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Post-PAMA: Government Report Warns of Medicare Overspending(!) for Lab Tests

As if the deep price cuts inflicted by PAMA weren't infuriating enough, now the US Government Accountability Office (GAO) is claiming that labs may be getting overpaid. In a report issued late November, the GAO warns that the new PAMA rates could lead to the government paying billions in excess Medicare reimbursements to laboratories through 2020.

Who's the Victim?

The new PAMA market-based rates that took effect for the first time in 2018 resulted in a $670 million "savings" in lab revenue, according to the CMS's own numbers. Of course, one party's savings is the other's loss—in this case, a highly unfair one. Hence the continuing ACLA lawsuit challenging not the PAMA legislation but how CMS implemented it.

But while the lab industry saw huge losses due to PAMA, GAO contends that it's the government that's getting the raw end of the deal from PAMA implementation. The new report claims the government is paying more than it should for lab tests.

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LDTs: FDA Announces New Approach to 510(k) Approvals

Last month, the FDA floated a plan to overhaul and modernize the 510(k) premarket review pathway allowing for faster, safer approval of medical devices, including diagnostics. Here's a quick recap.

The 510(k) Pathway & the Need to Modernize

Device and diagnostics manufacturers can use the 510(k) pathway to get expedited approval for new products that they can show are substantially equivalent to products that were grandfathered in when Congress created the pathway in 1976. *Translation:* Technology that's 40 or more years old is being used as the standard for letting new products into the market.

There's a perception that we've gone too far in stretching what's "equivalent," and that new 510(k) approvals should be compared to

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Post-PAMA: Government Report Warns of Medicare Overspending(!) for Lab Tests, *from page 1*

The Reporting Labs Issue

Ironically, the reason the GAO cites for the perceived problem, i.e., insufficient number of labs submitting data for use in calculating PAMA CLFS rates, is the same argument industry has used to claim it's being underpaid.

But according to GAO, the problem wasn't in the determination of which labs to count but the failure of labs that were counted to report their required data. GAO says that incomplete data could have a larger effect on the accuracy of Medicare payment rates in future years when PAMA allows for greater payment rate reductions.

The Bundled Payment Issue

The GAO also notes that after PAMA took effect, CMS stopped paying a bundled payment rate for certain panel tests because its authority to do so under the law was unclear. GAO estimates that if reimbursement for panel tests were to remain unbundled and CMS had to continue to pay for each test individually, Medicare expenditures could increase an additional $10.3 billion from 2018 through 2020 compared to estimated Medicare expenditures using lower bundled Medicare rates.

The National Limitations Amounts Issue

The GAO contends that CMS used the 2017 national limitation amounts, or the maximum Medicare payment rates, as a baseline to start rate reductions instead of actual Medicare rates. In some cases, this resulted in Medicare paying higher rates than it had previously paid on average.

Last but not least, the report cites errors in data collection.

What Happens Now?

The GAO recommends that CMS take additional steps to safeguard Medicare funds, including:

- Collecting all data from labs required to report;
- Ensuring that the data collected was accurate;
- Using bundled rates for panel tests and, if necessary, seeking clear legislative authority to do so; and
- Phasing in payment rate reductions based on actual payment rates paid by Medicare prior to 2018 rather than national limitation amounts.

Reaction

HHS agrees that more complete, accurate data is needed, but has indicated neither agreement nor disagreement with the GAO's other recommendations.

Meanwhile, the lab industry agrees that CMS' data collection was incomplete and flawed but not the conclusion of the GAO report. "The report is a clear acknowledgment that CMS dropped the ball on data collection and failed to get market representative data as part of the reporting requirements under PAMA," notes Julie Khani, president of ACLA. But, she adds, the "suggestion that laboratories are receiving substantial excess payments from Medicare misses the mark and fails to reflect the market reality."

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Phone: 1-888-729-2315
Fax: 1-855-649-1623
Web site: www.G2Intelligence.com.

Enforcement Trends: Opioid Crackdown Is Diverting Resources from Traditional OIG Enforcement Activities

The OIG won't admit it, but the opioid crackdown is diverting resources from traditional Medicare fraud and waste enforcement efforts. At least that's the most likely explanation for the dramatic decline across all enforcement metrics documented in the agency's most recent semiannual report for April to September 2018. This is both a continuation and acceleration of a trend that began last year.

