsuits, however, after Alere became the subject of government subpoenas and Abbott sought to exit the deal. The formerly $5.8 billion transaction now is estimated to have a $5.3 billion equity value, with Abbott paying $51 per common share of Alere rather than the original $56 per share.

At the time the deal was initially announced in 2016, Alere Chief Executive Officer Namal Nawana declared in a statement: "Our leading platforms and global presence in point-of-care diagnostics, combined with Abbott's broad portfolio of market-leading products, will accelerate our shared goal of improving patient care."

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Dx Jobs Market: Survey Highlights Importance of Soft Skills in Hiring of New Pathologists

Like any other professional, new pathology graduates need a combination of technical and "soft" skills to succeed. If you think that sounds like a truism, consider the new survey documenting how "soft" skills like flexibility, leadership, and relationship-building have emerged as a growing area of emphasis for prospective employers.

The CAP Study

Published in the February issue of the Archives of Pathology & Laboratory Medicine, the survey was conducted by Members of the College of American Pathologists (CAP) Graduate Medical Education Committee. The target respondents: CAP fellows with

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Survey Highlights Importance of Soft Skills in Hiring of New Pathologists, *from page 1*

five or more years of U.S. practice experience and responsibility for hiring a new (i.e., in the workforce for three years or less) in-practice pathologist (NIP).

The survey addressed 18 skills and attributes employers consider when hiring, grouped into the categories of interpersonal style, work style, career motivation and job search, and technical proficiency. Respondents were asked to rank each skill using a five-point scale. 630 pathologists responded.

Soft Skills Outweigh Technical Skills in Hiring

The majority (71 percent) reported experiencing some degree of difficulty hiring entry-level pathologists across practice settings (not-for profit hospital, academic center or hospital, and pathologist-owned laboratory). Reasons cited included inadequate training during residency and applicants' unrealistic expectations regarding work load/hours. Other common reasons for reluctance to hire included poor interpersonal and communication skills (including difficulty with the English language), poor technical proficiency and poor references.

The positive factors affecting hiring across practice settings ranked as the most important were:

- Ethics/integrity (76 percent);
- Work ethic (66 percent);
- Professionalism (61 percent);
- Diagnostic skills (58 percent);
- Emotional stability (55 percent);
- Team attitude (54 percent); and
- Communication skills (53 percent).

Note that with the exception of diagnostic skills which finished in the middle of the pack, all of these positives were "soft" skills and attributes. "Regardless of practice setting, employers place a great deal of importance on interpersonal and communication skills and professionalism, two core residency training competencies that both applicants and residency training programs may prioritize less than those related to medical knowledge and patient care," write the authors led by Miriam Post, M.D., from the University of Colorado, Denver.

Other Important Findings

The CAP survey also offers valuable insight into the job market, hiring and training processes. Respondents said that NIP pathologist hiring is expected to continue at healthy rates, with 85 percent saying they anticipated hiring at least one in the next five years. Expected hiring in academic settings is even more robust, with 92 percent reporting anticipated hiring within the next five years and 21 percent of those practicing in an academic setting expecting to hire four or more NIP pathologists over that time frame.

In terms of job search, the results stress the importance of networking and not relying on traditional job postings. Respondents noted that up

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to 70 percent of jobs are not publicly posted and 83 percent identified "networking/word of mouth" as the most common recruiting method.

Respondents were also asked to provide advice to new hires during training. The responses were grouped into three broad themes:

- Capitalize on opportunities during training to enhance leadership skills;
- Develop interpersonal and communication skills; and
- Be flexible and know your preferred job characteristics.

Takeaway: While the fact that NIP pathologists may lack some necessary skills for effective practice on day one is not surprising, trainees should be aware of the growing importance being placed on soft skills that may not be the primary focus of residency and fellowship training.

23andMe Wins FDA Approval for DTC Genetic Test

23andMe and the U.S. Food and Drug Administration (FDA) announced this month that the agency has allowed marketing of 23andMe's Personal Genome Service Genetic Health Risk (GHR) tests for 10 diseases or conditions. "These are the first direct-to-consumer (DTC) tests authorized by the FDA that provide information on an individual's genetic predisposition to certain medical diseases or conditions, which may help to make decisions about lifestyle choices or to inform discussions with a health care professional," said the FDA in its statement.

