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Covering Government Policy For Diagnostic Testing & Related Medical Services

Celebrating Our 38th Year of Publication

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Upcoming Events

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

Medicare Reimbursement: CMS Proposes MACRA Physician Performance Requirements for 2018

On June 30, CMS issued a Proposed Rule addressing a key part of Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) implementation: the Quality Payment Program (QPP) for 2018, the second Performance Year. Here's a quick overview of the Proposed Rule.

MACRA, 101

The MACRA system, which won't be fully in place until 2019 at the earliest, eliminates the old sustainable growth rate formula in favor of the QPP system. There are 2 QPP tracks. The first is the Merit-Based Incentive Payment System (MIPS), in which value of Part B physician services is based on 4 performance categories:

- **Quality**—physicians must report on 6 measures;
- **Advancing Care Information**—providers can select "customizable measures" for reporting day-to-day use of technology and demonstrate interoperability;
- **Clinical Practice Improvement Activities**—such as care coordination and patient safety;
- **Cost**—based not on physician reporting but on Medicare claims data that use "40 episode-specific measures."

The second track is incentive payments for participating in certain Advanced Alternative Payment Models (APMs). Providers who participate in APMs are exempt from MIPS reporting.

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Labs to CMS: Push Back PAMA & Add Hospital Labs to CLFS Mix

The lab industry continues to wait nervously for word from CMS regarding PAMA.

Demand 1: Fix the Fee Schedule Methodology

The industry's paramount concern remains the formula CMS proposes to use to calculate market rates for lab tests in setting the Clinical Laboratory Fee Schedule (CLFS) under PAMA, specifically the

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CMS Proposes MACRA Physician Performance Requirements for 2018, *from page 1*

The 5 Proposed MIPS Changes

The Proposed Rule includes changes to both tracks for the 2018 Performance Year. The 5 key MIPS changes:

1. Raising the Low-Volume Threshold

- *2017 Threshold:* $30,000 in Medicare Part B allowed charges or less than or equal to 100 Medicare patients;
- *Proposed 2018 Threshold:* $90,000 in Medicare Part B allowed charges or less than or equal to 200 Medicare patients;
- *Impact:* More physicians would be exempt from participating in MIPS in 2018. Physicians who fall below the low-volume threshold will be allowed to opt-in to MIPS starting in the 2019 Performance Year.

2. New Virtual Groups Requirement

Disparate providers who don't belong to a medical group must form virtual groups for purposes of aggregating and reporting their MIPS data. Physicians will have to submit a written agreement among members of the virtual group to CMS by December 1, 2018.

3. Allow for Continued Use of 2014 CEHRT

The Proposed Rule would allow providers to continue using a 2014 Certified Electronic Health Record Technology in 2018; but providers who implement a 2015 edition product may qualify for a bonus.

4. Cost Performance of Zero Percent

Under the Proposed Rule, the cost performance category of the MIPS score for the 2018 Performance Year would be set at zero percent to give CMS more time to develop and provide feedback to providers on episode-based measures.

5. Facility-Based Performance Evaluation

The Proposed Rule establishes a method to assess the quality and cost performance of individual providers who carry out their primary responsibilities in a health care facility based on the facility's performance.

The 2 Proposed Advanced APM Changes

The Proposed Rule also includes changes to the APM track.

1. New Qualified Advanced APM (QP) Determination Process

Under the Proposed Rule, CMS would be permitted to make determinations of a Qualifying APM Participant (QP), i.e., eligible provider participating in an Advanced APM to a sufficient degree for Advanced APMs that start or end during the QPP performance year and which operate continuously for at least 60 days. In those circumstances, CMS will use only data from Advanced APMs where they operated within the QPP performance year to make QP determinations.

CMS is also asking for comments on a proposal that would allow QPs to receive participation credit for Medicare Advantage as part of the Medicare Option rather than the All-Payer Combination Option. Under current rules, providers looking to become QPs have only 2 scoring options based on their participation in Advanced APMs: the Medicare Option (only Medicare as the payer) and/or All-Payer Combination Option (payers other than Medicare).