OIG Enforcement By the Numbers Year Over Year (April through September)

Metric	2018	2017
Expected investigative recoveries	$3.43 billion	$4.13 billion
Criminal actions against individuals or entities relating to HHS programs	764	881
Civil actions	813	826
Exclusions of individuals and entities	2,712	3,244

Labs Figure Prominently in OIG's Newest Top 10 Challenges List

Although the OIG has its flaws, lack of transparency isn't among them. Exhibit A: the agency's ongoing list of top 10 management and performance challenges facing the Department of Health and Human Services in the coming year.

Historically, the items change little over the years with maintaining Medicare and Medicaid program integrity topping the list. while not expressly spelled out, we all know that "program integrity" is code for billing and payment of lab and diagnostic services, among other things.

But the newest list features a new number one: Curbing the opioid epidemic. Here's the entire Top 10:

Top 10 HHS Management & Performance Challenges

1. Curb Opioid Epidemic
2. Ensure Medicare Program Integrity
3. Ensure Medicaid Program Integrity
4. Ensure Integrity in Managed Care and Other Programs Delivered via Private Insurers
5. Protect Health and Safety of Vulnerable Populations
6. Protect Integrity of Public HHS Grants
7. Improve Financial and Administrative Management and Reduce Improper Payments
8. Ensure Safety of Food, Drugs and Medical Devices
9. Ensure Program Integrity and Quality in American Indian and Alaska Native Populations Programs
10. Protect HHS Data, Systems and Beneficiaries from Cyber Threats

FDA Watch: Agency Approves New Flu Tests and Drug

As the flu season begins, the FDA has issued significant approvals of new products for diagnosing and treating the disease.

New Flu Assays

On October 24, Abbott announced that the FDA has granted CLIA waivers for its next-generation Influenza A & B 2 and Strep A 2 molecular assays for point-of-care testing. The new assays enable the fastest ever time-to-results, Abbott claims. The enhanced Influenza A & B 2 assay offers point-of-care molecular detection and differentiation of influenza A and B virus in 13 minutes or less, with early call out of positive results in as little as five minutes. It also allows for room temperature storage of all test components, simplifying and streamlining test ordering and storage.

The Strep A 2 provides molecular detection of Group A Streptococcus bacterial nucleic acid, the primary cause of bacterial pharyngitis (sore throat), in six minutes or less, with call out of positive results as early as two minutes with no culture confirmation required for negative results. The new assays are available in a broad range of outpatient and inpatient settings where patients are increasingly accessing healthcare services, including emergency rooms, physician offices, walk-in clinics and urgent care centers.

First New Flu Treatment Drug in 20 Years

The FDA also approved Roche Group member Genentech's Xofluza (baloxavir marboxil) for the treatment of acute uncomplicated flu influenza in patients 12 years of age and older who've been symptomatic for no more than 48 hours. This is the first new antiviral flu treatment with a novel mechanism of action approved by the FDA in nearly 20 years, noted FDA Commissioner Scott Gottlieb, M.D. He cautions, however, that antiviral drugs to treat flu are no substitute for yearly vaccination.

The CDC currently recommends three antiviral drugs to treat the flu:

- Tamiflu (oseltamivir) (Roche);
- Relenza (zanamivir) (GlaxoSmithKline); and
- Rapivab (peramivir) (BioCryst).

Last year's severe flu season saw increased demand and spotty shortages of Tamiflu.

New Laws: Proposed Federal Legislation Would Allow Medicare Payment for Genetic Counselling

A new bill introduced in the U.S. House of Representatives in October calls for CMS to recognize certified genetic counselors as healthcare providers. Here's a quick overview of the bill and why it matters.

What Does It Do?

Under current Medicare rules, genetic counseling is a covered benefit but genetic counsellors can't be reimbursed for providing such services. As a result,

Medicare beneficiaries have limited access to counselling. H.R. 7803: *Access to Genetic Counselor Services Act of 2018* is designed to fix that problem by allowing genetic counselors to receive payment for services.

Why Now?

The proposed legislation, developed in collaboration with the National Society of Genetic Counselors (NSGC), comes at a time when consumer interest in and access to genetic testing continues to grow and genetic testing plays a greater role in medical care.

