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PAMA: ACLA Loses Court Lab Fees Battle But May Still Win Regulatory War

It was a long shot to begin with. But that doesn't ease the disappointment of what happened in a Washington, DC courtroom when a federal judge tossed a lab industry lawsuit challenging the legality of CMS's new "market-based" PAMA Part B fee schedule for lab tests. Here's a rundown of the latest developments and why the new court ruling is *not* the end of hope for PAMA relief.

The Case against PAMA Lab Fees

When PAMA was adopted in 2014, the lab industry actually embraced it and the idea of basing Medicare payments for lab tests on competitive rates paid in the private market. The problem—and the thrust of the case brought by the American Clinical Laboratory Association (ACLA) on industry's behalf—is that the CMS formula for *implementing* market prices is unfaithful to the intent and spirit of the PAMA legislation.

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Medicare Reimbursement: Labs Propose Solutions to PAMA Part B Pricing Problem

CMS recently issued its annual proposed rule on 2019 Medicare Part B reimbursement. For many labs, the number one concern is the proposed extension of the controversial PAMA "market pricing" scheme to a second year. (See the related article above) Industry continues to oppose the CMS' methodology of price setting as overly narrow and wants the agency to include data from thus-far excluded labs, particularly hospital outreach labs, into the pricing calculation. Here's a look at and has proposed concrete methods to fix the problem.

1. Fixing the Hospital Outreach Lab NPI Disconnect

Some lab industry groups are asking CMS to do away with the requirement for submitting test pricing that says labs must bill Medicare under their National Provider Identifier (NPI) number. This process, they say, creates problems for the majority of hospital outreach labs that bill under the NPI number used by the *entire hospital*. According to the College of American Pathologists (CAP), hospital out-

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Specifically, PAMA directed HHS (via CMS) to gather private market payment data from a broad spectrum of labs participating in Medicare and use that data to set reimbursement rates. The problem is that CMS ended up collecting data from a miniscule percentage of the market and completely excluded higher-charging hospital labs. The result was an artificial and unfair downward skewing of prices. In the lawsuit, ACLA argued that CMS's refusal to count hospital labs in the definition of "applicable laboratories" required to report pricing data was an "unreasonable interpretation" of PAMA and "abuse of discretion" resulting in an "arbitrary and capricious" pricing formula.

What really sticks in the craw is that the judge acknowledged that the ACLA's claims that CMS mangled PAMA seemed to have merit.

A Painful Ruling

As any administrative attorney can tell you, the chances of getting a court to strike down regulations for violating the statute they're designed to implement are pretty tenuous. So, the fact that the ACLA's case, aka, ACLA v. Azar, didn't survive motion to dismiss isn't all that surprising.

What really sticks in the craw is that the judge acknowledged that the ACLA's claims that CMS mangled PAMA seemed to have merit. Her decision to dismiss was based not on the substance but a legal technicality, i.e., the court's supposed lack of jurisdiction or legal authority to rule on HHS' rate-making authority specifically stated in PAMA. We're not asking you to review rate-making but how the agency collected its rate setting data, ACLA argued. But the court didn't buy it.

The Court Case May Be Lost…

Continued legal options are few and not likely to lead to better outcomes. One option, filing a new complaint to correct the defect stated in the complaint, isn't available in this particular case, notes Seattle health attorney David Gee.

ACLA can try the appeals court. But Gee's Davis Wright Tremaine LLP partner Jordan Keville thinks the chances of winning on appeal are slim. Even if the ACLA defied the odds and won, an appeal could still take at least a year. And winning on appeal wouldn't decide the outcome on the merits—it would just send the case back to the district court with the instruction that ACLA can bring the lawsuit, Keville explains.

…But the Legislative/Regulatory Battle Continues

Another notable difference between the DAIA and TA is the latter's proposed framework for pre-market approval, provisional approval and pre-certification of tests, with a substantial portion of tests being exempt from pre-market review and other requirements.

More realistic hopes for PAMA relief come from the legislative or regulatory front, which ACLA is also pursuing, notes Gee. In July, proposed rulemaking to change the formula/calculations of the rates was issued. There was also a request for comments on new approaches to collecting data. One ap-

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proach would include more hospital labs in data gathering increasing rates. The ACLA, he notes, is in favor of using this approach, although hospital associations voiced opposition.