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2. New Other Payer Advanced APM Determination Process

The Proposed Rule would establish a process allowing payers to request that CMS make a determination about whether a payer's program meets Advanced APM status starting before the 2019 Performance Year. Payers eligible to request such determinations include, among others, Medicaid, Medicare Advantage, Programs of All Inclusive Care for the Elderly plans and Medicare-Medicaid plans.

Takeaway: Public comments on the Proposed Rule close on August 21, 2017 and, based on what happened last year, CMS will likely issue a final rule in November. That could prove too narrow a window for some of the Program Year 2018 deadlines, most notably the requirement that virtual groups submit an agreement among group members to CMS by December 1, 2108.

Utilization Trends: HIV Testing Among Vulnerable Populations Remains Disturbingly Low, Says CDC

Identifying patients who are unaware of their positive HIV status and linking them to care is crucial to reducing HIV infection, particularly among sexually active teens and young adults remains low. But a troubling new U.S. Centers for Disease Control and Prevention (CDC) report indicates that testing rates for these vulnerable populations remain behind stated U.S. goals.

The CDC Findings

The June 23 report is contained in the CDC's Division of HIV/AIDS Prevention in *Morbidity and Mortality Weekly Report* (MMWR). The report includes analysis of CDC-funded program data for youths submitted by 61 health departments (state and local) and 123 community-based organizations that provided HIV testing and related services in 2015.

In 2015, more than 3 million CDC-funded tests were run with 28 percent provided to youths—primarily ages 20–24 years (74 percent), female (55 percent), and black (50 percent). More than three-quarter of tests were provided in health care facilities and in medium and high prevalence areas (97 percent). Tests in health care facilities were less likely to yield new diagnoses than tests performed in non-health care facilities, the report finds.

An average of 22 percent of high school students who had sexual intercourse and 33 percent of young adults (ages 18 to 24) reported ever receiving an HIV test. Among the nearly 4,900 HIV infections identified among youths, 39 percent had been previously diagnosed, but 92 percent of those youths with previously diagnosed infection were not in HIV medical care at the time of testing. Young men who have sex with men accounted for 83 percent of new diagnoses among all youths in non-health care facilities and received 28 percent of HIV tests in those settings.

Recommendations for Increasing HIV Testing

"Increasing the number of youths at risk for HIV infection who are tested for HIV on a regular basis and ensuring that youths who receive positive test results for HIV are rapidly linked to and retained in appropriate medical care,

including early initiation of antiretroviral therapy, are essential steps for reducing HIV infection in this vulnerable population," writes Renee Stein, Ph.D., in the report. "Including HIV testing as part of routine medical care for youths is key to increasing early diagnosis, and a health care provider's testing recommendation is the most important predictor of testing among adolescents at risk for HIV infection."

The CDC suggests that the necessary increased testing could be accomplished via a combined strategy of routine HIV testing among youths, especially young men, in health care settings, and targeted testing in settings where youths at risk for HIV infection congregate. Additionally, the CDC calls for measures to encourage health care providers to include HIV testing as a routine part of health care for youth and suggests schools can also play an important role in facilitating access to HIV testing.

Takeaway: Strategies are needed to increase HIV testing among young adults, including measures to make HIV testing routine in the health care setting and expand nontraditional settings where at-risk youth may congregate.

Case of the Month: Foundation Medicine Faces Lawsuits from Shareholders & a Business Rival

A start-up diagnostics firm on the precipice of a lab product breakthrough becomes a Wall Street darling. But, alas, the product fails to meet its lofty expectations. The firm's stock tanks and the investors left holding the bag sue the lab for fraud. No, we're not talking about Theranos. This case pitting a lab against its former investors comes from a different sector of the diagnostics market.

The Foundation Medicine Case

Established in 2009, Foundation Medicine, Inc. is a provider of molecular diagnostic information known for its next-generation sequencing-based cancer assays, including FoundationOne for solid tumors and FoundationACT for circulating tumors.

At up to $7,200 per test, Foundation's business is heavily reliant on major insurance coverage. So when Foundation and its officers made a series of statements suggesting that Medicare coverage of the tumor tests was likely, the company's common stock took off. But things didn't pan out. In July 2015, after nearly 18 months of optimism, the company disclosed that the expected coverage approval from Medicare would not be forthcoming any time soon and slashed its financial guidance for the year. The announcement caused a 24% ($7 per share) decline in stock price. In November, came more bad news and deeper guidance cuts causing the stock to plummet even farther.