What Are Genetic Counselors?

Genetic counselors are key providers of services to consumers. According to NSGC, certified genetic counselors "bring expertise to the healthcare team by guiding and supporting patients seeking more information about how inherited diseases and conditions might affect them or their families, and to interpret test results."

The bill defines "genetic counselor" as "licensed as a genetic counselor by the state in which the individual furnishes genetic counseling services or in the case of an individual practicing in a state that does not license genetic counselors, meets such other criteria as the [HHS] Secretary establishes."

What's the Impact?

According to NSGC, passage of the bill would improve the overall health system. "Lack of access [to genetic counselors] can result in harm such as incorrect interpretations of genetic rest results, failure to identify individuals' genetic risk, and inaccurate risk assessment leading to inappropriate medical management and sometimes death."

In addition, NSGC cites financial benefits, indicating that the legislation "will also help lower healthcare costs by shifting genetic counseling services sometimes administered by physicians and nurse practitioners to genetic counseling experts, who can ensure the appropriate use of genetic testing."

So, stay tuned and *NIR* will keep you apprised on the bill's progress.

Industry Buzz: Obamacare Repeal Sends Tremors through Insurance Markets

What came as a Christmas gift to many Republicans may be a lump of coal in the stocking of many others. On Dec. 14, a federal judge in Texas ruled that the entire *Affordable Care Act* (aka, Obamacare), is unconstitutional. While a group of attorneys general from Democratic states are promising to appeal the decision, the new more conservative make up of the Supreme Court makes ACA's ultimate fate less then certain.

Background

Six years ago, the U.S. Supreme Court in *NFIB v. Sebelius* upheld Obamacare stating that, because the mandate with the penalty could be considered a federal tax, it was a constitutional exercise of the U.S. Congress's powers.

Then, when the Republicans came into power in Washington, they lowered the penalty for not having health insurance to $0 beginning in 2019.

The plaintiffs in *Texas v. United States* argue ACA in its entirety should now be thrown out because:

- Since *Sebelius* upheld the individual mandate as constitutional because, with the penalty, it could be considered a tax, zeroing out of the penalty to $0 in 2019 makes the mandate unconstitutional.
- Since the individual mandate is not severable from the rest of the law, the entire ACA should be invalidated.

The judge in *Texas*, Judge Reed O'Connor of the Federal District Court in Fort Worth agreed, and declared the individual mandate unconstitutional and all the remaining provisions of ACA invalid.

So What Happens Now?

A group of Democratic attorney generals are promising to repeal the decision to the Fifth Circuit court of appeals, a circuit known for leaning conservative, so Judge O'Connor's decision is likely to be upheld. From there the case is likely to ultimately going to the Supreme Court, which previously upheld ACA as constitutional. The new more conservative make-up of the court, since Justice Brett Kavanaugh has been seated, however, could mean that ACA could ultimately wind up on the ash heap of history.

Pending the appeal of the case, the law remains in effect, so everything remains the same as the case winds it's way through the courts.

If the law is ultimately found to be unconstitutional, and the entire ACA is declared invalid the following will be impacted:

- Protections for people with pre-existing conditions.
- ACA Medicaid expansion.
- Requirements for employers to provide health insurance.
- Insurance for children under 26 who get insurance through their parents' plans.
- Annual and lifetime limits on coverage will again be permitted.
- Caps on out-of-pocket expenses can be eliminated.
- Insurers can again charge more based on age, gender and profession.
- Non-insurance-related ACA provisions such as: Closing of the Medicare drug donut hole, Creation of the Center for Medicare and Medicaid Innovation, and Restaurant menu labeling.

Future Democratic speaker of the House, Nancy Pelosi, vowed that when Democrats take control of Congress next month it would "move swiftly to formally intervene in the appeals process to uphold the lifesaving protections for people with pre-existing conditions and reject Republicans' effort to destroy the Affordable Care Act." Given that the US Senate and presidency are in Republican hands, however, it's unlikely that anything can be accomplished legislatively to maintain the ACA.