Keville thinks the ACLA may appeal the court case not so much in the expectation of winning the litigation but to strengthen its leverage in the regulatory battle. Winning in the district court may make HHS less willing to accept regulatory changes; but if an appeal, it might be more inclined to compromise, according to Gee.

Takeaway: Although it's a setback, the failure of the ACLA court challenge against PAMA pricing is just one prong of a wider strategy that might just provide real relief in the form of revisions to CMS regulations and even new legislation.

FDA Biological Products Agency Issues New Recommendations for Emergency Weather Response

With another hurricane season wreaking havoc, the FDA's Center for Biologics Evaluation and Research (CBER), which regulates biological products for human use, is calling on labs to pay attention to its guidelines for the storage and use of temperature-sensitive biological products that have been involved in a temporary electrical power failure or flood conditions. While most labs have emergency procedures for human safety, *product* safety can sometimes get overlooked.

Recommendations for Non-Blood Biologicals Requiring Refrigeration

- Note the time of the power outage;
- Do not open refrigerators and freezers until power is restored to keep the temperature low for a longer period of time;
- Once power is restored, record the temperature in the refrigerator or freezer as soon as possible and before the temperature begins to drop again;
- Continue recording the temperature at periodic intervals until it reaches the temperature range indicated on the product labeling as appropriate for product storage;
- Record the duration of increased temperature exposure. **Example:** Freezer temperature of 0° F at noon on day 1 when the power failed; 15° at 6 pm on day 2; and 0° at 7 am on day 3. This data enables the product manufacturer, in consultation with the FDA as necessary, to make calculations about the continued potency of the products.

Recommendations for Blood Products & Plasma Derivatives

Establishments that collect and store blood and blood components typically have written emergency response procedures. Problems or issues affecting the blood supply should be brought to the attention of the FDA. Blood establishments should contact their consumer safety officers if they need assistance with handling products impacted by power failures.

As for health facilities without emergency backup power, CBER notes that there's evidence that lyophilized coagulation products such as Factor VIII and Factor IX may be stored at room temperature for a fairly long period without loss of factor potency. If you're concerned about the exposure or efficacy of a particular product, call the supplier or manufacturer's customer service department.

Many immune globulin products are licensed for storage at 36° to 46° F, and some products may be stored at room temperature for all or part of the time before expiration. Because storage temperatures and times are specific to each product, CBER recommends following the package insert recommendations for Immune Globulin Intravenous (IGIV), intramuscular IG (IG), and subcutaneous IG (IGSC) products. Products requiring lower temperatures can be stored on wet ice. All of these products should not be frozen. If you have any questions about the storage of these products, you should consult the package inserts.

General Recommendations for Floods

The following CBER flood recommendations apply to facilities with either or both categories of biological products mentioned above:

- Elevate biological products on warehouse floors off the ground, e.g., on pallets;
- Make sure shelves containing products that must be kept dry are securely anchored;
- Elevate refrigerators used to store products above floor level using wheels, platforms or other methods;
- Discard blood components and other products that are exposed to flood waters even if they're kept in vials.

Diagnostics & Demographics: Is Your Lab Prepared to Accommodate an Aging Population?

Talk of an aging population isn't idle chatter. According to the U.S. Census Bureau, 2030 will mark a significant turning point in the nation's history. By then, all baby boomers will be older than 65. This means that one in every five residents will be retirement age. An aging population presents challenges from the standpoint of health care and related patient service issues. Is your lab prepared?

Beyond the Requirements

Although your testing lab has already addressed accessibility as required by the Americans with Disabilities Act (ADA), there are other steps you can and should take to accommodate older patients.

Here are a few places to focus:

- **Office entry.** Are the doors that lead to your facility easy to open? Even if your doors have an accessibility button, elderly patients who do

not have a disability may be reluctant to use the button. Bottom line: It shouldn't require superhuman strength to open your facility's doors.

While you're checking the doors, take note of any rugs or welcome mats that may be in or near the entry area. Do they tend to slip or roll up? If so, replace them or eliminate rugs altogether.

- **Patient check-in.** Review your patient check-in area. Is there a counter or table at or near the window where a patient can place a wallet or handbag, as he or she looks for her insurance card?