Now Foundation's investors have filed a class action lawsuit in Massachusetts federal court (Foundation is based in Cambridge) claiming that the company's officers knew all along that the representations about Medicare coverage of the tumor tests were false. From now through Sept. 26, the trial

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INSIDE THE DIAGNOSTICS INDUSTRY

New Laws: Do-It-Yourself Kits Bring Lab Testing to the Home

Health care in the 21st century is moving toward consumerization of medicine, patient empowerment and increased price awareness resulting from higher out-of-pocket medical expenditures. The growth of at-home testing products is one key manifestation of these trends in the clinical laboratories sector. (For a look at another example, co-branding testing collaborations between labs and mass retailers like Walmart, see "Quest Walmart Deal Latest in Mass Retailing of Lab Tests," *NIR*, July 2017.)

The Pros & Cons of At-Home Testing

It's hardly surprising that the number of companies offering at-home testing products continues to proliferate. At-home testing offers significant advantages to consumers, including not just convenience but privacy, which is a major consideration for sensitive testing like sexually transmitted diseases (STDs) assays. And in an era of shrinking insurance coverage, at-home tests make diagnostics accessible to the uninsured. Patient-initiated testing is entirely out-of-pocket (although health savings accounts can be used to pay for some tests.)

But at-home testing is also unproven. In addition to being a waste of treatment resources, some health care professionals are concerned that at-home testing may generate false results, especially when it's self-initiated. The concern is that patients may rely on these results to make vital treatment decisions like adjusting medication doses without clinician oversight.

Consumer Reports Weighs in on the At-Home Testing Products

In an article published earlier this year, Consumer Reports medical advisers listed FDA-approved tests that are worth trying at home (blood glucose, fecal occult-blood tests, HIV, urinary tract infections, yeast infections), and those to avoid as do-it-yourself tests (allergy, c-reactive protein, prostate cancer, testosterone, thyroid disease, and vitamin D).

Types of At-Home Testing Products

At-home products come in two basic forms:

- Mail-in tests in which patients collect their own samples (blood, mouth swab, urine or stool) and mail them to a lab for processing; and
- Instant tests in which sample collection *and* testing are performed at the patients' home with results available in minutes.

Instant tests leverage advancements in lateral flow technology (paper strips, much like easy-to-read pregnancy tests), as well as entirely new forms of testing, including portable analyzers intended for at-home use. Pregnancy tests and blood glucose monitoring may be the best known, do-it-yourself tests, but innovation is expanding the potential for routine home monitoring for both wellness and chronic conditions.

Overview of the At-Home Testing Market

Here's a quick profile of key companies offering products that are currently or soon to be commercially available in each product type space.

INSIDE THE DIAGNOSTICS INDUSTRY

Mail-In Testing Providers

Notable providers of at-home sample collection and mail-in testing products include:

- **MyLabBox** (Los Angeles, CA), which offers a nationwide home-based STD testing service that includes panels consisting of 4, 8 or 14 conditions, including HIV, hepatitis C, herpes, syphilis, chlamydia, gonorrhea, trichomoniasis, mycoplasma genitalium, and human papilloma virus. The panels range from $189 to $399.
- **Everlywell** (Austin, TX) which in addition to STD panels offers routine lab tests such as cholesterol and HbA1c, as well as and niche offerings like testosterone, thyroid and heavy metals testing.
- **Exact Sciences** (Madison, WI), which offers Cologuard, the first and only FDA-approved stool DNA, noninvasive screening for colorectal cancer. The test assesses for 11 biomarkers, including 7 DNA mutation markers, 2 DNA methylation markers, one hemoglobin marker and Beta actin. But Cologuard is different from most other at-home testing products in 2 important ways: first, it's available by prescription only; it's also more expensive than many at-home tests, listing at $649 (although some insurance carriers cover some or all of the cost).

