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# LABORATORY

# INDUSTRY REPORT™

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## Upcoming G2 Events

### Lab Institute 2017

October 25-27, 2017  
 Hyatt Regency Washington on Capitol Hill,  
 Washington, DC  
[www.labinstitute.com](http://www.labinstitute.com)

## 2017 Clinical Laboratory Fee Schedule: The 3 Changes Affecting Your Reimbursement

The Centers for Medicare and Medicaid Services (CMS) issued the final [2017 Clinical Laboratory Fee Schedule](#) (CLFS) on Nov. 21. *The winners:* The small group of labs that provide new specialty molecular tests that dodged the deep cuts proposed in the preliminary schedule; *The losers:* Just about everybody else. Here is a look at the three key changes you need to know about going into 2017:

### 1. Seven Molecular Assays Stave Off Big Cuts

At the center of the hullabaloo are the 16 CPT codes for molecular tests that CMS added to the CLFS this year. *The question:* How much should Medicare pay for these esoteric and pricey assays? In June, CMS proposed interim gapfill prices at a discount from their regionalized prices. Led by providers of the assays, the industry asked CMS to reconsider the interim rates. “The proposed gapfill rates are inconsistent with rates established by commercial payers and the Protecting Access to Medicare Act of 2014,” contended The Coalition for 21st Century Medicine.

*Continued on page 10*

## FDA Puts LDT Guidance on Ice

Whether you dreaded it or craved it, final guidance from the U.S. Food and Drug Administration (FDA) on laboratory-developed tests (LDT) will not be issued in December. The FDA confirmed that it will instead work with the new administration on appropriate reforms to ensure LDTs are safe and effective.

According to a statement from the FDA, which G2 received in response to a request for confirmation of the status of the guidance document:

“The FDA believes that patients and health care providers need accurate, reliable, and clinically valid tests to make good health care decisions—inaccurate or false test results can harm individual patients. We have been working to develop a new oversight policy for laboratory developed tests, one that balances patient protection with continued access and innovation, and realize just

*Continued on page 2*

## ■ FDA PUTS LDT GUIDANCE ON ICE, *from page 1*

how important it is that we continue to work with stakeholders, our new Administration, and Congress to get our approach right. We plan to outline our view of an appropriate risk-based approach in the near future. It is our hope that such an approach will help guide continued discussions.”

*“Today’s announcement by the FDA has paved the way for a transparent discussion on meaningful reform that would protect diagnostic innovation and patient access.”*

— Alan Mertz, President, ACLA

Agency representatives had previously indicated that they planned to release before the end of 2016 a final version of the 2014 draft guidance document setting out a framework for FDA oversight of LDTs.

### **Industry Reaction Mostly Positive**

The American Clinical Laboratory Association (ACLA) praised the FDA’s decision to work with lawmakers on LDT reforms. ACLA has vigorously opposed the framework set out in the October 2014 draft guidance—even hiring high profile legal counsel and issuing a white paper detailing legal arguments against the agency’s authority to impose the framework. ACLA’s legal team, former Solicitor General Paul D. Clement, now a partner with Bancroft PLLC, and Laurence H. Tribe, Professor of Constitutional Law at Harvard University, prepared a White Paper asserting that FDA regulation of LDTs is not supported in the language of the Food, Drug & Cosmetic Act (FDCA), the proposed regulation interferes with the practice of medicine, and FDA guidance flouts administrative law requirements for rulemaking.

“We appreciate the FDA’s acknowledgment that stakeholder input and the ongoing bipartisan work carried out in the House and Senate is the appropriate process to advance comprehensive statutory reform of the LDT regulatory framework,” said ACLA President Alan Mertz in a statement. “Today’s announcement by the FDA has paved the way for a transparent discussion on meaningful reform that would protect diagnostic innovation and patient access.”

Other laboratory industry stakeholders expressed similar happiness at the delay, as did congressional leaders who had been promoting alternatives to the FDA’s framework, including Energy & Commerce Committee Chairman Fred Upton who stated it “was the right call” and imposing regulations “via non-binding guidance documents is not the best approach.” He indicated the committee is working on bipartisan solutions and “forging significant consensus among a number of patient groups, labs, and manufacturers around a 21st century approach uniquely designed with all diagnostic tests in mind from the outset.”