  If a patient is required to fill out forms, is it clear what information is required? Is the type size large enough, so that it's easy to read? Are the boxes large enough to enter required information? It goes without saying that you should also provide a pen and a clipboard.

- **Reception area.** What is the seating like in your reception area? Is it sturdy and comfort height? Do chairs have arms, to facilitate sitting down and getting up?

- **Sample collection areas.** What is the seating like in your sample collection areas? Here again, chairs should be sturdy and comfort height, and have arms.

  If a patient must recline, is there a sturdy stool to facilitate getting onto the examination table?

- **Communication.** When leaving phone messages, do you clearly state the purpose of your call and repeat the information? Do you always leave a callback number?

  Are bills for services performed at your lab easy to read and understand? Take a look at a patient invoice with attention to information provided. Is it clear what the charge is for? Is there a number to call with any questions?

Also look at layout and type size. A number of top companies, including Verizon, have dramatically increased the type size used on their paper bills, to make it easier for customers to read and understand the charges.

When reviewing your lab's communication practices, ask yourself if your grandmother would be comfortable receiving a phone message like the ones you typically leave, or if she could clearly understand your standard invoice. If not, make the necessary changes.

Investigative Journalist Wins Kellison Award

John Carreyrou, the Pulitzer prize-winning journalist who exposed Theranos as a fraud, was presented with the Kellison & Company Distinguished Service Award at Lab Institute. Pictured here are Mark Ziebarth, Publisher and CEO at G2 Intelligence, which put on the 36th annual Lab Institute in Washington, DC Oct. 24-16 (left); award winner Carreyrou (center); and Kevin Ellison, founder of Kellison & Company, who presented the award (right). Carreyrou, a *Wall Street Journal* reporter, wrote a series of articles poking holes in the Theranos' claims of a breakthrough on testing with fingerprick samples of blood.

Reimbursement Trends: OIG Report Shows Slight Uptick in 2017 Medicare Part B Lab Payments

On Jan. 1, 2018, the new Medicare Part B PAMA Clinical Laboratory Fee Schedule (CLFS) in which lab test reimbursements are based on a single national fee lab schedule for lab tests rather than 57 separate local fee schedules took effect. To gather baseline pricing data, the PAMA law requires the OIG to analyze Medicare payments for the top 25 lab tests under the previous system. On Sept. 25, OIG released the results for 2017, the fourth and final year of baseline data.

2017 Medicare Lab Payments by the Numbers

In 2017, CLFS payments for lab tests totaled $7.1 billion, up slightly from the $6.8 billion Medicare paid in 2016 but little changed over the entire four years of the baseline period. The table below shows where that money went.

How Medicare Spent Its $7.1 Billion for Lab Tests in 2017

Tests	Beneficiaries	Labs	Providers
433 million: total tests billed **3.4:** average number of tests received by beneficiaries per day **17:** average number of tests per day for top 1% of beneficiaries	**28 million:** beneficiaries that received at least one test 16: average number of tests per beneficiary 86: average number of tests per beneficiary among top 1% of beneficiaries	**56,859:** labs that received Medicare payments **$125,388:** average payments per lab **$1.1 billion:** payments to top 3 labs	**655,771:** providers that ordered lab tests **466:** average tests ordered per provider **5,964:** average tests ordered by top 1% of providers

Source: OIG, "Medicare Payments for Clinical Diagnostic Laboratory Tests in 2017"
* **Note:** For a comparison to 2016 data, see *NIR*, Oct. 2017, page 1

What Medicare Paid for Top 25 Lab Tests

As required by PAMA, the OIG report includes detailed analysis of the 25 most frequently ordered lab tests. While the top 25 tests always generate the lion's share of payments, that trend was even more pronounced in 2017:

Year	Total	Percentage of All CLFS Payments
2017	$4.5 billion	64%
2016	$4.3 billion	63%
2015	$4.1 billion	58%
2014	$4.2 billion	59%

Other Report findings for the top 25:

- 17 of the top 25 tests have been in the top 25 for all four years of the review;

- The top five tests accounted for $2.2 billion, or 30% of all payments for lab tests in 2017;
- The rankings of the top five tests haven't changed in four years;
- One percent of labs (272 out of 27,171 labs) received 55% of all Medicare payments for the top 25 lab tests in 2017.