Providers of Instant Result Tests

Some of the notable providers of at-home tests that generate instant results include:

- **Scanadu** (Sunnyvale, CA), whose heavily hyped at-home consumer diagnostics products have yet to make it to the commercial market, including Scanadu Urine, a disposable paddle that consumers dip into a urine sample and use the Scanadu app and camera on their smartphone to read and analyze the results a minute later.
- **Cor** (San Francisco, CA), which closed its Indiegogo crowdsourcing campaign in May 2016 and is still validating its hardware platform for translating spectral data into quantitative chemistry insights. Users press the single use Cor Cartridge against their arm to get a surface-level blood sample using a fine needle that the company says is completely painless. The cartridge is then placed in the Cor Reader. (Cartridges are available for a $10-per-month subscription.)
- **Medical Electronics Systems** (Los Angeles, CA) which has received much attention for its FDA-approved, YO Home Sperm Test, the first home male fertility test kit powered by a smartphone platform and supported by an interactive app experience. The company also manufacturers commercial-grade semen analyzers. The at-home test allows users to view and measure the number of motile (moving) sperm in their sample, which the company says is a key measure of assessing male fertility.

INSIDE THE DIAGNOSTICS INDUSTRY

Takeaway: There are an expanding number of options for consumers to conduct at-home testing. The commercial market is growing for tests mailed in to CLIA-certified laboratories and is expected to see a number of new entrants for instant tests capable of providing results at home, as well.

Case of the Month, *from page 4*

lawyers are looking for investors who bought Foundation stock during the affected period (February 2014 to November 2015) to participate in the suit, including individuals who are willing to serve as the lead plaintiff.

Meanwhile, Foundation Renews Acquaintances with a Familiar Legal Adversary

Of course, Theranos is also facing securities fraud claims from its investors. But that is not the only similarity between the Theranos and Foundation cases. The other thing the labs have in common is a parallel consumer fraud lawsuit.

In the Theranos case, the complaint came from the Arizona Attorney General. Foundation's nemesis, by contrast, comes from the private sector. In June, Guardant Health filed a lawsuit in California federal court charging Foundation with making false and misleading claims by misrepresenting its tests as "best in class." In addition to being Foundation's competitor in the liquid biopsy market, Guardant Health is also a former litigation adversary. In 2016, Foundation sued Guardant Health for patent infringement. Now the tables have been turned and Foundation will occupy the defendant's seat.

Takeaway: Stay tuned. Both cases have just begun and will bear close watching in the months ahead. We'll keep you apprised on both fronts.

Compliance Perspectives: Do No Harm—Diagnostic Errors and the Lab

By Jennifer (McMahon) Dawson, MHA, DLM (ASCP)

"Do no harm" is the mantra that health care providers live by. Doctors, nurses and laboratory professionals alike enter into the business of health care because they are motivated to help people.

Why Mistakes Happen

Why then do 5% of adults in the U.S. experience diagnostic error annually in outpatient settings at the hands of these well-meaning providers?[1] Humans work in health care. Where humans are involved, there will be mistakes.

There's also a certain level of trial-and-error that's acceptable in the diagnosis of patients. Lab professionals often feel removed from the actual diagnosis of the patients that they serve.

The Role of Labs

Labs play a critical role as lab testing is often used to confirm initial impressions or rule out differential diagnoses. An estimated 70% of all health care decisions affecting diagnosis or treatment involve lab testing[2] and at least 10% of all diagnoses are not considered final until lab testing is complete.[3,4]

We can all agree that the identification of diagnostic errors in medicine is critical to improving patient safety; however, that's easier said than done. Historically, the lab industry has focused its quality improvement efforts within boundaries of the lab. We have been lab-centric in this respect and have not focused on collaboration with other members of the care team or patient outcomes. The lab has been very good at detecting and eliminating errors in the analytical phase. Less focus has been placed on identifying and remedying errors outside of the analytical phase, particularly those that occur outside the boundaries of the lab (pre-pre and post-post-analytical).

For the lab to have a positive impact on diagnostic errors, it must become part of the interdisciplinary patient-centered care team. Lab professionals need to view their services as contributing to patient outcomes, not just generating results.

Research on diagnostic errors and the lab's role has found that failure to order appropriate diagnostic tests, including lab tests, makes up 55% of missed and delayed diagnoses in the ambulatory setting and 58% of errors in emergency departments.[5] We know that health care providers don't understand our tests as well as we do. This statistic underscores the need for Clinical Lab Scientists to interact with and provide education to ordering providers on the proper use of the testing we provide.

