



NATIONAL INTELLIGENCE REPORT™

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Enforcement Trends: Labs Get Cameo, Rather than Starring Role in OIG's New Enforcement Report

The Office of Inspector General just published its Semiannual Report to Congress (covering Oct. 1, 2016 through March 31, 2017). It's mostly more of the same other than the fact that, for once, laboratories were not the focal point of the enforcement sections. Here's a quick overview of the key compliance takeaways.

1. Improper Payments

Improper payments continued their steady creep up totaling \$96+ billion in FY 2016, which included a reported:

- ▶ \$284.1 million and \$10.6 million in Express Lane payments to potentially ineligible Medicaid and Children's Health Insurance Program beneficiaries, respectively; and
- ▶ Over \$26 million in payments to dead Medicare and Medicaid beneficiaries.

Continued on page 2

Reimbursement Trends: 5 More New Molecular Tests Get the Medicare Green Light from Palmetto

Normally among the slowest payors to accept promising but unproven new tests, Medicare continues to loosen the reins for molecular assays. In May, Palmetto GBA (Columbia, SC), one of Medicare's most important contractors, issued favorable—albeit limited—draft local coverage determinations (LCDs) for five significant new molecular tests. Here are the details you need to be aware of.

1. Limited Coverage of Liquid Biopsy Test for Advanced Lung Cancer Test: Guardant360, Guardant Health's comprehensive liquid biopsy assay for lung cancer.

Proposed Coverage: Guardant360, which came onto the market in 2014 and is now widely ordered, would be covered only for patients with advanced non-small cell lung cancer, that is, stage IIIB or higher. Conditions would vary depending on treatment stage:

Continued on page 10

■ Labs Get Cameo, Rather than Starring Role in OIG's New Enforcement Report, *from page 1*

Improper payments for services that shouldn't have been billed:

- ▶ \$358.8 million of the total \$438.1 million paid by Medicare for chiropractic (82 percent) were for unallowable services;
- ▶ At least \$176 million in Medicaid payments to State Agencies for room and board costs under the HCBS Waiver Program; and
- ▶ \$2.7 million for hearing aid devices replaced without cost to the hospital or beneficiary.

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2. Problem Areas

The Report cites a pair of vulnerabilities and misaligned incentives that the OIG focused on during the period:

- ▶ The 2-midnight policy for determining inpatient/outpatient status for Medicare hospital billing; and
- ▶ The tripling of Part D catastrophic coverage spending, much of which attributable to new high-price drugs.

3. Enforcement Activities

Key enforcement numbers for the first half of FY 2017:

- ▶ \$2.04 billion in total recoveries;
- ▶ 468 criminal actions;
- ▶ 461 civil actions; and
- ▶ 1,422 exclusions.

Key areas of enforcement cited in the Report included prescription drugs, care in non-institutional settings and grant fraud. Laboratories did not make the list.

4. Enforcement against Labs

Medical device and pharmaceutical companies are getting a lot of the attention that the OIG used to concentrate on labs. Even so, labs continue to figure prominently in OIG enforcement activities. Several of the biggest cases cited in the Report involve labs, including:

- ▶ The \$6.1 million paid by Pharmasan Labs, NeuroScience and founder Gottfried Kellermann to settle claims of falsely billing Medicare for urinary transmitter testing, including via the use of "shift factor" measurement methods not properly validated under CLIA rules; and
- ▶ The \$1.3 million settlement by New Jersey-based MedNet for allegedly using "fee-for-service" and "direct-bill" agreements to pay hospitals and physicians for Medicare referrals.

Takeaway: For labs, the most important thing about the new OIG Semiannual Report is the relative lack of attention paid, at least compared to previous years. Although labs remain fixed on the OIG radar, the agency seems to be focusing more than ever on drugs, devices and state agencies. 

Electronic Health Records: The eClinicalWorks False Claims Settlement—Big Fines & Unprecedented CIA Obligations

False Claims Act actions targeting health care vendors have become more common. eClinicalWorks (ECW), one country's biggest electronic health records software vendors, learned that lesson the hard way on May 31 when it agreed to pay \$155 million to settle charges of misrepresenting the capabilities of its EHR software.

