G2 INTELLIGENCE
A DIVISION OF PLAIN LANGUAGE MEDIA

# NATIONAL INTELLIGENCE REPORT™

Covering Government Policy For Diagnostic Testing & Related Medical Services

Celebrating Our 39th Year of Publication

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### G2 Intelligence Upcoming Events

***Conference:***

**Lab Institute 2018**

Oct. 24-26, Washington, DC

www.labinstitute.com

## CLIA: After 36 Years, CMS Gives Lab Accreditation a Good Hard Look

"*May you live in interesting times.*" If you've been in the clinical labs business for a while, you probably appreciate the wisdom behind this ancient Chinese curse. The year 2018 is shaping up to be very "interesting" for the industry. After nearly four decades of stability, Medicare is moving to the new supposedly market-based PAMA fee schedule for Part B lab tests. And now we are learning that things are about to get "interesting" for another rock of lab regulatory stability—the *Clinical Laboratory Improvements Act* (CLIA).

But unlike with PAMA, the CLIA "interesting" promises positive results for the industry.

*Continued on page 2*

## Case of Month: Judge Takes Back Ruling that Labs Must Independently Verify Medical Necessity

Thanks for clearing that up. As if the lab industry doesn't already have enough legal *agita* to deal with, last June a federal D.C. District Court upheld a whistleblower's right to sue Boston Heart Diagnostics for false billing because it failed to *independently verify* that tests physicians ordered for certain diagnostics codes were actually medically necessary. The only good thing about the ruling was that it was so wrong that it just had to be invalid. At least that's what the legal experts said. And it turns out they were right.

### The *Groat* Case: Part I

A former United Healthcare medical director filed a whistleblower suit claiming that Boston Heart routinely billed Medicare for tests that were medically unnecessary for certain diagnostic codes. Boston Heart asked the court to dismiss, noting that all of the tests were properly ordered and that it was up to the physicians to determine whether the tests were necessary.

But D.C. District Court Judge Reggie Walton allowed the claim to go to trial. Having billed Medicare for the tests, Boston Heart had a duty to *independently* verify their medical necessity, Judge Walton

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CLIA: After 36 Years, CMS Gives Lab Accreditation a Good Hard Look, *from page 1*

## The Backdrop

CLIA is the 1986 law that establishes the basic quality standards labs must meet to gain and retain CMS and state certification for diagnostic testing of human samples. And it has not undergone changes since 1992.

## The CMS Proposal

With that in mind, CMS posted a request for information (RFI) on Jan. 9 to let the industry know that it is reviewing CLIA requirements and asking the industry for comments.

## What's on the Table

### 1. Personnel Requirements

The RFI calls for public comments on the following questions related to professional qualifications and other personnel issues:

- Should a bachelor's degree in nursing be considered equivalent to a bachelor's degree in biological science or a qualifying degree to meet CLIA requirements for moderate and high complexity testing personnel and technical consultants?
- Should a physical science degree be a CLIA qualification requirement and, if so, how should such a degree be defined?
- Which, if any non-traditional degrees should be considered as meeting current CLIA requirements for chemical, physical, biological or clinical lab science and/or medical lab technology degrees?
- Should general supervisors be allowed to perform competency assessment for personnel performing moderate complexity testing in labs that perform both moderate and high complexity testing?
- What lab training, experience and skills should all personnel be required to meet and how should those things be properly documented?

### 2. Proficiency Testing Referrals

Labs guilty of making intention proficiency testing (PT) referrals face automatic an automatic two-year CLIA revocation. But the 2012 TEST Act (*Taking Essential Steps for Testing Act*) gives CMS discretion to impose alternative penalties based on the nature and extent of the PT referral. The RFI raises questions on how the agency should use its TEST Act discretion, namely:

- Should the discretion apply to a case where a lab is found to have referred its PT samples to another lab and reported that other lab's PT results as its own and, if so, under what conditions?
- Is it feasible to impose alternative sanctions in cases of PT referrals involving waived testing?

### 3. Histocompatibility Requirements

CMS is reviewing current CLIA histocompatibility rules in light of advances in transplant medicine and lab testing. Specific issues under consideration:

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- Should virtual crossmatching in lieu of physical crosswalking be allowed for transplantation? If so, what criteria and decision algorithms should be used for virtual crossmatching?
- Should current CMS-3326-NC20 histocompatibility regulations be revised or totally eliminated given obsolescence and redundancy with other CLIA regulations?