In 2013, the FDA issued a warning letter to 23andMe requiring that it stop marketing its DTC Personal Genome Service. The FDA had concluded that the $99 saliva test was a class III medical device requiring FDA approval. But a little less than two years later, the company won FDA approval for a DTC genetic carrier test for Bloom Syndrome.

Now, the FDA has given 23andMe authority to market its DTC genetic testing report that indicates personal risk for certain diseases such as late-onset Alzheimer's, Parkinson's, and celiac. The approval was granted following de novo classification review—which can be used for low or moderate risk devices that are not substantially equivalent to existing devices. Tests reviewed under this approach will be subject to special controls regarding the test's "accuracy, reliability and clinical relevance." Future tests that are substantially equivalent to this DTC test will be able to utilize the 510(k) approval process.

"This is an important moment for people who want to know their genetic health risks and be more proactive about their health," declared 23andMe CEO and Co-founder Anne Wojcicki in a statement. "The FDA has embraced innovation and has empowered individuals by authorizing direct access to this information. It is a significant step forward for 23andMe and for the adoption of personal genetics."

Takeaway: After past troubles with the FDA, 23andMe continues to receive approvals for its genetic testing.

Liability Traps to Avoid:
Commission-Based Lab Marketing Arrangements

Contracts between labs and sales and marketing firms raise red flags under both the Anti-Kickback Statute (AKS) and Stark Law, especially when payment is by commission or based on the volume or value of sales generated. While acknowledging that "many advertising and marketing activities warrant safe harbor protection," the OIG has consistently taken the position that commission-based compensation to contract sales force will not meet the personal services and management contracts safe harbor because it "is not fixed in advance and is determined in a manner that takes into account the value or volume of business generated between the parties, including federal health care program business." Labs that fail to heed that warning do so at their own peril.

The HDL Case

If you don't believe it, just ask Health Diagnostics Laboratory (HDL). In a case which began as a series of *qui tam* suits, the US Justice Department accused HDL and two other labs (including Singulex, Inc.) of paying physicians sham processing fees in exchange for blood testing referrals, including medically unnecessary large multi-assay panels.

The charge focused on the labs' marketing arrangement with their outside sales consultant, BlueWave Consultants. The DOJ contended that the sales contract was illegal noting that in addition to a monthly consulting fee, BlueWave received a commission of 19.8% of lab revenue. The other problematic aspect was the marketing tactic of BlueWave's sales force, alleged to have encouraged physicians to order medically unnecessary blood testing via panels and offering doctors a fee per blood test (up to $20 from HDL and $10 from Singulex) for processing and handling samples. The result was billing of Medicare for millions in unnecessary tests.

On April 9, 2015, HDL agreed to pay $47 million to settle the FCA claims. Roughly two months later, it filed for Chapter 11 bankruptcy. Singulex shelled out $1.5 million to settle charges stemming from its role in the scheme. Both labs also entered into CIAs with the government.

Takeaway: While enlisting individuals and entities to furnish sales and marketing services for your lab may be crucial to success, you also need to be keenly aware of the AKS and Stark Law risks. The best way to manage these risks is to ensure that your arrangements satisfy a safe harbor:

1. *Structuring arrangements as bona fide employment agreements when hiring individuals; and/or*
2. *Structuring arrangements as bona fide personal services and management contracts when hiring agencies or individuals acting as independent contractors; and*
3. *In all cases, ensuring that compensation is reasonable, reflective of fair market value and NOT based on commissions or the value or volume of sales or business generated.*

EMERGING MARKETS

Blood-Based Concussion Diagnostic Tests

There is a great need for better tools to diagnose concussion. Currently, there is no single marker of panel of markers in widespread clinical use and diagnosis remains based on clinical judgment. But as evidenced by the recent flurry of publications and commercial partnerships, blood-based concussion testing may soon be a clinical reality, possibly even at the site of injury.

Metabolomics profiling is a promising new method of diagnosing concussion which may be amenable to point-of-care testing in the near future.

Clinical Barriers to Testing

Until recently, many researchers doubted that it would be possible to develop a blood-based test for concussion, given the risk that the blood-brain barrier would prevent movement of candidate markers from the brain to the blood. However, recent research shows that some markers, including metabolites and proteins, are present in the blood. The challenge is that candidate markers are often present only in low concentrations and can be difficult to detect, especially following mild injury.