EHR Certification, 101

Starting in 2009, providers can qualify for HHS incentive payments by demonstrating their “meaningful use” of EHR technology—not just any EHR technology, but certified EHR technology. Naturally, all of this gives EHR vendors incentive to get their products certified. To do that, the vendor must:

- ▶ Attest that the product meets HHS EHR criteria; and
- ▶ Pass testing by an independent, HHS-approved certifying entity.

The damages are only part of the story. Arguably, the most significant and groundbreaking aspect of the settlement is the Corporate Integrity Agreement.

The ECW Case

The Justice Department claims that ECW's cheated its way to certification by not telling the certifying entity that its EHR software didn't meet certain HHS criteria with regard to accurate recording of user actions in audit logs, drug interaction checking and data portability. To further the deception, ECW allegedly used “hardcoding” to modify its software for certification testing to ensure it would pass the test.

Result: The software was falsely certified. And because of that, provider claims for “meaningful use” incentives based on ECW's EHR software constituted false claims for which ECW was responsible.

Although it denied the claims, ECW decided that settlement was the wise course. At \$154.92 million, the settlement is the largest False Claims Act recovery in the District of Vermont and may even be the largest financial recovery in the history of the State of Vermont, according to the DOJ press release. Here is how the bill will be divvied up:

- ▶ Three of ECW's founding members, including its CEO and medical director will be jointly and severally liable for all \$154.92 million;
- ▶ One of the software developers will pay a separate \$50,000 out of his own pocket; and
- ▶ Two of the software's project managers will pay \$15,000 apiece.

The Corporate Integrity Agreement

The damages are only part of the story. Arguably, the most significant and groundbreaking aspect of the settlement is the Corporate Integrity Agreement. Five-year CIAs are par for the course in settlements of these cases. But the ECW includes some innovative elements designed to clean up the mess and ensure it does not happen again, including ECW's obligation to:

- ▶ Retain an Independent Software Quality Oversight Organization to assess the firm’s software quality control systems and issue written semi-annual reports to the OIG;
- ▶ Provide prompt notice to its customers of any patient safety issues that may result from not telling the truth about its EHR software;
- ▶ Maintain a comprehensive list of such safety issues and steps mitigate them on its customer portal;
- ▶ Offer customers updated versions of the EHR software free of charge;
- ▶ Offer customers the option of having ECW transfer their data to another EHR software vendor without penalties or service charges; and
- ▶ Retain an Independent Review Organization to ensure that its provider arrangements comply with the Anti-Kickback Statute.

[For more details about the ECW case, see *United States ex rel. Delaney v. eClinicalWorks LLC*, 2:15-CV-00095-WKS (D. Vt.)] 

Compliance Scorecard: Significant New HIPAA Fines

Health data and information security figured prominently in May enforcement activity. In addition to the blockbuster eClinicalWorks EHR software settlement discussed on page 3, there was an unusually high volume of HIPAA enforcement action. Here is a Scorecard summary of three big HIPAA cases that were reported in May.

DATE	PROVIDER	ENFORCEMENT ACTION	ALLEGED VIOLATION(S)
May 10	Memorial Hermann Health System (Texas, non-profit system comprised of 16 hospitals)	\$2.4 million settlement and agreement to implement Corrective Action Plan	Disclosed a patient's PHI without authorization to another patient who presented a fraudulent ID card to office staff and then compounded problem by issuing press release about incident that lists the victim's name
May 30	St. Luke's-Roosevelt Hospital Center (part of Mount Sinai Health System in New York)	\$387,200 settlement and agreement to implement Corrective Action Plan	Staff member improperly faxed HIV status, sexual orientation, mental health diagnosis, physical abuse, sexually transmitted disease and other PHI about a patient to his employer rather than sending it to requested personal post office box. Center should have been on guard especially since there had been previous incidents involving staff
May 31	Former employee of Tufts Health Plan (Boston area)	Three months in prison, three years of supervised release and \$52,000 in restitution payments	Stole names, birth dates, Social Security numbers and other PHI of over 8,700 customers, most of them over age 65, as part of a scheme involving filing of false income tax returns to claim tax refunds and Social Security benefits