But not everyone is ecstatic about the delay. Andrew Fish, executive director of AdvaMed Diagnostics, a trade association serving the medical device industry issued a statement stating that “AdvaMedDx is disappointed that FDA final guidance on LDT oversight is not forthcoming at this time.” Echoing Upton’s comments, Fish mentioned the need for a broader look at diagnostics oversight as a whole saying AdvaMedDx was “encouraged by congressional interest” in LDT oversight “in the context of broader diagnostics reform legislation.” The statement emphasizes the organization’s commitment to working with all stakeholders to achieve legislation addressing “risk-based oversight of all diagnostics, including LDTs” and stated it was “imperative that this legislation recognizes FDA’s critical oversight role and

serves public health and innovation, and we hope FDA will share its current thinking on LDT oversight to help inform the legislative discussion.”

### Delayed but not forgotten

As can be seen from AdvaMedDx’s reaction to the delay, continued conversation is welcomed but concern regarding LDTs isn’t going away.

*“[T]he FDA’s announcement focuses on balancing patient protections and innovation which is really where the sticking point has been in the whole debate.”*

— Jen Madsen, MPH,  
Arnold & Porter

Health care attorney Danielle Sloane, of Bass Berry & Sims in Nashville, commented that “Laboratories are collectively breathing a sigh of relief at the FDA’s announcement in conjunction with the knowledge that congressional action is also less likely to come to fruition under the new administration. However, the issues that drew the FDA’s concern remain, so I expect to see continued FDA vigilance in the market, particularly with respect to direct-to-consumer marketing of laboratory tests and situations in which the ordering practitioner is affiliated with the performing laboratories.”

Highlighting the same concerns Mertz mentions in ACLA’s statement, Jen Madsen, MPH, a health policy advisor at Arnold & Porter in Washington, DC points out that “the FDA’s announcement focuses on balancing patient protections and innovation which is really where the sticking point has been in the whole debate.” She predicts that if Congress does not pass compromise legislation in the upcoming user fee negotiations in 2017, it could be a significant period of time before a revised regulatory approach emerges, given that it will take some time for the new administration to get people sworn in, including a new HHS Secretary. “One barrier to congressional action is the lack of consensus in the community” about the right path to regulate LDTs, so the situation “will remain ambiguous for at least a while.” Noting various stakeholders favor modernization of CLIA in addition to or in place of heightened FDA involvement in LDT oversight, Madsen adds “the device industry has also been arguing that statutory change is needed” because the FDA’s medical device regulatory framework doesn’t apply perfectly to diagnostics, she says, “so there are arguments that a different review process is needed for all diagnostics, not just lab tests.”

This latest status update regarding FDA efforts is not a vast change from the agency’s prior statements other than to step away from its indication it would finalize the framework this year. In December 2015, at a hearing before the U.S. House of Representatives Energy and Commerce Committee, Jeffrey Shuren, director of the Center for Devices and Radiological Health at the FDA, had outlined the steps the FDA planned to take going forward which included:

- ▶ Coordinating with CMS on laboratory oversight and FDA plans to develop draft guidance regarding quality system requirements for LDTs, “to provide clarity for laboratories on how they can leverage compliance with CLIA requirements to satisfy those applicable FDA guidelines”;
- ▶ Working with CMS and accrediting bodies and CLIA-exempt state laboratory programs, “to identify any potential overlaps between CMS and FDA activities” and look for ways to increase efficiency; and
- ▶ “Ongoing meetings with stakeholders, including laboratories, patients, traditional IVD manufacturers, and medical practitioners.”

The FDA's current comments reflect a similar path, yet simply expanded to accommodate a change in administrations.

At that same hearing, Patrick Conway, CMS deputy administrator for Innovation and Quality and chief medical officer, deferred to the FDA on the issue of clinical validity of lab tests, stating that CMS through CLIA “merely regulates how and by whom the test is conducted and reported out, rather than the scientific principles behind or the clinical validity of the test system itself.” Conway explained that “CLIA does not regulate the scientific principles behind or the clinical validity of any test—that is, the ability of the test to identify, measure, or predict the presence or absence of a clinically relevant condition or predisposition in a patient.”

