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Inside this issue

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2017 Medicare Lab Payments: The 9 Changes that May Affect Your Reimbursements

As the clock ticks down to 2018 and the new *Protecting Access to Medicare Act of 2014* (PAMA) system for lab payments, the Centers for Medicare and Medicaid Services (CMS) issued final Medicare payment rules for 2017, the final year under the current system. Although there were few surprises in either the 2017 Clinical Laboratory Fee Schedule (CLFS) or Hospital Outpatient Prospective Payment System (OPPS) final rules, some providers fared better than others:

- **The winners:** Labs that provide specialty molecular tests that dodged the deep cuts proposed in the preliminary CLFS;
- **The losers:** Pathology and other outpatient facilities that bill under OPPS services and meet the criteria for an off-campus hospital "provider-based department."

Here is a look at the nine key changes for 2017 that lab and pathology managers need to be aware of.

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Brief Your CEO: Use New OIG Work Plan to Keep Your Lab Compliant in 2017

As the year comes to a close, lab managers need to brief their officers on the federal government enforcement initiatives that may affect operations in the coming year. The best place to turn for insight into what the feds are thinking is the Health and Human Services Office of Inspector General's (OIG) year-end Work Plan, the bi-annual report in which the agency summarizes its new and ongoing enforcement programs and priorities for the upcoming six months. Here are the nine items in the recently published 2017 Work Plan that you should include in your CEO briefing.

1. Mostly More of the Same for Labs

The OIG has often used the Work Plan to announce major initiatives targeting billing and payment of clinical laboratory services under Part B. But there is nothing like that in the 2017 Work Plan. All of the lab initiatives listed, including those listed as new items, are merely reprises of issues the OIG has raised many times before. Even so, the fact that they appear in the 2017 Work Plan indicates that the OIG continues to regard the matter as an enforcement priority. So make sure you mention these things in your CEO briefing.

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Brief Your CEO, *from page 1*

2. Billing of Lab Services in 2016

The OIG says it will analyze the top 25 most billed lab tests for 2016 and compare the findings to 2015 and 2014. But while it is listed as a new item, this is something the OIG is required to do every year under Protecting Access to Medicare Act of 2014 (PAMA).

Review of Medicare payments to independent clinical laboratories with an eye to labs that "routinely submit improper claims" has become a fixture for Work Plans and appears in the 2017 version as well.

3. Independent Clinical Lab Billing

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4. Histocompatibility Lab Billing

The OIG says it will continue to review payments of tests required for bone marrow and solid organ transplant services and ensure that the cost reports submitted by histocompatibility labs are accurate and detailed enough to support reimbursement.

5. Billing of Diagnostic Sleep Tests

Improper billing of sleep testing by independent and hospital labs, particularly repeat tests performed on the same patient, have become a growing concern for the OIG and have now landed in the Work Plan.

6. Billing and Payment of Hyperbaric Oxygen (HBO) Services

The 2017 Work Plan also includes a handful of new non-lab-specific items that may still have an impact on labs. One of these is OIG review of Medicare payments for HBO outpatient claims to ensure they meet Medicare and National Coverage Determinations Manual requirements (See 20.29(A), page 60) in response to concerns about billing for non-medically-necessary HBO services.

7. Chronic Care Management

The OIG will review Medicare payments for chronic care management services, non-face-to-face services to Medicare patients with multiple significant chronic conditions involving significant risk of death, acute exacerbation/decompensation or functional decline where the significant chronic conditions are expected to last at least 12 months or the patient's death.

8. Post-Death Service Dates

The OIG will review CMS' policies and procedures that ensure that payments are not made for Medicare services ostensibly rendered to deceased individuals.

9. PAMA & MACRA Implementation

OIG will review CMS implementation of not only PAMA but the Quality Payment Program under the Medicare Access and CHIP Reauthorization Act (MACRA) to address "timelines and key milestones CMS has established" for implementation, as well as "key challenges and potential vulnerabilities CMS is facing during implementation."

Takeaway: Even though it is short on new initiatives, it is important to brief your CEO about the ongoing lab billing compliance issues cited in the OIG's newly released 2017 Work Plan.

FDA Puts Final LDT Guidance on Ice—Agency Decides to Wait for Trump Administration

Whether you dreaded it or craved it, you will not be getting it—at least not any time soon. In the wake of the election, the U.S. Food and Drug Administration (FDA) let it be known that it will not issue final guidance on laboratory-developed tests (LDT) in December. The FDA said that it will put the guidelines on ice and work with the new administration on appropriate reforms to ensure LDTs are safe and effective.