New Reports: FDA Making Progress on Speeding Approvals; and If You Think the FDA Is Slow, Try Europe

The U.S. Food and Drug Administration (FDA) has been chronically plagued with understaffing, an ever expanding workload and criticism over how long the agency takes to issue approvals. And the new President has created a new woe: the threat of deep budget cuts. So far, the agency has been able to deflect the chopping block. And recent reports suggesting improvements in times required for drug and medical device approvals provide more welcome news—not just for the agency but the entire life sciences industry.

The authors say the speed of the U.S. regulatory review process will likely face scrutiny again as Congress debates reauthorization of the Prescription Drug User Fee Act, which is set to expire this October.

Drug Approvals

A [correspondence](#) published on April 6 in the *New England Journal of Medicine* adds some welcome context to the FDA's long lead times for approvals by comparing them to the situation in Europe. According to the correspondence, for new therapeutic agents that were approved between 2011 and 2015, the regulatory reviews by the FDA were, on average, 60 days shorter than those by the European Medicines Agency (EMA),

The authors say the speed of the U.S. regulatory review process will likely face scrutiny again as Congress debates reauthorization of the Prescription Drug User Fee Act, which is set to expire this October. To inform this debate, the authors, led by Nicholas S. Downing, M.D., from Brigham and Women's Hospital in Boston, assessed all new therapeutic agents that had been approved by the FDA or the EMA between 2011 and 2015 and compared the median total review times between the agencies.

The researchers found that over the four years studied:

- ▶ The FDA approved 170 new therapeutic agents versus the 144 approved by the EMA;
- ▶ The FDA's median total review time was 306 days, significantly shorter than the 383 days median total review time of the EMA;
- ▶ Among the 142 therapeutic agents that were approved by the FDA and EMA (with at least one of the approvals occurring during the study period), results were similar with median total review times of 303 days and 369 days, respectively.

Medical Device Approvals

There was also positive information on the medical devices front. The source: the regulatory consultancy firm Emergo's (Austin, Texas) recently released [2017 report](#) reviewing medical device applications submitted to the FDA from 2012 to 2016. While not exclusive to diagnostic products, the report offers some insights for the diagnostics industry.

In 2016, the number of devices that received 510(k) clearance fell to 2,957, the lowest number since 2010. The company says this decline in clearances is "entirely attributable" to fewer American companies submitting devices to

the FDA. For products cleared by FDA internal review, it took, on average, 177 calendar days from submission to clearance in 2016.

“The FDA—like many other regulatory authorities—has become much stricter about clinical evidence and testing requirements, thus lengthening the overall path to clearance,” Emergo writes in the report. “Most companies can plan on waiting about six months to get the green light from FDA, although that varies by device.”

The report also found that 58 percent of devices cleared in 2016 did so within six months of submission.

FDA Sources Say User Fees Fuel Progress

The results from both of these reports echo the FDA’s own analysis. In recent testimony before the House Committee on Energy and Commerce regarding reauthorization of the Medical Device User Fee Amendments (MDUFA), Jeff Shuren, M.D., FDA’s director of the Center for Devices and Radiological Health, credited the user fee program for reducing FDA decision times. He testified that the FDA has made “substantial progress” and said that in 2015 it took on average 133 days to reach a decision on a Section 510(k), an 11 percent decrease over five years.

Shuren also said that the FDA’s workload continues to increase about 10 percent every year, in part because of the increasing complexity of innovative medical devices and because of the need to use real-world evidence in post-market surveillance. As a result of this increasing workload, even if the Trump administration’s proposed cuts to regulation and staffing are made, the agency will still need the medical device user fees to continue to speed the review process.

Takeaway: Recent analyses shows the FDA is making progress to speed the regulatory review process across product types and the agency plans on continued need of user fees for continued improvements in review speed. 