Current State of Concussion Testing

G2 surveyed recent publications and industry announcements to assess the current state of concussion testing. Here is a rundown of what we learned.

Metabolomics Profiling

Metabolomics profiling is a promising new method of diagnosing concussion which may be amenable to point-of-care testing in the near future.

One source of evidence of the method's effectiveness is a study published in the December 2016 issue of *Metabolomics* finding that a panel of metabolites can identify concussions in athletes with more than 90 percent accuracy.

Plasma was obtained from 12 concussed and 17 non-concussed adolescent male ice hockey players. Controls were age-, sex- and activity-matched. Initially, the plasma was assayed for 174 metabolites with proton nuclear magnetic resonance and direct injection liquid chromatography tandem mass spectrometry.

The researchers found that using principal component analysis (PCA) of the leading 10 components, each containing 9 metabolites, could account for 82 percent of the variance between the groups. This differentiation relied heavily on changes in glycerophospholipids, which accounted for 50 percent of the variance between concussed and non-concussed athletes. It is "unclear" which metabolite changes are the result of injured cells, metabolic processes or a combination of both, the authors note.

The number of metabolites required to achieve the 92 percent diagnostic accuracy was minimized from 174 to 17 metabolites. Using receiver operating characteristic analyses the panel generated an area under the curve of 0.91,

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>
> —Mark Daley

indicating "excellent concussion diagnostic potential," the authors say.

"The attraction of metabolomics lies with the concept that metabolites fall downstream of genetic, transcriptomic, proteomic and environmental variation, thus providing an integrated and dynamic measure of a medical condition," write the authors led by Mark Daley, from Western University in Canada.

Markers of Recovery

Just as there is a lack of a reliable marker to diagnose concussion, there is also no objective measure to determine recovery and an athlete's readiness to return to play. However, measuring the blood protein tau just hours after injury may provide objective clinical information to inform decision-making about predicted recovery times and safe return to play, according to a study published online in Neurology on Jan. 6.

Athletes who return to play before full recovery and those receiving multiple concussions are at increased risk for long-term neurological complications. Most athletes see their post-concussive symptoms disappear within 10 days, but in some, the symptoms become chronic.

Tau is made by neurons and is known to get stuck in plaques in the brains of people with Alzheimer's and chronic traumatic encephalopathy, the neurodegenerative disease linked to the premature death of football players. Previous research also showed tau to be marker of neuronal injury following severe brain injuries.

Researchers from the National Institute of Nursing Research and Quanterix (Lexington, Mass.) measured tau levels using an ultrasensitive immunoassay after a sports-related concussion in 46 athletes (soccer, football, basketball, hockey, and lacrosse), as well as in 37 teammate without concussions and a group of 21 healthy, non-athletes. Sampling occurred at six hours, 24 hours, 72 hours, and 7 days post-concussion. Concussed athletes were grouped by the length of time until their return to play (RTP; long = more than 10 days, n = 23 and short = less than 10 days, n = 18).

Concussed athletes who needed a longer amount of recovery time before RTP had significantly higher tau concentrations at six, 24, and 72-hours post-concussion, compared to athletes with shorter RTP. These findings were consistent in in both male and female athletes, as well as across sports type. Receiver operator characteristic analyses showed that higher plasma tau 6 hours post concussion was a significant predictor of RTP with an area under the curve 0.81.

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> "In the future, this research may help to develop a reliable and fast clinical lab test that can identify athletes at higher risk for chronic post-concussion symptoms."
>
> —Patricia A. Grady Ph.D., R.N.

"In the future, this research may help to develop a reliable and fast clinical lab test that can identify athletes at higher risk for chronic post-concussion symptoms," said NINR director Patricia A. Grady Ph.D., R.N., in a statement.

The study utilized Simoa, a highly sensitive, fully automated immunoassay platform (Quanterix). The company reports they plan on launching a clinical trial with the National Football League this year. In the meantime, they are working on shrinking the platform to permit sideline testing. Ultimately, they say, the goal is to get the test sensitive enough to have a tau result within 15 minutes of the injury.