*Takeaway: Labs get at least a temporary reprieve from increased oversight of laboratory-developed tests as the FDA waits for the new administration and further congressional and stakeholder input.* 

## So, Now What? How a Trump Presidency Will Impact Labs & the ACA

Needless to say, the election of Donald Trump will have major ramifications on not just labs but the entire health care industry. But while changes are a certainty, it is far from clear what and how dramatic they will be, especially with regard to “Obamacare,” aka the Affordable Care Act (ACA). Although we do not have a crystal ball, based on what we know and what we are hearing from our sources, we are in a position to make an informed—albeit preliminary and unscientific judgment about what Trump will and will not do to the ACA and other federal initiatives affecting labs.

### Immediate change faces significant hurdles

ACA repeal was a central theme of the Trump campaign. But like the dog chasing the car, now that Trump and Republicans have captured the prize, they face the challenge of figuring out what to do with it. Additionally, here are some challenges that will slow down any major changes:

- ▶ **Filibuster.** Our existing legislative processes do present a challenge to repealing ACA entirely. “One would assume once you have Republican control of both the House and Senate you should have an easier time enacting legislation,” said Bill Hoagland, senior vice president of the Bipartisan Policy Center. But he explains that while the Republicans have control of both the house and the senate, there are fewer than 60 Republicans in the Senate which is the “critical number to overcome a filibuster.” “There is a firewall or a check and balance against policy,” he explains. Thus, any action taken through a regular process will require some bipartisanship,” he explains, particularly in the Senate.
- ▶ **Unpopularity.** Not only does President-elect Trump enter the office with a low popularity rating—as evidenced by demonstrations in which many constituents angrily declare he is “not [their] president”—but the members of Congress are also plagued by popularity woes, with a November Gallup poll revealing only 11% of Americans approve of Congress. The silver lining is that this unpopularity could be an incentive for both sides to work together, suggests Hoagland.

- ▶ **State insurance role.** One of the proposed changes to health care insurance is to allow insurers to sell across state lines. Hoagland points out, however, that state policies could be a stumbling block—state insurance commissioners set rates and policies. Additionally, there is concern that such sales could create a race to the bottom, he adds.
- ▶ **Packed agenda.** “Congress has a lot on their plate,” notes Hoagland. As he discussed in his keynote presentation at G2’s recent Lab Institute in Washington, D.C. the federal debt limit comes up in March—requiring Congressional attention—and Congress also will need to address Supreme Court, Cabinet and other appointments. That packed agenda could delay or slow down any legislative action with regard to health care.

### Complete repeal already scaled back

Although significant details of any plan remain to be revealed, President-elect Trump has already stepped back from total repeal by indicating in an interview with *60 Minutes* and in other statements that he intends to keep the ACA provisions concerning pre-existing conditions and children remaining on parent’s health insurance until age 26.

It is also noteworthy that in a Nov. 21 video update about the policy plans for the first 100 days, President-elect Trump mentioned several initiatives his administration will tackle in the first 100 days with executive actions that will be implemented “day one.” The only reference to health care at all came when he stated his agenda is based on a core principle of “putting America first” and making sure the “next generation of production and innovation” happen in America, whether it be “producing steel, building cars or curing disease”—and this statement was made in the context of creating jobs and wealth for American workers.

### Budget reconciliation option for change

There is one alternate route to make changes more swiftly or easily for the new administration and that is the budget reconciliation act process—which only requires a simple majority, Hoagland says. He cautions that if that reconciliation path is used to repeal the ACA without any democratic support it could cut a rough path forward for any policies approved in that process.

Alan Mertz similarly cautioned the attendees at G2’s recent Lab Institute to watch what might be included in any budget reconciliation legislation—and highlighted the risk that lab copays could make a reappearance.

### Value focus unlikely to change

Another question on the forefront of laboratories’ and providers’ minds is any potential impact on reimbursement reforms such as PAMA and MACRA and the shift to value-based health care delivery and payment models. “Republican and democratic policy analysts [agree] that fee for service reimbursement system is part of the problem of cost escalation,” responds Hoagland. He doesn’t foresee a change in that focus on shifting from fee for service to value based reimbursement. “It’s hard to argue against paying for value.”