Case of the Month: False Billing of Nuclear Stress Tests at Center of \$50 Million Cardio Fraud Scheme

The feds arrested a cardiologist, neurologist and four others for their role in an elaborate fraud scheme. The government contends that over a 12-year period, the defendants’ New York City medical practice billed Medicare and private insurers for \$50+ million worth of cardiology and neurology tests and procedures that were either medically unnecessary or not actually provided, including nuclear stress tests (NSTs) on patients who didn’t need them. In addition to prison time, the defendants face the risk of treble damages and civil penalties under the False Claims Act.

NST Billing & Coding

NSTs measure blood flow to the heart both when the patient is resting and stressed (either via exercise or chemical inducement). There are three possible CPT codes for billing the imaging part of the test:

- ▶ **Codes 78451** (SPECT) when only one set of images is taken, either at rest or stress;
- ▶ **Code 78543** (Planar) when only one set of images is taken, either at rest or stress; and
- ▶ **Code 78452** may only be used when two sets of images are taken.

Lack of MD Options in Superbill

The problem was that the practice listed only one code for “Nuclear Studies” in its superbill: 78452. The result was that physicians were forced to indicate that they performed both a resting and stress study, even if they actually performed only one part of the study.

Takeaway: Although the case involved cardiology testing, the same “bundling” risks arise in physician ordering of laboratory tests, particularly with regard to test panels. To avoid “bundling” charges, labs must ensure that their requisition forms list not just the test panel but the component tests it contains so that the physician has the option of ordering the test(s) individually. 

New Laws: House Bans Firing Whistleblowers for Disobeying Orders to Break the Law

It's clearly against the law to fire an employee in retaliation for filing a whistleblower suit against your lab. So it goes without saying that the ban on retaliation also prevents you from firing an employee for refusing to obey an order to break the law.

Right?

Actually, not so right.

A Glitchy Little Loophole...

The CDC says its update reflects new data suggesting that Zika virus antibodies may stay in the body for months (beyond 12 weeks) in some infected individuals. Therefore, test results may not be able to determine how recently a person was infected.

...Which Is about to Be Plugged

And that's why on May 2, the House of Representatives passed a bill called *The Follow the Rules Act* to fix that and other glitches in federal laws, including an item making it clear that whistleblower retaliation protection covers employees who refuse to obey an order requiring them to break the law.

But Is Something Being Overlooked?

The bill, which is bipartisan legislation—yes, believe it or not, such a thing still exists—sponsored by Rep. Sean Duffy (R-Wis.) and Gerry Connolly (D-Va.), is a clear no-brainer. But it's also fair to ask whether in fixing one quirk, the House may be creating another. After all, the bill is missing something pretty important, namely, clarification that the new protection from retaliation applies retroactively. 

CDC Updates Zika Testing Recommendations

The U.S. Centers for Disease Control and Prevention (CDC) issued a [Health Alert Notice](#) with updated guidance for testing women who live in or frequently travel to areas with a CDC Zika travel notice. The guidance includes an update on interpreting Zika virus Immunoglobulin M (IgM) serological tests and a recommendation for nucleic acid test (NAT) testing at least once per trimester.

The Problem

The CDC says its update reflects new data suggesting that Zika virus antibodies may stay in the body for months (beyond 12 weeks) in some infected individuals. Therefore, test results may not be able to determine how recently a person was infected.

The CDC's Recommendations

The CDC suggests that there may be a better, albeit still not conclusive, way to determine the timing of an infection. The following principles, the agency says, should be followed for testing pregnant women living in or frequently traveling to areas with Zika virus transmission or with a partner who tests positive for Zika virus infection:

- ▶ Test pregnant women promptly, using NAT, if they develop symptoms at any point during pregnancy or if their sexual partner tests positive for Zika virus infection;
- ▶ Consider Zika NAT testing at least once per trimester in asymptomatic women, in addition to IgM testing as previously recommended. The CDC warns, though, that a negative NAT test result does not rule out recent infection because viral ribonucleic acid (RNA) declines over time.
- ▶ NAT testing of amniocentesis specimens may provide additional information to help determine whether positive IgM test results suggest a recent infection.
- ▶ Consider IgM testing as part of pre-conception counseling to establish baseline IgM results before pregnancy. 