Medicare Reimbursement: ACLA Court Appeal Maintains 2-Front War for PAMA Relief

It's official. The ACLA is appealing the September federal court decision to dismiss its PAMA lawsuit (*ACLA v. Azar*). Here's a quick rundown of the three things you need to know.

1. The Legal Argument

The ACLA contends that HHS' methods of implementing the PAMA market-based lab reimbursement exceeded its authority under the statute and defeated Congress's intent to establish real market rates for lab tests. The district court dismissed the claim citing the part of PAMA that exempts HHS—via CMS' determinations of lab payment rates from legal challenge. The ACLA argues that the heart of the case isn't so much about how HHS used the pricing data but collected it and that the district court was wrong to intertwine data collection with rate setting.

2. The Chances of Success

The ACLA has a roughly 50/50 shot at winning the appeal, says Jordan Keville of Davis Wright Tremaine LLP. Appeals courts generally give lower courts wide discretion to rule on the facts. But because this appeal turns on interpretation of the PAMA law, the normal deference rules don't apply. According to Keville, ACLA has a viable argument that Congress didn't intend to exempt CMS' data collection under PAMA from review because the exemption language refers only to rate-setting. Conversely, government agencies are typically entitled to some level of deference in interpreting the statutes they're charged with administering.

3. What's Really Going On

ACLA may be pursuing a two-prong strategy based on the recognition that negotiation rather than litigation represents the most likely source of PAMA relief. Continuing the lawsuit keeps up the pressure on CMS and increases the industry's leverage in the negotiations over PAMA changes. And in case negotiation does fail, the lawsuit and chance to secure a favorable court ruling gives the industry another avenue for PAMA relief.

Correction: PAMA Relief

The original version of an article posted on our website last month, "Medicare Reimbursement: 2019 CLFS Offers Some PAMA Relief But Not Nearly Enough" contains two errors that we'd like to correct.

1. Rejection of 14X TOB Inclusion

The piece says that CMS rejected the ACLA's recommendation to include hospital outreach labs that use the Form CMS-1450 14x TOB to bill for non-patient lab services in the definition of "applicable laboratories." The Final Rule actually does incorporate the recommendation. Accordingly, labs using the Form CMS-1450 14x TOB will count as "applicable" labs for the next data collection (Jan. 1, 2019 thru June 30, 2019) and data reporting (Jan. 1, 2020 thru March 30, 2020) periods, provided they get an NPI and meet the other regulatory requirements like the regulatory low expenditure threshold.

2. Wrong Legislation

While the description of CMS's efforts to remain true to intent of the legislation" in the subsection on industry's response to the Final Rule is correct, the referenced legislation should have been PAMA, not the *Affordable Care Act*.

G2 would like to apologize for the errors and thank the user who pointed them out to us.

Labs IN COURT

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

Owner of MD Practices Settles Fraud Charges for $3.07 Million

Case: Individual physicians implicated in frauds committed by the practices and clinics they own is this month's predominant theme. Leading off is the MD owner of a pair of medical practices in Delaware and Maryland doing business as Got-A-Doc Walk-In for alleged false billing of Medicare and Medicaid for lab services, including services:

- Not medically necessary;
- Not performed by an eligible provider;
- Not provided at all; and
- Not properly documented.

Significance: As part of the settlement, the doctor has agreed to surrender his medical licenses. And the doctor's misery is just beginning insofar as the settlement covers only the civil charges and not his potential criminal liability stemming from the scheme.

Pain Clinic Co-Owner Pleads Guilty to Drug Testing Kickback Charges

Case: The Louisiana physician received $336,000 in kickbacks from a drug testing lab representing a percentage of the reimbursement proceeds generated via the referrals of Medicare patients' urine samples for testing over a two-year period. He'll be sentenced in March.

Significance: The other physician co-owner of Louisiana Spine & Sports LLC was indicted last year for his part in an alleged $4.4 million false billing scheme involving medically unnecessary quantitative urinalysis tests and billing for minor surgical procedures performed on days before or after patient visits.

New York Doctor Busted for Falsely Billing Medicaid for Lab Drug Tests

Case: The State claims that the physician billed for $939,000 worth of drug testing services that his lab didn't and couldn't actually provide. For example, instead of charging for a single test on a patient, he charged for 11 nonexistent tests. Other alleged offenses include performing medically unnecessary services and operating the lab without a director.