Key Market Players for Concussion Tests

A number of other companies are carrying out clinical trials and regulatory submissions for blood-based concussion tests. Such companies include:

Banyan Biomarkers: San Diego-based Banyan Biomarker's research is focused on ubiquitin C-terminal hydrolase L1, which is found in brain neurons, and glial fibrillary acidic protein (GFAP) found in specialized glial cells in the central nervous system called astrocytes. The company has partnered with several diagnostics firms including Abbott, Philips, BioMérieux, and Quanterix to develop a handheld test for traumatic brain injury. It says that a test based on these proteins could reduce the need for CT scans to evaluate concussion.

Abbott: Abbott says it is currently developing a blood-based concussion test to detect specific proteins associated brain injury. The test will be available on Abbott's i-STAT analyzer, a handheld device used by the military to perform a broad range of common blood tests. Initial test development began in 2014 with funding from the U.S. Department of Defense. The test will reportedly first be available in India while U.S. trials are underway.

Takeaway: As research continues to identify reliable tests to diagnose concussion, early blood-based concussion tests are beginning to enter the commercial market.

ACA Impacts Screening Test Usage

As efforts to replace the Affordable Care Act (ACA) have not yet resulted in its repeal, it appears there has been an uptick in preventive screening caused by the ACA. Yet, cancer-screening rates in the United States still remain below Healthy People 2020 goals. More people received screenings to prevent cancer and heart disease in 2015 than in 2012, according to a March 2017 data brief from the National Center for Health Statistics (NCHS), although the growth in screening was not consistent.

> "The Affordable Care Act has helped to reduce such barriers by expanding insurance coverage and eliminating cost sharing, in most insurance plans, for preventive services."
>
> —Arica White, Ph.D.

The ACA was intended to improve access to health care through both greater numbers of insured and coverage of "essential health benefits" (certain clinical preventive services) without copayments.

Two studies led by researchers at the U.S. Centers for Disease Control and Prevention (CDC) used 2015 National Health Interview Survey to assess utilization of screening services in a nationally representative adult civilian population. Actual screening rates were compared to the estimated number who should be screened based upon recommendations from the U.S. Preventive Services Task Force or national targets from Healthy People 2020.

- **Colonoscopy:** In 2015, just under two-thirds of insured adults aged 50 to 75 years were screened for colorectal cancer within the recommended intervals. This is up substantially from the colonoscopy rate of 49.1 percent the CDC reported in 2010.

  In the second study, published March 3 in *Morbidity and Mortality Weekly Report (MMWR)*, the authors note the rate of colorectal cancer screening of 62.4 percent in 2015 is below the Healthy People 2020 target of 70.5 percent. Despite progress in increasing screening in many groups, low screening use was reported by persons without a usual source of health care (26.3 percent) and the uninsured (25.1 percent).

- **Pap Testing:** In 2015, more than 8 out of 10 insured women aged 21 to 65 years were screened for cervical cancer (83 percent) in accordance with recommendations. Cervical cancer screening test use was lowest (63.8 percent) among uninsured women.

  The screening rate for cervical cancer actually decreased slightly between 2000 and 2015 and remains below the target of 93.0 percent by 2020. However, the *MMWR* authors note that cervical cancer screening recommendations changed in 2012. The new extended screening intervals may have contributed to the slight decline in cervical cancer screening.

- **Glucose Testing:** In 2015, roughly two out of three overweight and obese insured adults aged 40 to 70 years had a fasting blood test for high blood sugar or diabetes in the past 12 months.

"The Affordable Care Act has helped to reduce such barriers by expanding insurance coverage and eliminating cost sharing, in most insurance plans, for preventive services," write the *MMWR* authors, led by Arica White, Ph.D., from the CDC's Division of Cancer Prevention and Control. "Persons without a usual source of health care and the uninsured had the lowest test use, with the overwhelming majority of the uninsured not up to date with breast and colorectal cancer screening."

Takeaway: The ACA is credited with increasing rates of some preventive health screening, although screening rates remain below Healthy People 2020 targets.

Abbott and Alere Resolve to Move Forward with Deal on New Terms, *from page 1*

"The combination of Alere and Abbott will create the world's premier point of care testing business and significantly strengthen and grow Abbott's diagnostics presence," added Miles D. White, Abbott's chairman and chief executive officer in the same statement. "We want to offer our customers the best and broadest diagnostics solutions. Alere helps us do that."