*Takeaway: Though change to ACA and health care systems may be coming, it may not come quickly or be as wholesale as promised or anticipated.* 

# Inside The Lab Industry

## Quest Diagnostics Unveils a Pair of Personalized Medicine Blockbusters

**P**ublic support for personalized and precision medicine (PM) is running ahead of the health care industry's plans to develop and implement PM-based clinical strategies. At least that is the conventional thinking, supported by two recent studies. (See "Public Ahead of Providers in Support of Personalized Medicine," *Lab & Pathology Insider*, Oct. 26, 2016, for details on the study findings.) But based on the deals we are seeing, the theory that the industry is dragging its feet on PM simply does not hold up—at least within the diagnostics realm.

And it is not just startups and research institutions. Now the giant labs are stepping up and launching actionable PM clinical solutions. Quest Diagnostics has been among the most active on this front. Last month, Quest made national headlines by partnering with IBM Watson Health to launch a new precision medicine service combining genomic tumor sequencing with cognitive computing. (See *Diagnostic Testing & Emerging Technologies*, May 11, 2015, for more about IBM's Watson and genomic analysis for cancer care.)

On Nov. 21, Quest announced another PM blockbuster: QuestDirect, a pilot service in Colorado and Missouri that allows patients to order certain lab tests without a physician's order by downloading a special order form posted on the company's website. "In today's consumer-driven health care environment, people want to play a more active role in managing their own health and wellness," Quest CEO Steve Rusckowski explained in a statement.

Although the Quest deals command the attention, the real impetus for development of PM solutions that consumers can use now, either directly or via their physician, is coming from the growing volume of smaller deals that fly under the radar. The "Scorecard" below lists just a few of the notable PM deals from November.

### Scorecard: Notable Personalized/Precision Medicine Deals from November

- ▶ **Nov. 1:** Genomics startup Helix partners with Mount Sinai for apps enabling consumers to assess their risks of transmitting genetic disorders similar to the deal it made with Invitae earlier this year;
- ▶ **Nov. 2:** Amazon begins sales of VeriYou, Good Start Genetics' next-generation sequencing (NGS) test that couples planning to have children can use to screen for cystic fibrosis and spinal muscular atrophy;
- ▶ **Nov. 4:** Cancer Genetics launches Focus: Renal, an NGS panel for PM in renal cancers;
- ▶ **Nov. 11:** Phillips announces a pair of partnerships involving its IntelliSpace Genomics solution for personalized cancer treatments—one with Westchester Medical Center Health Network, the other with interpretation services provider N-of-One;
- ▶ **Nov. 16:** Paradigm Diagnostics closes a \$7 million Series B financing to fund rapid commercial expansion of its PCDx tumor sequencing test enabling physicians to offer personalized treatment to cancer patients;

# Inside The Lab Industry

- ▶ **Nov. 18:** OneOme launches RightMed, a 22-gene pharmacogenomics assay designed for integration into routine clinical care;
- ▶ **Nov. 29:** CombiMatrix secures New York State approval for its NGS screening test for women prior to in vitro fertilization.

*Takeaway: The popular perception that personalized medicine is more of a consumer attitude than a clinical reality is being belied—at least within the diagnostics realm—not just by lab giants like Quest but the literally dozens of smaller genomic deals being transacted each week.* 

## OPPS 2017: The 4 Things Labs Need to Know

**W**hile Obamacare as we know it is on borrowed time, the provider payment reforms of the *Affordable Care Act* (ACA) are likely to survive repeal. And on Nov. 1, the Centers for Medicare and Medicaid Services (CMS) published [final rules](#) on a key reform, the Medicare Hospital Outpatient Prospective Payment System (OPPS) for 2017. Although hospitals will feel the brunt, OPPS also affects labs and pathologists that treat Medicare patients in an outpatient setting. But the final rule runs hundreds of pages. Rather than slog through all those pages, you can instead review this summary of the four things lab and pathology managers need to know about the final rule.