Significance: This case is typical of the current pattern of health care fraud enforcement—focus on drugs and drug testing and sweep in all related charges, in this case violating federal and state requirements that labs employ a director to oversee operations.

North Carolina Hospital Settles Self-Disclosed Kickback Claims for $2.2+ Million

Case: Rex Hospital, Inc. d/b/a UNC Rex Healthcare, agreed to shell out $2,277,762 for kickbacks violations stemming from its deal to lease a doctor from a community hospital to provide cardiology services. In addition to paying the community hospital a market-based fee for the lease, the OIG contends Rex paid kickbacks by also paying the physician's salary and bonuses for the cardiology services provided, reimbursements that should have been made by the community hospital.

Significance: The price of the settlement appears relatively high, especially when you consider that Rex self-disclosed to the OIG.

10x Genomics Ordered to Pay $23.9 Million for Infringing Bio-Rad's Patents

Case: The Federal District Court jury found that 10x willfully infringed three genetic analysis technology patents that Bio-Rad licensed from the University of Chicago on an exclusive basis. Specifically, the jury concluded that all single-cell and linked-read genomics products sold by 10x, including GemCode Long Read, Chromium Genome/Exome and Chromium Single Cell 3 willfully infringed the patented technology.

Significance: The court case is just one front in the IP war between the firms. 10x has filed a complaint with the International Trade Commission accusing Bio-Rad of illegally importing microfluidic systems violating its own patents into the US for sale. 10x also issued a statement expressing its strong disagreement with the court verdict and its intention to appeal.

LDTs: FDA Announces New Approach to 510(k) Approvals, *from page 1*

the benefits and risks of modern technology, notes Philadelphia attorney Janice Hogan who represents companies in the 510(k) process.

The New Proposal

The FDA recognizes the problem and has taken steps to address it. In April 2018, the agency suggested that substantial equivalency of new products be evaluated based on objective performance criteria rather than predicate devices. The November guidance advances that objective via establishment of an alternative 510(k) pathway (to be called the "Safety and Performance Based Pathway") that allows manufacturers of certain-well-understood device types to rely on objective safety and performance criteria to demonstrate substantial equivalence.

The proposal also calls for modernization via embarrassment via publication of manufacturers and products relying on predicate technology over 10 years old.

Impact on the Lab Industry

Hogan suggests that the new rules will have less impact on diagnostics than therapeutics given the former's current reliance on newer predicates. What's more, adds Hogan, 510(k) may become moot for diagnostics if some version of the *Diagnostic Accuracy and Innovation Act* (DAIA) (see *NIR*, September, 2018) is passed. *Explanation:* DAIA would establish a new pathway for diagnostic tests instead of continuing to include them in the definition of a medical device within the scope of the 510(k) process.

Although it has bi-partisan support, Hogan cautions that DAIA is far from being a done deal. And unless and until it passes, new diagnostics will still have to go through the 510(k) process reach the market.

Industry Trends: Continued Momentum for Lab-Retail Collaboration

The Theranos debacle hasn't dissuaded retailers from partnering with labs. Here's a rundown of some recent deals.

LabCorp & Walgreens

In fact, Walgreens, Theranos's ex-retail partner, has moved on and entered into an agreement with another blood-testing firm. But instead of an unproven start-up, the nation's second-largest pharmacy store has gone with a known entity, LabCorp.

Walgreens recently announced that it will open 600 blood-testing sites in its drugstores over the next four years, inclusive of the 17 locations that have opened since the initiative launched in June 2017.

Quest & Walmart

Walgreens is hardly the only giant retailer to offer lab services. Last year, Walmart entered into an agreement with Quest Diagnostics to bring co-branded lab drug testing services to 15 Walmart in-store pharmacy locations in Florida and Texas.

Quest & Albertsons

Quest also has a retail collaboration with Albertsons, the parent company of supermarket chains Randalls, Safeway, Tom Thumb and Vons. As of Dec. 1, there were Quest Diagnostic Patient Service Centers at 183 Albertsons locations in 11 states. Each Quest Diagnostic Patient Service Center has its own entrance inside the store, frosted privacy windows, a customer waiting area and a private restroom for patients' use. Walk-ins are welcome, but scheduled patients get priority.