**4. CLIA Fees**

The other issue on the table are current CLIA fees, specifically the current methods used by CMS to determine fees it charges labs:

- For seeking a revised CLIA certificate due to changes in the lab's name, location, director, services or certification type;
- For determination of program compliance?
- As additional fees based on type and/or volume of testing performed and other criteria CMS deems appropriate; and
- For performing other CLIA compliance performance activities such as follow-up visits, complaint investigations and activities associated with imposition of sanctions.

### Nothing Is Exempt from Review

If you have a beef with some other aspect of CLIA, you'll be happy to know that the RFI states that in addition to the above areas, CMS is open to comments on any aspect of CLIA that needs changing.

### What Happens Next

CMS will field comments on the RFI through March 9. It will then have 90 days to prepare a Proposed Rule summarizing and responding to those comments.

*Takeaway: Although there has been no official response as of yet, the lab industry is bound to embrace CLIA review—in fact, it's something the industry has wanted for over a decade.*

## FDA Watch: Labs Warned that Biotin Interferes with Test Accuracy

In late November, the FDA issued a safety communication warning that the supplement biotin (Vitamin B7) may interfere with lab testing results.

### Biotin Concerns…

Over-the-counter (OTC) use of biotin supplements has steadily increased. These products, which purportedly strengthen hair, skin, and nails, range in biotin dosage from 50 µg in multivitamin to as high as 10 mg in some biotin-only products. The FDA notes these high-dose OTC products may contain biotin levels up to 650 times the recommended daily intake of biotin (30 µg/day). Additionally, physicians recommend extremely high doses for treatment of neuropathy and multiple sclerosis.

High-sensitivity immunoassays made by companies like Abbott, Beckman Coulter, Ortho Clinical Diagnostics, Roche and Siemens Healthcare Diagnostics are all susceptible to biotin interference.

The FDA biotin warning comes on the heels of a Roche study demonstrating that an eight-hour wait time or washout period is necessary for accurate test results when using streptavidin–biotin immunoassays following high doses, over 5 mg/day, of biotin. There have also been a number of case reports of biotin interference leading to incorrect diagnoses in both adults and children, particularly for cardiovascular and hormone tests.

High-sensitivity immunoassays made by companies like Abbott, Beckman Coulter, Ortho Clinical Diagnostics, Roche and Siemens Healthcare Diagnostics are all susceptible to biotin interference. Excess biotin in patient samples can result in falsely high test results with competitive assay design and falsely low results with sandwich assay design. A study in the *International Journal of Pharmacokinetics* found that manufacturers provide a "spectrum of guidance" in package inserts ranging from no mention or vague generic warnings of biotin interference to comprehensive specification on serum biotin concentrations.

### …And What Labs Can Do to Address Them

To minimize the risk of biotin interference with lab tests and the adverse consequences they can produce, the FDA is recommending that lab personnel:

- Be aware that biotin levels above the recommended daily allowance may cause significant interference with particular lab tests;
- Talk to physicians and patients about use of assays with biotin technology;
- At draw centers, specifically ask patients if they are taking biotin;
- Educate health care providers about biotin interference with specific tests;
- Talk directly with the test manufacturer if they have any questions or concerns about potential biotin interference with a particular test.

## Lab Industry Report: The Year in Diagnostics Mergers & Acquisitions

Continuing recent trends, most of the wheeling and dealing that took place in the lab industry in 2017 involved strategic alliances rather than mergers and acquisitions. Thus alliances outpaced M&A deals by a rate of over 3 to 1 as most firms preferred collaboration to digesting their competitors. But while M&A deals were relatively light in both volume and drama, there were a few blockbusters. Here's a quick and dirty analysis of the deals that did come down during the year;

### The Abbott Bookends

As in 2016, Abbott stole the 2017 M&A headlines with bookend acquisitions of St. Jude Medical ($25 billion) in early January and Alere in October. But while the St. Jude deal was fairly standard, the Alere merger was anything but.

Announced in February 2016, the merger stood on the precipice by year's end with both parties poised for a court battle. But the posturing died down and in mid-April, Abbott and Alere announced that their on-again off-again

deal was on again. And so it was. In addition to dropping their lawsuits, both sides agreed to new terms essentially giving Abbott a discount to compensate for the erosion in equity value that Alere incurred since the original deal was announced by cutting the purchase price to $5.3 billion.