Alere, which specializes in in vitro tests for influenza, hospital-acquired infections, toxicology and cardiology, received FDA 510(k) marketing clearance earlier this month for a rapid flu test for point of care and laboratory use. The Alere™ Reader "is the first rapid antigen influenza test to achieve 510(k) clearance as a Class II assay under the new FDA reclassification requirements," according to Alere's statement announcing the FDA approval. Additionally, as *LIR* reported last month, the FDA is considering what would be the first approved POC HbA1c diagnostic test for diabetes in the US. Alere's Afinion HbA1c Dx would be considered a moderate-complexity test, i.e., labs would have to perform proficiency testing and follow other quality controls.

Before the acquisition can be completed, regulatory approvals will still need to be secured and Alere shareholders must approve the terms of the deal. If those approvals are secured, the deal is expected to be completed by the end of the third quarter in 2017. As part of the terms, both Abbott and Alere have agreed to drop their lawsuits against each other. You may recall that in December 2016, Abbott sought to have a Delaware Chancery Court let it out of the deal, claiming that Alere has lost "substantial value." Alere had filed litigation to move the deal forward and force Abbott to pursue regulatory filings needed for the deal. Earlier in 2016, Abbott had tried to negotiate an exit, offering Alere between $30 million and $50 million to call it off but Alere refused (See *LIR*, May 19, 2016).

Takeaway: Abbott's planned acquisition of Alere will move forward after the parties have resolved litigation over whether to proceed with the deal.

INDUSTRY BUZZ

Role of Healthcare AI in the Lab: Today & Tomorrow

By Jason Bhan, MD, Co-Founder, Chief Medical Officer at Prognos

Laboratories have traditionally directed their information technology (IT) focus to support their main business of testing. The IT infrastructure they have invested in allows them to address key business issues such as quality, turnaround times, and reimbursement.

Laboratories also excel at logistics, clinical operations, and point-to-point connections on the IT front. This focus on the operational aspects makes sense for laboratories, as many operate on single-digit margins and face pressure to maintain profitability.

Despite having significant amounts of data playing a vital role in clinical decision-making, most laboratories (with a few notable exceptions) have neither invested in data strategy nor leveraged their individual data assets. Meanwhile, the rest of the healthcare industry has made great strides in exploring the potential and harnessing the power of big data, advanced analytics, and Artificial Intelligence (AI) to grow business and improve patient outcomes.

Welcoming Healthcare AI in the Lab

Fortunately, the situation has recently begun to change. Several leading laboratories such as Quest Diagnostics and LabCorp now recognize the value of their data and have partnered with AI experts to leverage it and grow their businesses. Other laboratories are taking notice of this aggregated AI data strategy, which can have an immediate impact.

Diagnostic data is critical in the early detection of disease, and yet, most decisions made around population health management or patient care are based on medical claims or prescription information. Both are transactional in nature and both only indicate decisions already made. When combined with advanced analytics and AI, diagnostic information can be used to identify or predict events well before the claim or prescription. This means that laboratories can put their data to work to help various healthcare stakeholders make better treatment decisions, earlier.

Multiple Beneficiaries of Lab Data Insights

Physicians, patients, therapy developers, and health plans all can benefit from diagnostic data insights.

Payers require more clinical specificity to effectively identify and manage patients. The timely and clinically insightful data of laboratory test results can predict patients who need attention. Such early detection enables payers to better design interventions to improve patient outcomes and lower cost of care.

The benefits to patients and healthcare research communities include the ability to better understand disease patterns and positively impact people's lives. By having large clinical datasets that can longitudinally track patients across different laboratories, payers and providers will be able to better understand health outcomes and identify areas for improvement.

Labs Cannot Go It Alone

When it comes to gaining actionable insights from diagnostic data using healthcare AI, laboratories cannot go it alone. Among the approximately 5,000 community hospital, reference, and academic laboratories in the U.S., no single laboratory has the necessary amount of data to provide meaningful insights using AI. Actionable insights are possible only when large amounts of data are available, aggregated from hundreds of laboratories, then analyzed to identify patterns that can be used to predict risk or outcomes.

Healthcare AI companies use techniques such as machine learning and natural language processing, coupled with massive computational power, on these big data sets to make sense out of reams of non-standard, complex, and heterogeneous data.