### At a Glance: 2017 Payment Rates

OPPS rates for 2017 are going up by 1.65% based on the following factors:

- ▶ Market basket update of +2.7%;
- ▶ Productivity adjustment of -0.3%;
- ▶ Update for ACA payment cuts of -0.75%.

Overall, CMS estimates that OPPS payments will increase by 1.7% during the year.

### 1. Elimination of “-L1” Modifier for Unrelated Tests

**Current Rules:** Designated lab tests from the Clinical Laboratory Fee Schedule (CLFS) are among the ancillary and support services covered by the OPPS bundled rate paid to hospitals for services provided in the hospital outpatient department (HOPD). Exception: Lab tests appearing on the same claim as other hospital outpatient services are paid separately at the CLFS rate if they are “unrelated,” i.e., ordered by a different practitioner for a different diagnosis. Hospitals use the “-L1” modifier to seek separate payment for “unrelated” tests.

**Example:** A physician does an in-office biopsy and sends the sample to the hospital lab for testing. Later that day, the same patient shows up at the ER with a lacerated

elbow and receives blood testing. The hospital would add the blood test to the ED claim and use the “-L1” modifier to indicate that it was unrelated to the biopsy test.

**New Rules:** The final rule eliminates the “-L1” modifier. In addition to being confusing and hard to use, CMS determined that the modifier was no longer necessary. “We believe that, in most cases, ‘unrelated’ laboratory tests are not significantly different than most other packaged laboratory tests provided in the HOPD,” the final rule explains.

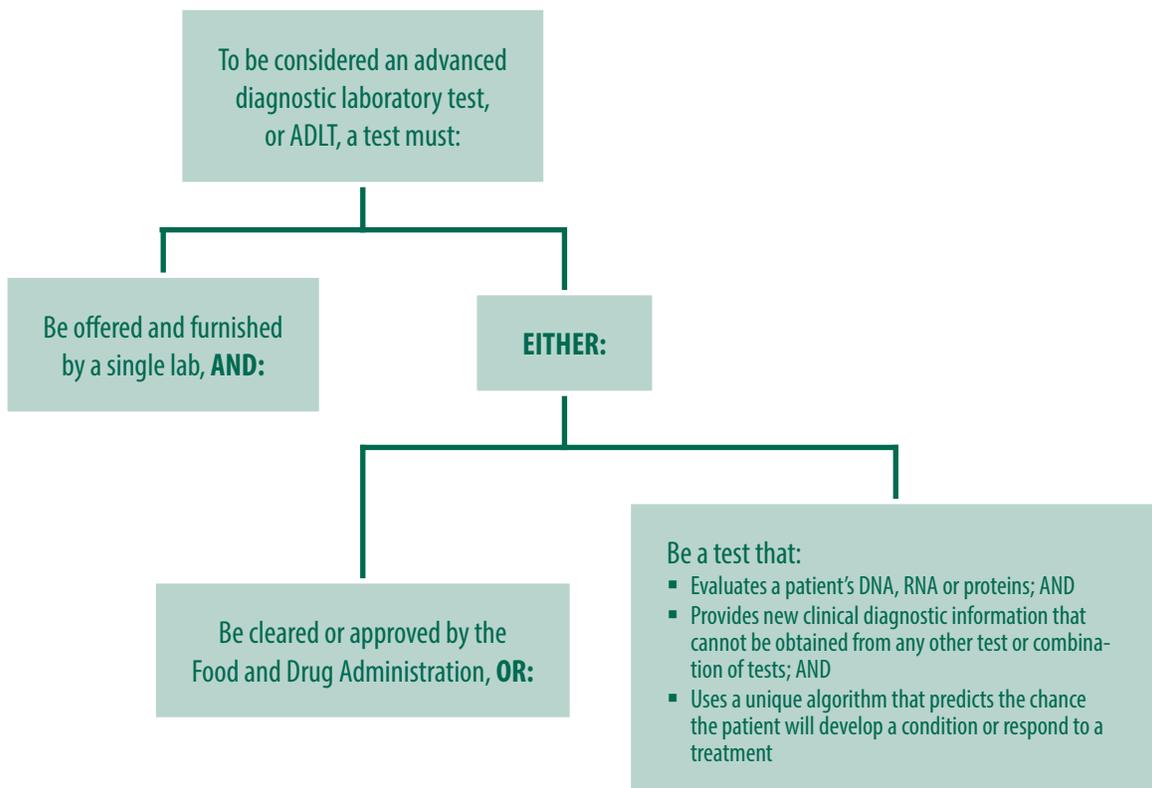
**Impact:** From now on, all lab tests listed on a claim with other hospital outpatient services will be bundled into the OPSS payment, even if ordered by a different provider for a different diagnosis.