Each firm also had to divest strategic assets to gain regulatory approval for the merger. Alere sold its triage MeterPro and BNP (B-type Naturietic Peptide) businesses to Quidel for $680 million and its Epocal point-of-care blood diagnostics unit to Siemens Healthineers for an undisclosed price.

### Thermo Fisher Acquires Patheon

Thermo Fisher's $7.2 billion purchase of contract development and manufacturing organization (CDMO) Patheon in September was the year's biggest M&A deal in terms of dollar value (not counting the $25 billion St. Jude deal which closed on Jan. 4). In acquiring the North Carolina-based provider of drug development support for pharmaceutical firms, Thermo Fisher secured its access to the $40 billion CDMO market and created $120 million in synergies ($90 million in cost and $30 million in revenues synergies). Thermo Fisher absorbed Patheon's 9,000 employees and $1.9 billion in annual revenues into its Laboratory Products and Services division.

### The Surprise Deal of the Year

In perhaps the most surprising (and intriguing) M&A deal of the year, Konica Minolta plunked down $1 billion in cash for genetic testing firm Ambry Genetics. Almost overnight, the Japanese technology giant known for business products became a major player in the global precision medicine market and acquiring a vehicle for commercializing high-sensitivity tissue immunostaining technology for clinical pathology and pharmaceutical trials.

### The Other Billion-Dollar Deals

The only other nine-figure M&A diagnostics deals to close in 2017 were:

- Grifols' $1.85 billion buyout of Hologic's blood screening assets, a move that seems to have worked out for both sides by goosing Grifols' revenues blood screening revenues 7% while leaving Hologic, its former partner in the realm, free to concentrate on its core women's diagnostics business;
- PerkinElmer's $1.3 billion cash acquisition of Euroimmun Medical Laboratory Diagnostics, which establishes PKE as a global leader in autoimmune testing and bolstering its position as a provider in infectious disease and allergy testing in China and other leading markets; and
- LabCorp's purchase of UK contract research organization Chiltern for $1.2 billion, creating a CRO unit of 20,000+ employees and strengthening its Covance business in the biopharma market.

### LabCorp v. Quest

As usual, LabCorp and rival Quest Diagnostics were among the most active players. But while the two have been waging a kind of M&A arms race for years, LabCorp flipped the script in 2017 by acquiring Mt. Sinai Health System outpatient labs and the ownership interests of Washington-based

Pathology Medical Laboratories, LLC (PAML) in five different outreach lab joint ventures (Colorado Laboratory Services, Kentucky Laboratory Services, MountainStar Clinical Laboratories, PACLAB Network Laboratories and Tri-Cities Laboratory). In the past, LabCorp has focused on acquiring specialty labs to bolster the sophistication of its product lines, while the strategy of acquiring health system outreach labs has largely been Quest's *modus operandi*. Sure enough, Quest made seven more such acquisitions during the year, including Cleveland HeartLab, MedFusion, Cape Cod Health Care, to name a few.

Other firms with the largest number of purchases during the year included:

- LabCorp, which in addition to the above noted PAML, Mt. Sinai and Chiltern deals acquired health and nutrition test firm ChromaDex;
- Thermo Fisher Scientific, which in addition to the big Patheon acquisition, acquired a trio of smaller firms including Linkage BioSciences, Core Informatics and Finesse Solutions;
- Invitae, which acquired AltaVoice, CombiMatrix, Good Start Genetics and software maker Ommdom; and
- Bruker, which a few months after announcing the acquisitions of SCiLS and InVivo Biotech Services on the same day, picked up Merlin.

**Top 10 Biggest M&A Deals of 2017 in Diagnostics (Deals with 2017 closing dates)**

| Rank | Acquiring Company | Target Company | Price | Closing Date |
|---|---|---|---|---|
| 1 | Abbott | St. Jude Medical | $25 billion | Jan. |
| 2 | Thermo Fisher Scientific | Patheon | $7.2 billion | Sept. |
| 3 | Abbott | Alere | $5.8 billion | Oct. |
| 4 | Grifols | Hologic (blood screening business) | $1.85 billion | Feb. |
| 5 | PerkinElmer | Euroimmun Medical Laboratory Diagnostics | $1.3 billion | Dec. |
| 6 | LabCorp | Chiltern | $1.2 billion | Sept. |
| 7 | Konica Minolta | Ambry Genetics | $1 billion | Nov. |
| 8 | Quidel | Alere's triage MeterPro and B-type Naturietic Peptide (BNP) assay businesses | $680 million | Oct. |
| 9 | Bruker | InVivo Biotech Services | $276 million | Jan. |
| 10 | Thermo Fisher Scientific | Finesse Solutions | $220 million | Feb. |

Note: Only includes deals in which price and other financial terms were disclosed.