Ways Labs Can Reduce Dx Errors

One way that clinical lab professionals can affect positive change is by collaborating with other health care providers to establish evidence-based decision-making guidance for ordering tests. Providing feedback to providers detailing improper test utilization patterns, both over- and under-utilization, is another way that lab professionals can help to reduce diagnostic errors. Other ways the labs can help reduce diagnostic errors include reflexive testing, consultative services and improved test reporting.

Unfortunately, standardized feedback systems and reliable evidence-based decision support mechanisms do not yet exist on a large scale. In the meantime, we are reliant largely on our non-conforming event management systems to capture diagnostic errors. The success of these systems, whether you choose a manual or electronic option, is contingent on the establishment of a reporting culture.

A reporting culture is a culture of trust where employees feel safe, supported and comfortable pointing out errors, which may include their own, in the interest of patient safety and continuous improvement. The types of errors captured will include lab errors, errors generated outside the confines of the lab and near misses. A near miss is "any event that could have had an adverse patient consequence, but did not, and was indistinguishable from a

full-fledged adverse event in all but outcome."[6] A near miss is the perfect quality improvement opportunity, as we have the opportunity to eliminate the root cause before a patient is harmed. It is only after we are made aware of an event or near miss that a root cause analysis and corrective action can be formulated to prevent the event's recurrence.

The identification of diagnostic errors to which the lab has contributed is a crucial piece of the puzzle in our effort to improve patient safety and outcomes. The lack of comprehensive information on the incidence of diagnostic errors should not prompt us to conclude that these errors are uncommon or unavoidable.[7]

In addition to the patient safety benefits, the shift from fee-for-service to value-based purchasing is already requiring us to become more patient-centric and outcomes-focused. This way of thinking is in line with the way we will be reimbursed in the future. The lab can help to reduce diagnostic errors by focusing on becoming more patient-centered, educating providers on lab testing, providing consultative services, initiating feedback loops that extend beyond the walls of the lab and ensuring that we have an effective non-conformity management system.

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Labs IN COURT

A roundup of recent cases and enforcement actions involving the diagnostics industry

Anthem Settles Data Breach Lawsuit for Record $115 Million

Case: Anthem, the nation's second largest health insurer, has agreed to shell out $115 million to settle a class action lawsuit over a massive 2015 cyberattack in which hackers stole the names, addresses, birthdates, Social Security numbers and other personal information of roughly 78.8 million plan members and employees. Under the deal, the biggest settlement ever for a data breach, Anthem will furnish 2 additional years of credit protection monitoring to the individuals affected and set aside a $15 million fund to cover victims' out of pocket costs.

Significance: The takeaway from the settlement isn't just the money but the specific improvements it requires Anthem to make to its data security systems over three years, including implementation of:

- Strict access requirements;
- Data retention periods;
- Mandatory information security training for associates; and
- Annual IT security risk assessments.

Five More Doctors Convicted in BLS Bribery Scheme

Case: The biggest medical bribery scandal of all time continues to grow with 5 more doctors pleading guilty to taking bribes from now defunct Biodiagnostic Laboratory Services LLC (BLS) in Parsippany, New Jersey. Here's the Scorecard for the latest defendants:

Name	Practice	Allegations
Jorge J. Figueroa	Internal medicine, Fair Lawn, NJ	Accepted $200K from BLS employees for roughly $1.4 million in illegal lab business between May 2007 and April 2013
George & Nicholas Roussis (brothers)	Pediatrician and OBGYN (respectively) Staten Island, NY	Accepted $175K in BLS cash payments for roughly $1.7 million in lab referrals from Oct. 2010-April 2013; BLS also paid for strip club trips, lap dances and sexual favors
Basel Batarseh	Internal medicine, Wayne, NJ	Accepted monthly bribe checks of $3.2K ($104K in total) for generating roughly $1.3 million in lab business from Nov. 2007 to Aug. 2010
Yousef Zibdie	Internal medicine, Woodland, NJ	Accepted $80K worth of monthly bribe checks for generating roughly $930K in illegal lab business for BLS

Significance: In a sneak preview of what the future may hold for these five when sentence is handed down in December, the very same day the above convictions were announced, a 79-year-old Bergen County (NJ) family physician was sentenced to 41 months in prison for taking $200,000 in bribes for approximately $3 million's worth of illegal lab business to BLS. The latest BLS "body count" is 50 convictions, 36 of them doctors.