**2. Expansion of Molecular Pathology Test Exception to ADLTs**

**Current Rules:** Another exception to bundled payments is molecular pathology tests. *Reasoning:* These are relatively new tests with use patterns that differ from conventional lab tests. And because they are less tied to the primary service provided in the HOPD, they should be paid separately from the OPSS bundle.

**New Rules:** The final rule expands the OPSS packaging exemption to all advanced diagnostic lab tests (ADLT) regardless of whether they are molecular pathology lab tests. The same rationale for excluding molecular pathology lab tests from bundled payments applies to all tests that meet ADLT criteria, according to CMS.

**Impact:** To qualify for the exemption, the test must qualify as an ADLT under section 1834A(d)(5)(A) of the ACA:



## 2 Other Situations when Lab Tests Are Separately Payable

As before, HOPD lab tests will be payable separately, i.e., not covered by the OPSS bundled payment, if:

1. The tests are the only services provided to a beneficiary on a claim; or
2. The tests are preventive.

## 3. Packaging Based on Claim Rather than Date of Service

**Current Rules:** Whether payment for an outpatient service is made as part of the OPSS bundle or separately is designated at the code level by assigning a status indicator to CPT and HCPCS codes. So-called “conditional packaging” indicators are used for lab tests that can be paid either way depending on the circumstances. Some of these indicators, e.g., “Q1” + “S,” “T” or “V,” are used to package services with other services provided on the same date of service; other indicators, e.g., “Q2,” package services on the same claim regardless of date of service.

**New Rules:** The final rule changes the rules for “Q1” and “Q2” to ensure consistency in package indicator use. “We do not believe that some conditional packaging status indicators should package based on date of service,” CMS explains, “while other conditional packaging status indicators package based on services reported on the same claim.”

**Impact:** From now on, all packaging will occur at the claim level and not be based on the date of service. The change will principally affect packaging of lab tests covered by the OPSS provided during a hospital stay lasting longer than one day.

## 4. Off-Campus Hospital Outpatient Department Rules: Impact on Labs

The part of the OPSS that has gotten the most attention are the provisions affecting services provided in off-campus hospital outpatient departments that recently began billing under the OPSS. From now on these services will be paid not under the OPSS but the physician fee schedule at rates of roughly 50 percent of the OPSS rates.

**The good news:** The de facto 50 percent rate cut does not apply to services currently paid under the OPSS based on other Medicare fee schedules. And since OPSS lab rates are based on the CLFS, the new rules will not affect labs.

**The bad news:** However, the new “OPSS-lite” physician fee schedule will cover pathology services provided by entities that meet the criteria for being an off-campus provider-based department that started billing under OPSS on or after Nov. 2, 2015.

**Takeaway: 4 Things to Do—If you receive payment from Medicare for hospital outpatient lab services under the OPSS, you’ll need to make the following adjustments in 2017:**

1. Stop using the “L-1” modifier to claim separate payment for lab tests provided by a different provider for a different diagnosis;
2. Seek separate payment for tests that qualify as ADLTs;
3. Use the new “Q1” and “Q2” status indicators to package lab tests provided during a hospital stay lasting longer than one day;
4. Bill for outpatient pathology services at the new physician fee schedule rather than OPSS rate if: i. you qualify as an off-campus hospital outpatient department; and ii. you began OPSS billing on or after Nov. 2, 2015. 