The Anti-Climax

There was no big announcement. Word of deferral came in a statement that G2 received from the FDA in response to a request for clarification on the timing of guidelines finalizing draft guidance issued in October 2014. As you can see, the FDA response was fairly nondescript for an issue of such magnitude:

> "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 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."

And so the wait continues.

Industry Reaction Mostly Positive

Although the lab industry generally wants guidance, response to the October 2014 draft guidance was far from enthusiastic. As a result, reaction to the FDA's deferral was largely positive. For example, the American Clinical Laboratory Association (ACLA) praised the FDA's decision to work with lawmakers on LDT reforms. ACLA has vigorously opposed the framework for FDA regulation set out in the 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 their happiness with the delay, as did congressional leaders who had been promoting alternatives to the FDA's framework. For example, Energy & Commerce Committee Chairman Fred Upton stated it "was the right call" and that imposing regulations "via non-binding guidance documents is not

the best approach." He also 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 others were disappointed with the delay. One of those was Andrew Fish, executive director of the medical device industry group AdvaMed Diagnostics, who issued a statement saying that "AdvaMedDx is disappointed that FDA final guidance on LDT oversight is not forthcoming at this time." Echoing the sentiments of Chairman Upton, 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 Aborted

Although welcome, the delay represents a reprieve, not a permanent scrapping of FDA LDT regulation.

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 user fee negotiations slated for 2017, it could take a significant period of time for a revised regulatory approach to emerge, given the new administration's need to get its new HHS Secretary and other people sworn in. "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 that 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."

Madsen and Sloane participated in a panel presentation at G2's recent Lab Institute in Washington, D.C. (Oct. 26-28, 2016) and highlighted the FDA's growing concern about LDTs marketed direct-to-consumer as well as surveyed the number of alternative regulatory proposals being promoted in efforts to influence the structure of any regulatory oversight of LDTs.

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.

Texas Federal Court Puts a Hold on Overtime Pay Change

Employers were set to face a new Fair Labor Standards Act (FLSA) rule that was to go into effect on Dec. 1, 2016 and would double the minimum salary threshold for the overtime exemption—rendering more than 4 million employees eligible for overtime. But on Nov. 22, a Texas federal court granted a reprieve, issuing a preliminary injunction preventing the change from taking effect until the court has a chance to decide the issues raised in litigation challenging the change to the overtime exemption. More than 20 states and numerous business groups sued to stop the change, claiming the requirement unconstitutionally regulates the states, forcing them to adopt a wage policy.

For further discussion and analysis of the court's decision and what it means for employers, see "Insight: The New Overtime Rules are Put on Hold. What Does That Mean for You?" written by guest blogger, Mike O'Brien, an employment attorney and litigator. *Insight* is a new feature available on the G2 Intelligence website and the *Lab & Pathology Insider* weekly email newsletter.

2017 Medicare Lab Payments, *from page 1*

1. Molecular Assays Avoid Cuts and Get Rate Hikes

Suspense leading up to promulgation of the new CLFS focused on how much Medicare would pay for the 16 CPT codes for the esoteric molecular tests that CMS added to the Schedule this year. The discounted interim gapfill prices CMS proposed in June sparked protest from the industry. "The proposed rates are inconsistent with rates established by commercial payers and PAMA," contended The Coalition for 21st Century Medicine.

CMS apparently had a change of heart, either restoring or actually increasing the regional prices for seven of the 16 tests that had been slated for deep cuts. Companies benefiting from the change 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

(**boldface** tests are those for which discounts were proposed but not adopted)

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
81432	**Hereditary Breast Cancer Panel, 14 Genes**	**$925.00**	**$622.53**	**$925.00**
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
81493	**Corus CAD**	**$1,035.10**	**$741.01**	**$1,050**
81525	**Oncotype DX**	**$2,062.10**	**$848.86**	**$3,104**
81538	**Veristrat**	**$1,341.87**	**$283**	**$2,112**
81540	**bioTheranostics**	**$2,355.46**	**$1,522.17**	**$2,900**
81545	**Affirma**	**$2,864.45**	**$2,240.16**	**$3,200**
81595	**AlloMap**	**$1,920.98**	**$732.00**	**$2,821**
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

In 2016, CMS issued HCPCS G codes for four definitive drug tests capable of identifying individual drugs and distinguish between structural isomer: G0480, G0481, G0482 and G0483. Payment for such tests was based on a crosswalking formula under which:

- The first two tests performed were paid at the full price of the crosswalk CPT code 82542; and
- Remaining tests within that code were paid at 25 percent of the crosswalk price.