LabCorp Pays $45.4K for Self-Disclosed Excluded Individual Offense

Case: Laboratory Corporation of America agreed to pay $45,466 in Civil Monetary Penalties for allegedly hiring an employee that it knew or should have known had been excluded from participating in federal health care programs. The alleged offense, which LabCorp self-disclosed, took place at one of its Florida labs.

Significance: This is the third fine against a major lab in 2017 for a self-disclosed violation to the OIG:

- In Feb., Quest Diagnostics agreed to pay $315,093 for alleged kickbacks to a referral source in the form of above fair market rent payments by one of its New Jersey labs to a medical practice; and
- In March, Quest settled a trio of CMP offenses, two of which were Electronic Health Records-related for $1.151 million.

Compliance Planning: OIG Switches from Semi-Annual to Monthly Work Plan Updates

When it comes to running a laboratory compliance plan, the semi-annual OIG Work Plan can be a big help to because it enables you to keep track of new enforcement initiatives and respond to emerging fraud and abuse issues quickly and effectively. But you'll no longer be able to count on OIG Work Plans every 6 months. Starting in July, the OIG began updating the Work Plan every month. Here's a look at the new approach and what it means to your own compliance efforts.

Navigating the New OIG Work Plan Website

Under the new regime, the key to staying up to date will be to navigate the OIG Work Plan website, which will now be organized into three categories:

- **Recently Added**, containing new items for the month;
- **Active Work Plan Items**, into which the Recently Added items will be shifted after a month and remain until the OIG deems them "complete"; and
- **Work Plan Archive**, containing Work Plan reports dating back to 1997.

The First New Monthly Updates

Key new enforcement initiatives in the first monthly Work Plan updates of June and July that may affect labs include review of:

- Medicare payments for nonphysician outpatient services provided under the inpatient Prospective Payment System;
- Medicare claims for telehealth services provided at a "distant site," i.e., the practitioner's location, that don't have corresponding claims for the "originating site," i.e., the beneficiary's location; and
- Quality data reported by Accountable Care Organizations that have received earned share savings payments under the Medicare Shared Savings Program to ensure compliance with quality measures data reporting rules.

Takeaway: The need to adjust your lab's fraud and abuse compliance efforts to address new OIG Work Plan enforcement initiatives is nothing new. But from now on, you'll have to assess the need for such adjustments on a monthly rather than semi-annual basis. The good news is that if you don't feel like dealing with the OIG website, you can get regular monthly OIG Work Plan updates from NIR's sister publication, GCA.

NIR to Provide Regular OIG Work Plan Updates

NIR will begin including regular OIG Work Plan reports in each monthly issue to help you track the latest twists and turns in OIG enforcement strategy without having to navigate the OIG's website.

Push Back PAMA & Add Hospital Labs to CLFS Mix , *from page 1*

omission of hospital outreach labs from the definition of "applicable labs." In addition to pressing CMS, representatives of the American Clinical Laboratory Association (ACLA) met with members of Congress last month to "reiterate our belief that the current PAMA regulation effectively excludes hospital outreach labs, which are a significant segment of the laboratory marketplace."

The big labs have made it clear that they are fully behind the ACLA's lobbying efforts. In a conference call following the release of its recent earnings report, Quest President and CEO Steve Rusckowski stated that "while we support reform of the Medicare payment system, we believe any modification should be market-based and appropriately include all applicable independent and hospital outreach laboratories." Meanwhile, LabCorp Chairman and CEO David King complained that the current dataset CMS is reviewing in establishing CLFS reimbursement rates as part of the PAMA process represents only 5 percent of hospital lab-based testing volume.

Demand 2: Delay PAMA Implementation

Meanwhile, the industry wants CMS to postpone the new PAMA-based CLFS pending resolution of the "applicable labs" issue. The ACLA has asked the agency to delay CLFS implementation for at least 6 months. Quest's Rusckowski also indicated that he is recommending that CMS publish the new CLFS no earlier than July 1, 2018.