### ■ 2017 CLINICAL LABORATORY FEE SCHEDULE, from page 1

CMS apparently took heed, dropping the rate cuts and either restoring or increasing the regional prices for seven of the 16 tests listed. Companies benefiting from the change of course included:

- ▶ **CareDx**, which instead of a 77 percent cut got a 47 percent increase on its AlloMap test to identify heart transplant recipients at low risk of rejection (CPT 81595);
- ▶ **Biodesix**, which got a 57 percent hike on its Veristrat lung cancer aggressiveness test (81538);
- ▶ **Genomic Health**, which got a 51 percent hike on its Oncotype DX colon cancer recurrence test (81525);
- ▶ **BioTheranostics**, which got a 23 percent hike on its metastatic tumor origins diagnostic test (81540);
- ▶ **Invitae**, which avoided a 33 percent cut on its hereditary breast cancer panel (81432);
- ▶ **CardioDx**, which instead of a 28 percent cut got a modest 1.4 percent increase on its coronary artery disease risk test Corus CAD (81493); and
- ▶ **Veracyte**, which instead of a 22 percent cut got a 12 percent increase on its thyroid nodule assessment assay Affirma (81545).

### 2017 Medicare Rate for New Molecular Diagnostic Tests

(Tests for which discounts were proposed but not adopted are shown in **boldface**)

CPT Code	Test	Final National Limitation Rate	Proposed National Limitation Rate	2017 Price
81412	9-Gene Ashkenazi Jewish Screen	\$597.91	\$597.91	\$597.91
<b>81432</b>	<b>Hereditary Breast Cancer Panel, 14 Genes</b>	<b>\$925.00</b>	<b>\$622.53</b>	<b>\$925.00</b>
81433	Hereditary Breast Cancer, Duplications/Deletions Panel	\$159.48	\$159.48	\$159.48
81434	Hereditary Retinal Disorder Screen	\$597.91	\$597.91	\$597.91
81437	Hereditary Neuroendocrine Tumor	\$597.91	\$597.91	\$597.91
81438	Hereditary Neuroendocrine Tumor, Duplications/Deletions	\$597.31	\$597.31	\$152.21
81442	Noonan Gene Screen	\$597.91	\$597.91	\$597.91
81490	Vectra Screen	\$586.50	\$586.50	\$597.91
<b>81493</b>	<b>Corus CAD</b>	<b>\$1,035.10</b>	<b>\$741.01</b>	<b>\$1,050</b>
<b>81525</b>	<b>Oncotype DX</b>	<b>\$2,062.10</b>	<b>\$848.86</b>	<b>\$3,104</b>
<b>81538</b>	<b>Veristrat</b>	<b>\$1,341.87</b>	<b>\$283</b>	<b>\$2,112</b>
<b>81540</b>	<b>bioTheranostics</b>	<b>\$2,355.46</b>	<b>\$1,522.17</b>	<b>\$2,900</b>
<b>81545</b>	<b>Affirma</b>	<b>\$2,864.45</b>	<b>\$2,240.16</b>	<b>\$3,200</b>
<b>81595</b>	<b>AlloMap</b>	<b>\$1,920.98</b>	<b>\$732.00</b>	<b>\$2,821</b>
0009M	VisibiliT	\$132.86	\$132.86	\$598
0010M	4K Score	\$260	\$260	\$260

CMS also increased pricing for fetal aneuploidy trisomy risk testing (CPT 0009M) from \$132.86 to \$598.

## 2. New Pricing Formula for Differential Drug Testing G Codes

The other significant development in the final CLFS affects pricing of the four definitive drug tests capable of identifying individual drugs and distinguishing between structural isomers, for which CMS issued HCPCS G codes in 2016—G0480, G0481, G0482 and G0483. To pay for these tests, CMS used a crosswalking formula under which: i. the first two tests performed were paid at the full price of the crosswalk CPT code 82542; and ii. remaining tests within that code were paid at 25% of the crosswalk price.

Industry asked CMS to modify the formula for 2017 claiming that it understates the true costs of performing accurate tests. They expressed concerns that physician office labs without quality control and multiple calibrations were generating high volume of G0483 claims in the first part of 2016. CMS made two proposals to address their concerns:

- ▶ **Proposal 1:** Change the crosswalk formula to allow four tests to be priced at the full crosswalk price; and
- ▶ **Proposal 2:** Create a new G code to recognize labs that perform a less sophisticated version of differential drug tests.