Notorious File: Feds Take Down Three More Doctors in BLS Lab Bribery Scheme

The Biodiagnostic Laboratory Service (BLS) case continues to be the poster child for the evils of fraud and greed in the health care industry, generating record numbers of prosecutions against medical professionals in a single bribery case.

Last month, a Yonkers, New York, internist became the 31st doctor convicted in the \$100 million bribery scheme. The doctor admitted to accepting \$400,000 in cash from BLS employees in return for referring blood specimens to the New Jersey lab for testing. The illegal referrals generated \$1.4 million in business for BLS over a three-year period, the feds contend. The physician now faces up to five years in prison and a maximum fine of \$250,000.

So far, most of the BLS prosecutions have been civil cases. But four doctors have also been indicted. On June 6, that list increased to six when a federal jury indicted a pair of cardiologists with a Patterson, NJ practice for their role in the BLS scheme. One of the doctors allegedly received a \$500,000 loan, a free trip to Florida for fishing and visiting strip clubs and other bribes from BLS. His wife was also indicted for setting up the sham company through which the bribes were funneled. The other doctor is accused of taking bribes in exchange for over \$900,000 in lab referrals.

In addition to the 45 total convictions secured so far, the case forced BLS to close shop and forfeit all of its business assets. And even as the prosecution list continues to grow, the case is a long way from over.

Labs IN COURT

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

Quest Fined for Self-Disclosed Violations for Second Time in 2017. Case: Quest Diagnostics, Inc., New Jersey agreed to pay over \$1.151 million for three Civil Monetary Penalties Law involving:

- ▶ Performance of services outside the scope of employment by Quest phlebotomists in Texas, Maryland, Ohio and New Jersey;
- ▶ Failure to meet documentation requirements in connection with Quest's donations of electronic health records software and information technology to clinical laboratory referral sources; and
- ▶ Failure to collect timely second-year payments from physician clients as required in electronic health record donation agreements.

Significance: One of the key things to note about the case is that the allegations were self-disclosed. This is the second reported case of 2017 in which the OIG fined Quest for violations it voluntarily self-disclosed. In February, Quest agreed to pay \$315,093 for allegedly paying kickbacks to a referral source in a case involving rent payments at above fair market value to a medical practice made by a Quest lab in New Jersey.

Pathology Practice Settles Claims for False Billing of Specially Stained Specimens. Case: The case began when a pathologist filed a *qui tam* whistleblower claim against his North Carolina practice for allegedly billing Medicare for medically unnecessary tissue tests. The practice denied the charges. But after the government took over the case, it decided that discretion was the better part of valor and agreed to settle for \$601K–\$120,200 of which will go to the pathologist. **Significance:** Among other things, the complaint accused the practice of applying special stains to test specimens without first giving pathologists a chance to review specimens stained with more routine (and less expensive) hematoxylin and eosin (H&E) stains. And under Medicare rules, the pathologist must first review the routine H&E stained specimen for the special stains to be deemed medically necessary.

Pathology Labs Pays \$897K to Settle Off-Label Marketing of Cell Stain Tests . Case: Memphis providers conducted a multi-year campaign promoting their immunohistochemical mast cell tryptase stain test for its ability to definitively diagnose a condition known as "mast cell enterocolitis." The claims went beyond the test's FDA approval and unsupported by evidence, according to the government. Rather than slug it out in court, the defendants agreed to fork over \$897,640 to settle the case. **Significance:** The case is a useful illustration of the interplay among FDA approval, medically necessary and false claims act requirements. Because the promoted use was off-label, the tests were deemed not medically unnecessary under Medicare. And billing Medicare for medically unnecessary tests would have made the providers guilty of submitting false claims.