# EHR: Private Whistleblowers Getting in on "Meaningful Use" Crackdown

Wrongful payment of electronic health records (EHR) "meaningful use" incentives has become a growth area in federal health care fraud enforcement. (See GCA, July 10, 2017). And now private whistleblowers are getting in on the act by leveraging EHR fraud to bring suits for money damages in civil courts.

## The Government EHR Fraud Crackdown

While EHR abuse has been on the government radar for a while, 2017 proved to be a breakthrough year. In June, the OIG issued a report citing CMS for paying $729.4 million in wrongful EHR incentive payments between May 2011 and June 2014 and declaring the agency's intention to get that money back.

Just two weeks earlier, the Justice Department announced that leading EHR software vendor eClinicalWorks had settled false claims charges stemming from allegedly overstating the capabilities of its product. In addition to paying $155 million, the Massachusetts-based vendor agreed to enter into a Corporate Integrity Agreement imposing onerous restrictions.

## The Privatization of EHR Fraud Litigation

The new EHR fraud is case against over 60 Indiana hospitals unsealed on Nov. 21 breaks new ground: it is the first such case in which the government is not involved. Instead, the case was filed as a civil lawsuit by a whistleblower without any government intervention.

The other novel aspect of the $325 million *qui tam* case is the identity of the whistleblowers. A group of medical malpractice attorneys who claim they were among the victims to suffer personal harm as a result of the hospitals' alleged inclusion of inaccurate and untimely data about their medical records processing practices in their EHR meaningful use attestations. The relators claim they relied on the faulty data in bringing malpractice claims on behalf of their clients. The relators also claim that a national "release of information" provider overcharged patients for copies of their records in violation of HIPAA.

*Takeaway: On a related note, the U.S. Supreme Court has been asked to decide whether patients can bring a private lawsuit against a provider for failing to furnish timely notification that its protected health information has been breached.*

# Labs IN COURT

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

## Standing Orders Not Enough to Justify Urine Specimen Validity Testing

**Case:** A Vermont lab has agreed to pay $815K to settle false claims charges. Over a five-year period, the lab routinely billed Medicare and Medicaid for urine specimen validity testing even when not specifically ordered by referring physicians.

**Significance:** The lab's big mistake was relying on standing orders executed by physicians to perform specimen validity tests automatically. The case is the latest example of how seemingly standard ordering practices like standing orders and reflex testing leave labs vulnerable to charges of failing to comply with medical necessity criteria for each individual test ordered.

## Retired Indiana M.D.s in Hot Water for Drug Test Billing Abuses

**Case:** A husband-and-wife physician team has been charged with falsely billing the Indiana Medicaid program for over $1.1 million in urine drug tests. The government contends that from 2011 to 2013, the now retired physicians routinely required patients seeking opioid prescriptions to furnish a urine specimen to be tested for nine different classes of drugs using a multiplex screening kit costing no more than $5 per day. They then billed and were paid $171.22 per patient, getting around the $20.83 per patient limit allowed under Indiana Medicaid billing rules by falsely certifying that they had collected and tested nine separate samples.

**Significance:** As the opioid crackdown continues, physicians need to be extra scrupulous in documenting the medical necessity of the drug tests they order for patients prescribed legal opioid and painkillers.

## Heart Center Busted for Taking Illegal Consulting Fees from Lab Company

**Case:** A cardiovascular clinic in Philadelphia will pony up $50,000 for allegedly accepting kickbacks from a lab company in the form of:

- Blood collection processing, handling and collection fees; and
- Consulting fees.

**Significance:** Self-disclosure is often a wise course of action. Questionable consulting and processing fee arrangements are often a recipe for 6- and 7-figure penalties, especially when charges of both are levelled. But the relatively low penalty meted out in this case is likely attributable to the fact that the provider self-disclosed the conduct to OIG.

## Owners of NYC Testing Clinics Charged in $44 Million Fraud Scheme

**Case:** Kickbacks were just the tip of the iceberg. According to the indictment, the three co-owners of diagnostics clinics in Brooklyn not only solicited and received roughly $19 million in bribes for test referrals but compounded their sins by misrepresenting which clinic actually did the tests and using shell companies to conceal payments in violation of money laundering and tax laws.