How Medicare Spent Its $7.1 Billion for Lab Tests in 2017

Rank	Test Description and Procedure Code	National Limitation Amount	Number of Tests (in millions)	2017 Medicare Payments (in millions)	Changes from 2016 Payments (in millions)
1	Blood test, thyroid-stimulating hormone (TSH) (84443)	$23.05	21.5	$484	+$1.6
2	Blood test, comprehensive group of blood chemicals (80053)	$14.49	41.6	$473	+$3.0
3	Complete blood cell count (red blood cells, white blood cells, platelets) and automated differential white blood cell count (85025)	$10.66	41.5	$432	-$1.3
4	Blood test, lipids (cholesterol and triglycerides) (80061)	--	28.9	$415	+$4.4
5	Vitamin D-3 level (82306)	$40.61	8.9	$348	-$1.9
6	Drug test(s), definitive, 22 or more drug class(es), including metabolite(s) if performed (G0483)	$253.87	1.3	$307	+65.3
7	Hemoglobin A1C level (83036)	$13.32	19.7	$257	+$6.2
8	Testing for presence of drug (80307)	$79.81	3.3	$240	New code in 2017
9	Drug test(s), definitive, per day, 15-21 drug class(es), including metabolite(s) if performed (G0482)	$204.34	0.8	$162	+$35.8
10	Blood test, basic group of blood chemicals (80048)	$11.60	13.2	$130	-$3.7

Source: OIG, "Medicare Payments for Clinical Diagnostic Laboratory Tests in 2017"

Labs IN COURT

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

Alabama Hospital and Lab Subsidiary Agree to $4.25 Million Kickback Settlement

Case: Aperian Laboratory Solutions and its parent East Alabama Medical Center will fork over $4.25 million + legal costs to settle charges of paying kickbacks for referrals and then falsely billing Medicare for the ill-gotten tests. The case contends that Aperian paid percentage commissions kickbacks to a pair of nationwide marketing companies in exchange for arranging doctors to refer toxicology tests to the lab. The companies, Summit Diagnostics and Compass Laboratory Solutions, entered into separate settlements of nearly $2 million.

Significance: The case began when a former Aperian employee told his supervisors about the scheme and asked them to stop it. When those calls fell on deaf ears, he brought a qui tam whistleblower lawsuit and now stands to collect between 15% to 25% of the total recovery.

Florida MD Practices Shell Out $58.3K for Accepting Millennium Test Cup Freebies

Case: The round up of physicians that accepted free point of care test (POCT) cups from Millennium Laboratories continues with a pediatrician and internist and their respective Jacksonville practices the latest to get roped in. The now bankrupt lab used the freebies as a form of remuneration paid to physicians in exchange for referrals of custom profile panels and other tests to carry out what the feds claim is the largest ever kickback scandal involving lab services.

Significance: After collecting $256 million from Millennium, the feds have spent the past 12 months targeting the physicians on the receiving end of the POCT cup scandal. (For more on the physician crackdown, see, *GCA*, June 18, 2018). The $58,300 the Jacksonville defendants agreed to pay in this case is the second lowest of the settlements so far.

Millennium Free POCT Cup Physicians Settlement Scorecard

Date	Provider(s)	Settlement Amount	Individual Physicians Also Charged?
Sept. 6, 2018	Doctor's Inlet Pediatrics and Primary Care, P.A., and Avenues Pediatrics and Internal Medicine (Florida)	$58,370	YES
May 24, 2018	Recovery Pathways, LLC (Michigan)	$64,555	NO
April 5, 2018	Affordable Medical Care f/k/a Andalusia Medical Center (Alabama)	$40,500	YES
Feb. 28, 2018	The Pain Institute, Inc. d/b/a Space Coast Pain Institute (Florida)	$95,302	YES
Dec. 5, 2017	Addiction Medical Care of Norwalk, Practice Management Associates Norwalk, LLC, Addiction Medical Care of Columbus, and Practice Management Associates, LLC (collectively, "AMC") (Ohio)	$79,880	NO
Sept. 27, 2017	Advanced Pain Management (Arizona)	$186,210	NO
Sept. 18, 2017	Parallax Center, Inc. (New York)	$64,203	NO

Opko Health, CEO Named in Pump-and-Dump Stock Fraud Scheme

Case: The U.S. Securities Exchange Commission charged billionaire drug entrepreneur Phillip Frost and his company, Opko Health, for participating in a market manipulation scheme allegedly organized by investor Donald Honig. According to the SEC complaint, Honig and his associates planted puff pieces about three companies they controlled and then dumped their shares leaving investors the who ponied up $27 million to purchase them with grossly overvalued stock. Opko denies the charges and plans to fight it out in court.