Not Documenting M.D. Response to Urine Drug Tests Leads to Medicare Exclusion. Case: A Michigan physician and pain management specialist agreed to a three-year Medicare and Medicaid exclusion for failing to meet medical necessity documentation standards. According to the OIG, the physician didn't adequately document his response to results of urine drug screenings and discussions with patients who:

- ▶ Tested positive for illicit drugs and/or controlled substances;
- ▶ Tested positive for noncontrolled substances he didn't prescribe; and/or
- ▶ Tested negative for controlled substances he did prescribe.

Significance: : This case serves as a reminder of two important morals on physician documentation of medical necessity of lab tests:

- ▶ Proper documentation isn't just a favor to help the lab get paid for ordered tests—it's a core standard of health care quality that physicians must meet to participate in Medicare; and
- ▶ To document medical necessity properly, physician must show not simply why they ordered the tests but how they actually used the test results to treat the patient. 

■ 5 More New Molecular Tests Get the Medicare Green Light from Palmetto, *from page 1*

Medicare Coverage Conditions of Guardant360 for Advanced Lung Cancer

Diagnosis Stage	Progression Stage
<p>Condition 1: Patient not genomically tested for:</p> <ul style="list-style-type: none"> ■ EGFR alterations ■ ALK and ROS1 rearrangements, or ■ PD-L1 expression <p>Condition 2: Patient must be ineligible for tissue-based testing because either:</p> <ul style="list-style-type: none"> ■ Biopsy tissue is insufficient or ■ Biopsy not possible for medical reasons 	<p>Condition 1: Patient not genomically tested for targets in question</p> <p>Condition 2: Tissue-based testing is medically infeasible</p> <p>Coverage also provided for patients progressing on an EGFR tyrosine kinase inhibitor regardless of genetic testing history</p>

The draft LCD would **not** cover use of Guardant360 for:

- ▶ Repeat testing for therapeutic monitoring; or
- ▶ Assessing germline variants.

Context: The new Guardant360 LCD comes less than three months after Palmetto’s approval of the molecular blood test Xpresys XL2 for limited lung cancer screening, namely:

- ▶ To assess lung nodules of between 8 and 30 mm in diameter; and
- ▶ For patients over age 40 who have a pre-test cancer risk of 50 percent or less.

In June 2016, Palmetto outlined its coverage criteria for assessing the analytical performance of liquid biopsy tests to detect genetic variants in tumors. (See [NIR, June 30, 2016](#).)

2. Expanded Coverage of Molecular Prostate Cancer Screening Assay

Test: Oncotype DX® Genomic Prostate Score™ (GPS) from Genomic Health, Inc., a test for assessing the current state and future risk of prostate cancer.

Proposed Coverage: GPS, which is currently covered for clinically-low risk men, would also be covered for patients with favorable intermediate-risk prostate cancer under National Comprehensive Cancer Network (NCCN) guidelines. This would expand the number of Medicare beneficiaries from 50,000 to 80,000.

Context: In January 2017, Palmetto approved the competing drug, Myriad’s Prolaris, which measures the aggressiveness of prostate cancer by analyzing 31 cell cycle progression genes, for men with favorable intermediate risk of prostate cancer under NCCN criteria. (See, [LIR Jan. 6, 2017](#)).

3. Limited Coverage of Test Helping Breast Cancer Patients Avoid Chemotherapy

Test: Myriad Genetics’ EndoPredict test, which uses a 12-gene molecular assessment score combined with tumor size, nodal status and other pathological features to determine if it is medically safe for clinically low-risk breast cancer patients to skip chemo.

Proposed Coverage: EndoPredict would be covered only for postmenopausal women diagnosed with early-stage estrogen-receptor (ER) positive, HER2-negative breast cancer who are either:

- ▶ Lymph node-negative; or
- ▶ Who have up to three positive nodes and are being considered for treatment with adjuvant endocrine therapy.

Context: There are two other breast cancer prediction molecular assays on the market that have received favorable Medicare coverage determinations from Noridian:

- ▶ Oncotype DX Breast from Genomic Health, Inc.; and
- ▶ Prosigna from Nanostring Technologies.