**Significance:** Not surprisingly given the involvement of the IRS and scale of alleged inactivity, i.e., $44+ million in fraudulent claims, the Medicare Fraud Strike Force spearheaded this case.

AMC is not the first provider busted for accepting free test cups from Millennium Labs. The exact same forbidden fruit was the damnation of Parallax Center, a New York City drug addiction treatment center earlier this fall.

## Free Test Cups Yield Astronomical Liability Costs

**Case:** Accepting free point of care testing cups from Millennium Labs came back to bite a group of addiction centers (aka, AMC) right in the posterior. Something that seemed so inconsequential as a bunch of paper cups was valuable enough in the eyes of the OIG to constitute remuneration creating an improper financial relationship and turn AMC's subsequent referrals to Millennium into illegal kickbacks. While AMC doubtlessly disagreed with the OIG's theory, it opted to pay $79,880.50 to settle the case.

**Significance:** AMC is not the first provider busted for accepting free test cups from Millennium Labs. The exact same forbidden fruit was the damnation of Parallax Center, a New York City drug addiction treatment center earlier this fall. The settlement bill: $64,203. Neither case is all that big a surprise when you consider that over the years, the OIG has gone out of its way to remind labs (and other providers) that compensation need not be elaborate to establish an illegal relationship between the lab and referral source. And if the referrals are tainted, billing for the resulting claims amounts to submitting a false claim under the False Claims Act.

## Processing & Handling Fees Cross Kickback Line

**Case:** Speaking of kickbacks, a North Carolina medical clinic and its physician owner have agreed to pay $60K to settle charges of accepting illegal remuneration from labs to which it referred patients in the form of "process and handling fees."

**Significance:** Unfortunately, it is almost impossible to figure out what the physician did wrong since the OIG did not release the details of the case. But in general, paying fees to referring physicians for processing, handling and other services is an anti-kickback violation unless it qualifies for the so called "bona fide employee" exception:

- The services covered by the fee are clearly identified;
- The fee reflects fair market value for the provided services; and
- Volume or value of federal program referrals by the physician are not a factor in determining the fee amount.

## Methadone Clinic & CEO Settle Improper Urine Testing Charges for $884K

**Case:** A substance abuse clinic and its CEO settled claims of incorporating on-site testing of patients into the bundled weekly rate it charged the Connecticut Medicaid Program for all services rendered. The problem is that it was referring those tests to an independent lab in Massachusetts, meaning Medicaid was paying twice for those tests. *The settlement bill:* $883,859.

**Significance:** If you have been following these urine test cases throughout the year, you may notice that the settlement amount seems a bit high. And there's a good reason for that. The Connecticut Dept. of Services detected the "bundling" issue during an audit two years earlier. Continued non-compliance with the weekly rate payment rule would result in penalties later, the audit report warned. But the clinic apparently ignored the warning and ended up having to settle at above the usual going rate for these cases.

Judge Takes Back Ruling that Labs Must Independently Verify Medical Necessity, *from page 1*

reasoned. The ruling cites a California case (called *Garcia v. Sibelius*) stating that Medicare regulations "place the burden of establishing the medical necessity of diagnostic tests on the entity submitting the claim." But, as attorneys noted at the time, it was an apples and oranges comparison because unlike in *Groat* where the lab billed for the tests, the ordering physician was the billing entity in the *Garcia* case [*U.S. ex rel. Groat v. Boston Heart Diagnostics Corp.*].

> *"The Court is now convinced that a laboratory cannot and is not required to determine that tests billed to Medicare are medically necessary."*
>
> — Judge Reggie Walton, D.C. District Court

### The *Groat* Case: Part II (What I really meant was…)

On Dec. 11, Judge Walton took back what he said back in June—at least in part. I "overstated" that whole independent medical necessity duty of labs business, the Judge wrote. "The Court is now convinced that a laboratory cannot and is not required to determine that tests billed to Medicare are medically necessary," he said. "The OIG Guidance makes clear that 'laboratories do not and cannot treat patients or make medical necessity determinations,' but 'should be able to produce or obtain from the treating physician. . . the documentation to support the medical necessity of the service the laboratory has provided," he added.

However, Judge Walton stopped short of tossing the case. While breach of independent duty to verify was no longer in play, the whistleblower could still prove her false claims allegations by showing that Boston Heart's preprinted order forms encouraged physicians to order screening tests that were not medically necessary [*U.S. ex rel. Groat v. Boston Heart Diagnostics Corp.*].