CVS & MinuteClinic

The largest pharmacy healthcare provider in the country, CVS also offers lab testing. However, these services are part of larger offerings through its MinuteClinic; lab testing is only available in conjunction with a standard service.

MinuteClinic, originally founded in 2000 as QuickMedx, was the first "retail clinic" in the US. Today, it's a full-blown division of CVS operating more than 1,000 in-store clinics across 32 states and the District of Columbia.

MinuteClinic offers in-clinic and send-out labs and tests. In-clinic labs and tests include A1C, Adeno test, blood sugar test, flu test influenza A & B, lipid panel, mono test, pregnancy test, strep test, and urine dip stick. Send-out labs and tests include follow-up strep test and urine culture.

Why Go There?

On the surface, offering lab testing services in retail environments may seem odd. But it's part of a larger trend to offer customers and patients greater convenience.

The arrangement also provides a new source of revenue for large clinical lab operators and retailers. In addition, it's a way for retailers to differentiate themselves from the competition.

At the same time, it is indicative of a shift in focus in the healthcare market—a shift that has created what would have previously been considered unusual, if not highly questionable, partnerships. CVS's $69 billion acquisition of health insurer Aetna, which closed in late November, is an example of this.

As the healthcare market continues to evolve, look for more partnerships with the potential to impact the lab industry.

Genetic Testing: 23andMe Gets FDA Clearance for Direct-to-Consumer Marketing of Personal Genome Service

The FDA is allowing direct-to-consumer marketing, with special controls, of the 23andMe Personal Genome Service Pharmacogenetic Reports test for genetic variants to detect 33 variants for multiple genes associated with a patient's ability to metabolize certain medications to help inform discussions with a healthcare provider. The announcement was made Oct. 31.

"This test is a step forward in making information about genetic variants available directly to consumers and better inform their discussion with the healthcare providers."

— Tim Stenzel

About the Test

Pharmacogenetics is the process of understanding what role, if any, genetics plays in a patient's reaction to drugs. The Personal Genome Service test analyzes DNA from a self-collected saliva sample and generates a report describing if a person has variants in certain genes that may be associated with a patient's ability to metabolize some medicines.

The 23andMe Personal Genome Service Pharmacogenetic Reports test isn't intended to provide information on a patient's ability to respond to any specific medication. The test doesn't describe an association between the detected variants and any specific drug nor whether a person will or will not respond to a particular drug. Furthermore, healthcare providers shouldn't use the test to make any treatment decisions. Results from this test should be confirmed with independent pharmacogenetic testing before making any medical decisions.

The FDA's Reasoning

"This test is a step forward in making information about genetic variants available directly to consumers and better inform their discussion with the healthcare providers," noted Tim Stenzel, director of the Office of In Vitro Diagnostics and Radiological Health in the FDA's Center for Devices and Radiological Health. "We know that consumers are increasingly interested in genetic information to help make decisions about their health care."

At the same time, Stenzel expressed caution regarding the test's use. "This test should be used appropriately because it does not determine whether a medication is appropriate for a patient, does not provide medical advice, and does not diagnose any health conditions. Consumers should not use this test to make treatment decisions on their own," he said. "Any medical decisions should be made only after discussing the results with a licensed health care provider and results have been confirmed using clinical pharmacogenetic testing."

The Review Process

The FDA's review of the test determined, among other things, that the company provided data to show that the test is accurate (i.e., can correctly identify the genetic variants in saliva samples) and that it can provide reproducible results. The company submitted data on user comprehension studies that demonstrated that the test instructions and reports were understood by consumers. The test report provides information describing what the results might mean, what the test does not do, and how to interpret results.

The Special Controls

The FDA reviewed data for the test through the de novo premarket review pathway, a regulatory pathway for novel, low-to-moderate-risk devices that are not substantially equivalent to an already legally marketed device. Along with its authorization, the FDA is establishing criteria, called special controls, which set forth the agency's expectations in assuring the test's accuracy, clinical performance, and labeling. For this category of device, the FDA established six special controls, including a labeling requirement that a warning statement must be included noting that the consumer should not use the test results to stop or change any medication. These special controls, when met along with general controls, provide reasonable assurance of safety and effectiveness for this test.