4. Limited Coverage of Sequencing Test for Kidney Transplant Rejection Risks

Test: AlloSure, targeted next-generation sequencing test from CareDx that quantifies donor-derived cell-free DNA in kidney transplant recipients.

Proposed Coverage: LCD would cover use of AlloSure only for measuring the probability of allograft rejection in kidney transplant recipients for whom there is a clinical suspicion of rejection at least two weeks post-transplant. Other limitations:

- ▶ Patients must be over 18; and
- ▶ Before ordering, physicians must assess patients for probability of active renal allograft rejection.

Context: CareDx claims that AlloSure is the only non-invasive test that uses donor derived cell-free DNA as a biomarker to identify probability of active rejection and directly measure allograft injury.

5. Coverage of Nucleic Acid GI Pathogen Tests

Test: Another draft LCD proposes coverage of molecular tests that use nucleic acid amplification to detect gastrointestinal pathogens.

Proposed Coverage: Coverage is limited to tests identifying up to five bacterial targets that Palmetto claims account for 90-95 percent of all foodborne infections: i. *Salmonella*; ii. Shiga toxin-producing *E. coli*; iii. *Shigella*; iv. *Cryptosporidium*; and v. *Campylobacter*. Coverage would not include:

- ▶ Testing for viruses due to the lack of virus-specific therapies that viral test results would inform;
- ▶ Epidemiologic testing by national, state or local agencies; or
- ▶ Testing to confirm another test result.

The Reimbursement Losers: 2 New Molecular Tests that Didn't Make the Cut

For the companies who make the molecular Dx tests that got a favorable Medicare coverage decision from Palmetto, May was a good month. But, alas, not all shared in the bounty as Palmetto also dished out a couple of key rejections. Here's who took it on the chin.

1. Makers of Respiratory Virus PCR Tests

On practically the same day it accepted coverage of nucleic acid amplification tests for GI bacteria, Palmetto turned thumbs down on Polymerase Chain Reaction (PCR) testing for respiratory syncytial viruses. Pathogen targets in RSV panels don't represent a common syndrome, Palmetto reasons. The multiplex PCR respiratory viral patterns don't meet Medicare "reasonable and necessary" standards, according to the LCD, because they "are effectively a one-size-fits-all diagnostic approach."

2. Prometheus Labs

Prometheus also nixed Prometheus IBD sgi Diagnostic test, which uses panels of serological, genetic immune response and inflammatory biomarkers for differentiating inflammatory bowel disease from Crohn's disease and ulcerative colitis. The draft negative coverage decision cites flaws in the supporting study, including lack of methodology details and replication of the findings.

In addition, GIP test panels cannot be unbundled and billed as individual components. *Exception:* Where *C. difficile* is not included in a panel, testing for it “may be reasonable and necessary when ordered additionally,” as long as documentation in the medical record supports reasonableness and necessary.

Context: As Palmetto notes, at least five different companies produce FDA-approved GI pathogen assays that meet or exceed the LCD’s five-target limit:

GI Pathogen Assays Covered by New Palmetto LCD

Company	Progression Stage
BD Diagnostics	BD MAX Enteric Bacterial Panel
Biofire Diagnostics	FilmArray GI Panel
Hologic	ProGastro SSCS
Luminex	xTAG Gastroenterology Panel
Nanosphere	Verigene Enteric Pathogens

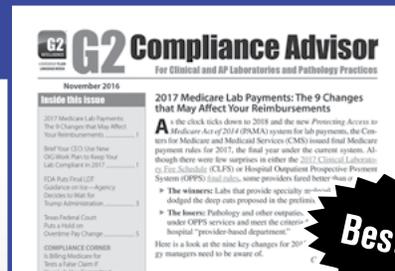
Takeaway: Although these are positive developments for the molecular diagnostics community, the pace of Medicare coverage remains piecemeal and frustratingly slow. Although influential, Palmetto is only one of several key Medicare contractors. Moreover, the spate of favorable LCDs belies the fact that a number of other commercially popular molecular tests failed to make the cut. (See the related item on page 11.) **G2**



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