Significance: As surely as day follows night, SEC stock fraud charges lead to private shareholder litigation. Accordingly, as many as 10 law firms are lining up to file class action lawsuits against Opko for failing to disclose the firm and Frost's role in the scheme. The market reaction to the SEC announcement forced Nasdaq to suspend trading in Opko stock for a week.

Massachusetts Lab Fined $1.374 Million for Free Test Supplies Kickback Scam

Case: A federal court ordered Calloway Laboratories, Inc. to pay $1,374,058 to settle claims of falsely billing Medicare and TRICARE for urine drug tests over a six-month period in 2014. As part of the settlement, the now defunct Woburn-Mass.-based lab admitted to offering free testing supplies to physicians in exchange for testing referrals. What would have been simply a kickback offense became a *False Claims Act* when Calloway subsequently billed Medicare and TRICARE for those tests.

Significance: The Medicare and TRICARE civil judgment is the latest chapter for a lab involved in what the Massachuesetts Attorney General described as "one of the most egregious Medicaid abuses our offices has handled." In 2013-14, Calloway's chief operating officer and three other individuals were convicted of using straw companies to funnel money bribes to employees of sober houses to generate urine drug testing referrals for patients covered by the MassHealth Medicaid program.

Jail for Urine Drug Testing Kickback Co-Conspirators

Case: Urine samples produced by patients of a Maryland-based pain clinic were a billables gold mine for a Jersey City testing lab, well worth the $1.37 million in kickbacks it ultimately paid to secure them. The lab CEO was sentenced to a year and a day in jail, ordered to forfeit $241,600 and fined $5,000. His marketing consultant and co-conspirator got three months' supervised release in home detention, a $23,400 forfeit order and a $4,000 fine.

Significance: The defendants seem to have gotten a pretty good plea deal considering the scheme. According to the court documents, the parties agreed to split the profits 50/50, with the marketer getting a 5% cut for putting the deal together. Among the three clinic defendants, one was just sentenced to eight years in jail (the extra sentence reflecting the extra crimes of tax evasion and fraudulent billing of anesthesia), one died and the other is a fugitive.

Medicare Reimbursement: Labs Propose Solutions to PAMA Part B Pricing Problem, *from page 1*

reach lab use of the hospital-wide NPI skews the reimbursement calculation to the extent it "excludes the private payment rates received by a large segment of the nation's laboratories."

2. The CMS 1450 14x Bill Type Proposal

The American Clinical Laboratory Association (ACLA) proposes that CMS replace the NPI number with a CMS 1500, a CMS 1450 form using a 14x bill type, or their electronic equivalents for hospital outreach lab data collection reporting. "This approach would account only for the hospital laboratory business that competes in the marketplace with independent clinical laboratories," the ACLA says.

3. The Weighted Median Formula Proposal

Standard charges are based on customary care and don't take into account emergency or acute situations. In other words, standard pricing assumes a best case scenario which doesn't always prove to be realistic. This puts labs in a ticklish position when actual patient charges end up being higher than the previously quoted prices. The potential result is damage to not only customer relations but the trust on which the patient relationship is based.

4. The Data Collection Expansion Approach

CAP likewise supports use of a CMS 1450 4X bill type but recommends that CMS expand its overall data collection process. In its comment letter to the proposed 2019 Part B rule, CAP "encourages CMS to explore options to collect applicable information from a randomly selected and statistically valid subset of applicable laboratories—including hospitals, large independent laboratories, small independent laboratories and physician office laboratories—and use the information reported to determine Medicare rates for subsequent data collection periods."