Collaborating with other healthcare solution providers eliminates the need for laboratories to invest into building up the informatics infrastructure necessary to capture value from their own data. In order for a laboratory to establish a footprint in the AI space, it would need to invest in hiring expert staff, invest in new technology, and acquire a broader set of data. These are things not within the core capabilities of the typical lab. Laboratories can also benefit financially from sharing their data as well as gain a definitive sense of the markets that they serve and their market share.

What's Next?

While AI is no silver bullet for laboratory industry challenges, it has great potential to highlight the tremendous value of lab testing in the care of patients. Laboratory data is most valuable when it is integrated into larger clinical datasets, which enable AI to work and deliver impactful insights. Healthcare AI will further understanding of clinical patterns, highlight treatment opportunities, and help predict disease earlier.

***Jason Bhan**, MD, is Co-Founder and Chief Medical Officer at Prognos, www.prognos.ai, an innovative healthcare AI company. He is an expert in the applications of technology to healthcare and medicine. Dr. Bhan obtained his medical degree at the University of Miami School of Medicine.*

FDA Exempts 71 Class I Device Types From 510(k) Filings

The FDA has determined that 71 device types, including some diagnostic test kits, should be exempt from 510(k) filings. These devices are deemed "sufficiently well understood and do not present risks that require premarket notification to provide a reasonable assurance of safety and effectiveness," the FDA said in a statement regarding the determinations.

Generally, devices introduced to market after 1976 require either FDA notice under 510(k) or premarket approval, depending on their risk classification. Class 1 devices are the lowest risk devices, for which the agency has determined general controls will be "sufficient to assure safety and effectiveness." A 510(k) filing gives the FDA notice of the intent to market a device and allows the FDA to decide if the new device is "substantially equivalent" with a device already on the market that doesn't require full premarket approval.

The FDA announced the 71 class I device types in a notice published in the April 13, 2017 Federal Register. It is the result of efforts to streamline agency review under the 21 Century Cures Act, which was signed into law in December 2016. That Act requires the FDA to announce in the Federal Register within 120 days of enactment those devices that don't require 510(k) reporting to give the agency assurance of safety and effectiveness. The FDA must also publish similar determinations at least once every five years.

The FDA considered the following in creating this list:

a. "risk inherent with the device and the disease being treated or diagnosed (e.g., devices with rapidly evolving technology or expansions of intended uses)"

b. history of adverse event reporting regarding the device type; and

c. history of product recalls related to the type of device.

The list currently includes some diagnostic devices including test kits. Limitations to the exemption are included in some cases, however. For example, some test kits are only partially exempt with the exemption not applicable to use of the kit for donor screening tests.

The devices in the list will still be required to satisfy general controls and remain subject to other statutory or regulatory requirements for which an exemption hasn't been expressly issued.

Takeaway: 21st Century Cures Act efforts to streamline the path to market begin to take effect.

CMS Enforcement Discretion Eases Pressure on Labs

After we went to press last month, the Centers for Medicare and Medicaid Services (CMS) announced just in the nick of time that it wouldn't impose civil monetary penalties against labs which failed to meet the March 31, 2017 reporting deadline under the Protecting Access to Medicare Act (PAMA). That "enforcement discretion" will last until May 30, 2017. But, it

CMS acknowledged that some entities may need more time to collect and review their data, "address any issues identified during such review, and compile the data into CMS's required reporting format."

also noted that this enforcement discretion doesn't mean that those who are ready to report should delay their reporting until May 30.

CMS added that the 60-day enforcement discretion "is the maximum amount of time CMS can permit to still have sufficient time to calculate the CLFS payment rates scheduled to go into effect on Jan. 1, 2018." The agency explained its decision followed reports from the laboratory industry that some labs would have trouble reporting "a complete set of applicable information" in time for the March 31 deadline.

CMS acknowledged that some entities may need more time to collect and review their data, "address any issues identified during such review, and compile the data into CMS's required reporting format."

In fact, just days earlier on March 24, various industry associations including the American Clinical Laboratory Association, National Independent Laboratory Association, College of American Pathologists and Clinical Laboratory Management Association had sent a letter to Health and Human Services Secretary Tom Price indicating many in the industry continued to struggle with the data collection requirements. That letter also reiterated industry concerns about the impact of the current definition of applicable laboratory and sought a one-year delay in implementation of PAMA.