*Takeaway: While Boston Heart is no doubt bummed that it still has to go to trial, the greater significance of Judge Walton's mea culpa and clarified ruling on medical necessity is its welcome—albeit not unexpected—relief to the lab industry, including the American Clinical Laboratory Association which actually filed an amicus curiae (friend of the court) brief asking the Judge to do what he ultimately did—reconsider the decision after re-reading the OIG Guidance.*

# LDTs: Top 10 New FDA Diagnostic Approvals of 2017

While the FDA remains glacial in its tempo, jealous of its authority and suspicious of the industry, it is also, ever so slowly, changing its ways. While the new administration's dedication to cutting regulation is an obvious factor, the current thaw actually dates back to the previous administration. And it was on full display in 2017 as illustrated by not only the pace of new *in vitro* diagnostics approvals but types of products approved. Here's our vote for the 10 most important approvals of 2017 (from a regulatory rather than strictly business perspective):

**TOP 10 NEW FDA DX APPROVALS OF 2017**

| Rank | Manufacturer(s) | Product(s) | Comment |
|---|---|---|---|
| 1 | 23andMe | Personal Genome Service Genetic Health Risk (GHR) tests for 10 diseases | First time GHR tests approved for direct-to-consumer marketing—followed 7 months later by new FDA policy on DTC marketing of GHR tests |
| 2 | Memorial Sloan Kettering Cancer Center | MSK-IMPACT NGS tumor profiling assay | First comprehensive tumor-profiling LDT to receive FDA authorization through de novo premarket review pathway |
| 3 | Merck | Keytruda (pembrolizumab) PD-1/PD-L1 inhibitor | First approval of cancer drug administered on basis of genomic features of a tumor rather than where in patient's body the tumor is |
| 4 | Thermo Fisher Scientific | Oncomine Dx Target Test, NGS-based companion diagnostic for non-small cell lung cancer for detecting multiple gene mutations (BRAF, ROS1, and EGFR) from single tissue specimen | First NGS oncology panel approved for multiple therapies |
| 5 | Illumina + Amgen | Extended RAS Panel, companion diagnostic run on Illumina's MiSeqDx system to analyze variants in KRAS and NRAS genes to determine if patients will benefit from Amgen's Vectibix (panitumumab) | Only third NGS-based companion diagnostic approved by FDA in oncology |
| 6 | Foundation One | FF1CDx companion diagnostic for solid tumors | Simultaneously approved by CMS for Medicare coverage under new Parallel Review Program |
| 7 | Roche Diagnostics | Cobas test for detecting Zika virus in plasma specimens of human blood and organ donors | First Zika detection test approved for use by blood collection facilities in screening blood supplies |
| 8 | Royal Phillips | IntelliSite Pathology Solution | First US approval of digital pathology solution for primary diagnostic use by pathology labs |
| 9 | Accelerate Diagnostics Inc. | PhenoTest BC Kit | First approval of test identifying organisms causing bloodstream infections and antibiotics to which organism is likely to respond |
| 10 | Lia Diagnostics | Lia Pregnancy Test | First FDA-cleared, flushable, biodegradable pregnancy test, according to the company |

## Disagree with Our Choices?

Let us know which new FDA diagnostic approvals of 2017 you considered to be the most significant. (glennsdemby@gmail.com)

# PAMA-geddon: Lab Industry Goes to Court to Stop 2018 Medicare Fee Schedule

With CMS refusing to back down, the lab industry has escalated the dispute and asked a U.S. District Court to step in and prevent enforcement of the 2018 PAMA-inspired Part B Clinical Lab Fee Schedule (CLFS).

## The Claims

The Dec. 11 lawsuit filed by the American Clinical Laboratory Association asserts three basic claims:

1. CMS exceeded its PAMA statutory authority to determine market prices by deliberately excluding hospital labs, which represent the vast majority of the lab market;
2. Not counting hospital labs was an unreasonable interpretation of PAMA—specifically the term "applicable laboratories"; and
3. The CMS pricing formula is "arbitrary, capricious" and an "abuse of discretion."

## What ACLA Wants the Court to Do

Rather than award money damages, the ACLA wants the court to take injunctive action to resolve the problem by:

- Barring CMS from putting the 2018 CLFS into effect; and
- Ordering CMS to obey PAMA by revising its pricing formula to include hospital labs as "applicable laboratories" for purposes of calculating market rates.