5. The Concern over Lowering the Reporting Threshold

Another big concern for the lab industry is CMS' proposal to reduce the "low expenditure threshold" for reporting private payor lab prices by 50%, from $12,500 to $6,250. Reducing the threshold wouldn't make a significant impact on PAMA pricing and could overburden small labs, industry experts argue.

Dissenting Opinions

Not every industry association agrees with these ideas. Thus, the American Hospital Association (AHA) and Association for Molecular Pathology (AMP) oppose both the need to capture lab test pricing data from outreach hospitals and using the CMS 1450 form, citing operational difficulties.

Next Steps

CMS is collecting feedback and hasn't indicated when it will issue a final rule. To the extent feedback does result in changes, they would pertain to the 2019 PAMA data collection period and PAMA 2020 rates.

Industry Buzz: ACA Constitutionality Is Back in Play

After a series of court setbacks, Republicans challenging the constitutionality of Obamacare, aka, the Affordable Care Act (ACA) are back at it. And this time they may win.

Beating a Dead Horse?

The issues in this new case are the same as before, namely, the constitutionality of the individual mandate and entire ACA. Six years ago, the U.S. Supreme Court upheld the individual mandate as constitutional, reasoning that the mandate plus the penalty for not having health insurance constitute a federal tax and thus a constitutional exercise of Congress's constitutional powers to tax [*National Federation of Independent Business v. Sebelius*].

But things have changed since Sebelius. On Dec. 20, 2017, Congress passed the *Tax Cuts and Jobs Act* establishing the mandate penalty at $0 starting in 2019. The new case contends that a zero penalty is *not* a tax and thus no longer supportable as an exercise of Congressional taxing powers. And since the individual mandate isn't severable from the rest of the ACA, the entire ACA should be struck down as unconstitutional.

And then there's the legal defense team. Needless to say, the Trump Justice Department is far less dedicated to defending the ACA than its predecessor. The DOJ agrees that 16 parts of the ACA should be struck down. Where it differs from the plaintiffs is in deeming two parts of the law constitutional and worth defending. But with such a lukewarm endorsement, it's hardly surprising that attorney generals from 16 states and the District of Columbia have intervened in the lawsuit to bolster the ACA's defense.

The Texas Showdown

The venue for the new case, *Texas v. United States*, is the federal district court in the Northern District of Texas. On Sept. 5, Judge Reed O'Connor held a hearing on the plaintiffs' request for a preliminary injunction (PI), i.e., court order barring enforcement of the law pending the outcome of the case. A PI would effectively freeze the ACA unless and until either an appeals court overturned it or the court ultimately ruled on the merits in favor of the law's constitutionality.

The good news for ACA advocates is that getting a court to issue a PI is a pretty stiff task. To pull it off, the plaintiffs must prove four things:

1. They'll likely to succeed on the merits of the case;
2. They'll likely suffer "irreparable harm" if the PI isn't granted;
3. The balance of equities favors their argument;
4. Granting the PI is in the public interest.

What's At Stake

Obviously, there's a lot on the line in both the short- and long-term:

Short-Term: If the PI is granted, it would create a hot mess in insurance markets. The DOJ itself noted that a preliminary injunction could introduce

"chaos in the insurance markets" and asked the court to limit any declaratory ruling to the constitutionality of the individual mandate beginning in 2019. The DOJ also noted the need for additional briefing on the timing and impact of an injunction on state insurance markets, as well as the need to potentially issue new regulations and address the multi-year process by which insurers must get their products approved for sale.

Long-Term: Invalidating the entire ACA would adversely impact:

- Protections for people with pre-existing conditions;
- ACA Medicaid expansion;
- Children under 26 who get insurance through their parents' plan;
- Annual and lifetime coverage limits; and
- Caps on out-of-pocket expenses.

Accordingly, the DOJ has asked the court to defer any ruling on severability, i.e., whether invalidation of the mandate takes down the entire ACA, until 2019 after the close of the next open enrollment period and mid-term elections.

More to Come

Don't expect any immediate resolutions one way or the other. No matter how the court rules, an immediate appeal to the Fifth Circuit of Appeal is all but assured. And no matter how the Fifth Circuit ruled, the U.S. Supreme Court will be asked to intervene—although there's no guarantee it'll accept the case.