In the end, CMS opted for Proposal 1. Allowing the four tests to be priced at the full crosswalk price should adequately recognize the resources required to perform these procedures, CMS explains.

### New Formula for Crosswalking Price of G Code Differential Drug Tests

CPT Code	2017 Crosswalk Formula*
G0480	$4 \times 82542 + 3 \times .25 \times 82542$
G0481	$4 \times 82542 + 10 \times .25 \times 82542$
G0482	$4 \times 82542 + 17 \times .25 \times 82542$
G0483	$4 \times 82542 + 25 \times .25 \times 82542$

\* Note: 82542 = full crosswalk price for CPT code 82542

## 3. CMS Crosswalks 14 Codes

The final significant change in the 2017 CLFS is the crosswalking of 14 existing CPT codes. (See the [Table](#) on the G2 website for a summary of all the codes that were crosswalked.)

*Takeaway: Here are the three key things to know about the newly finalized CLFS:*

1. *Proposed deep cuts in molecular diagnostic tests were not implemented—in several cases, CMS actually granted significant price increases*
2. *The pricing formula for the four differential drug test G codes has been changed to allow for billing at the full crosswalk price of CPT 82542*
3. *CMS crosswalked 14 G and CPT codes into existing CPT codes to eliminate duplication.* 

# INDUSTRY BUZZ

## Is the Alere Dispute Hurting Abbott's Strategic Position?

**A**s the battle over the \$5.8 billion Alere merger enters a new and nastier stage, there are indications that the conflict may be harming Abbott's strategic standing and ability to do other M&A deals.

The mess started in February when the sides first announced the deal that would have made Abbott the nation's leading provider of point-of-care diagnostics. A month later, Alere revealed that the Justice Department was looking into its overseas business dealings in Africa, Asia and Latin America. Abbott got cold feet and offered Alere a reported \$50 million to call off the deal. Alere rejected the opt-out and demanded that Abbott consummate the deal.

Things got ugly with both sides accusing the other of bad faith. Frustrated by what it perceived to be Abbott's foot-dragging in securing Federal Trade Commission antitrust clearance, Alere escalated in August by filing a lawsuit to force Abbott to carry out its obligations under the merger agreement. The Delaware Chancery Court asked the sides to mediate but on Sept. 28, the talks broke down without a resolution. On Nov. 3, Abbott fired back, suing Alere for breach of contract.

### Signs of a Thaw?

Yet, at the end of the day, the nastiness and litigation may just be a big bluff. In its most recent SEC filing, Alere said that it "is highly confident that the merger will" proceed. For its part, Abbott claims that its lawsuit against Alere is designed not to bust the deal but to acquire the information it needs about Alere's business practices to bring it to consummation. Barring a resolution, nothing will happen until Jan. 27 when the sides are scheduled to meet in court for a hearing.

*Takeaway: The Strategic Implications for Abbott. We are hearing whispers that fallout from Alere may be compromising Abbott's ability to do other deals by making other potential targets wary of getting into bed with the diagnostic giant.*

*For example, one report cites point-of-care molecular testing company Cepheid Inc., which was acquired by Danaher Corp. for \$4 billion in cash on Sept. 6, as an example of a strategic opportunity that Abbott lost as a result of the Alere mess. It is also unclear what impact the Alere situation may be having on the resistance Abbott is encountering from the European Commission in its efforts to secure antitrust clearance for its \$25 billion acquisition of St. Jude Medical Inc. See [LIR, May 19, 2016](#), for more background on the Abbott/Alere merger.* 

## References

**Food and Drug Administration**  
888-463-6332

**Foundation Medicine**  
617-418-2200

**HIMSS Analytics**  
312-638-9400

**NeoGenomics**  
239-768-0600

**OPKO Health**  
305-575-4100

**Palmetto GBA**  
803-735-1034

**Quest Diagnostics**  
800-222-0446

**Randox Laboratories**  
44-28-9442-2413

**Veracety** 650-243-6350  
**WellCare** 800-960-2530

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