Industry claimed that the payment formula understated the true costs of performing accurate tests and that a high volume of G0483 claims was coming from physician office labs without quality control and multiple calibrations. CMS shared their concerns and made two proposals in the interim CLFS to address them:

- **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 final CLFS, 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 x 82542 + 3 x .25 x 82542
G0481	4 x 82542 + 10 x .25 x 82542
G0482	4 x 82542 + 17 x .25 x 82542
G0483	4 x 82542 + 25 x .25 x 82542

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

3. Revamped G Codes for Definitive Drug Testing

The final CLFS includes modified descriptors of the G codes for differential drug tests so that they identify the type of test involved more clearly (underlined text represents changes from 2016 descriptor).

- **G0480:** (Drug test(s), definitive, utilizing (1) drug identification methods able to identify individual drugs and distinguish between structural isomers (but not necessarily stereoisomers), including, but not limited to GC/MS (any type, single or tandem) and LC/MS (any type, single or tandem and excluding immunoassays (e.g., IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (e.g., alcohol dehydrogenase)), <u>(2) stable isotope or other universally recognized internal standards in all samples (e.g., to control for matrix effects, interferences and variations in signal strength), and (3) method or drug-specific calibration and matrix-matched quality control material (e.g., to control for instrument variations and mass spectral drift)</u>; qualitative or quantitative, all sources, includes specimen validity testing, per day; 1-7 drug class(es), including metabolite(s) if performed);

- **G0481:** (Drug test(s), definitive, utilizing (1) drug identification methods able to identify individual drugs and distinguish between structural isomers (but not necessarily stereoisomers), including, but not limited to GC/MS (any type, single or tandem) and LC/MS (any type, single or tandem and excluding immunoassays (e.g., IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (e.g., alcohol dehydrogenase)), (2) stable isotope or other universally recognized internal standards in all samples (e.g., to control for matrix effects, interferences and variations in signal strength), and (3) method or drug-specific calibration and matrix-matched quality control material (e.g., to control for instrument variations and mass spectral drift); qualitative or quantitative, all sources, includes specimen validity testing, per day; 8-14 drug class(es), including metabolite(s) if performed);
- **G0482:** (Drug test(s), definitive, utilizing (1) drug identification methods able to identify individual drugs and distinguish between structural isomers (but not necessarily stereoisomers), including, but not limited to GC/MS (any type, single or tandem) and LC/MS (any type, single or tandem and excluding immunoassays (e.g., IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (e.g., alcohol dehydrogenase)), (2) stable isotope or other universally recognized internal standards in all samples (e.g., to control for matrix effects, interferences and variations in signal strength), and (3) method or drug-specific calibration and matrix-matched quality control material (e.g., to control for instrument variations and mass spectral drift); qualitative or quantitative, all sources, includes specimen validity testing, per day; 15-21 drug class(es), including metabolite(s) if performed);
- **G0483:** (Drug test(s), definitive, utilizing (1) drug identification methods able to identify individual drugs and distinguish between structural isomers (but not necessarily stereoisomers), including, but not limited to GC/MS (any type, single or tandem) and LC/MS (any type, single or tandem and excluding immunoassays (e.g., IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (eg, alcohol dehydrogenase)), (2) stable isotope or other universally recognized internal standards in all samples (e.g., to control for matrix effects, interferences and variations in signal strength), and (3) method or drug-specific calibration and matrix-matched quality control material (e.g., to control for instrument variations and mass spectral drift); qualitative or quantitative, all sources, includes specimen validity testing, per day; 22 or more drug class(es), including metabolite(s) if performed)

4. 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.)

3 Takeaways for 2017 CLFS

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

5. New OPPS Payment Rates

The remaining noteworthy 2017 Medicare reimbursement changes affect outpatient lab and pathology services provided to hospital outpatients. Overall 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.

6. Elimination of "-L1" Modifier for Unrelated Tests

Under current rules, designated lab tests from the CLFS are treated as 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.

Change: The 2017 OPPS 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.

Bottom Line: From now on, all lab tests listed on a claim with other hospital outpatient services will be bundled into the OPPS payment, even if they are ordered by a different provider for a different diagnosis.

7. Expansion of Molecular Pathology Test Exception to ADLTs

Molecular pathology tests are also exempt from OPPS bundling. Reasoning: These are relatively new tests with use patterns that differ from conventional lab tests. And they are also less tied to the primary service provided in the HOPD.

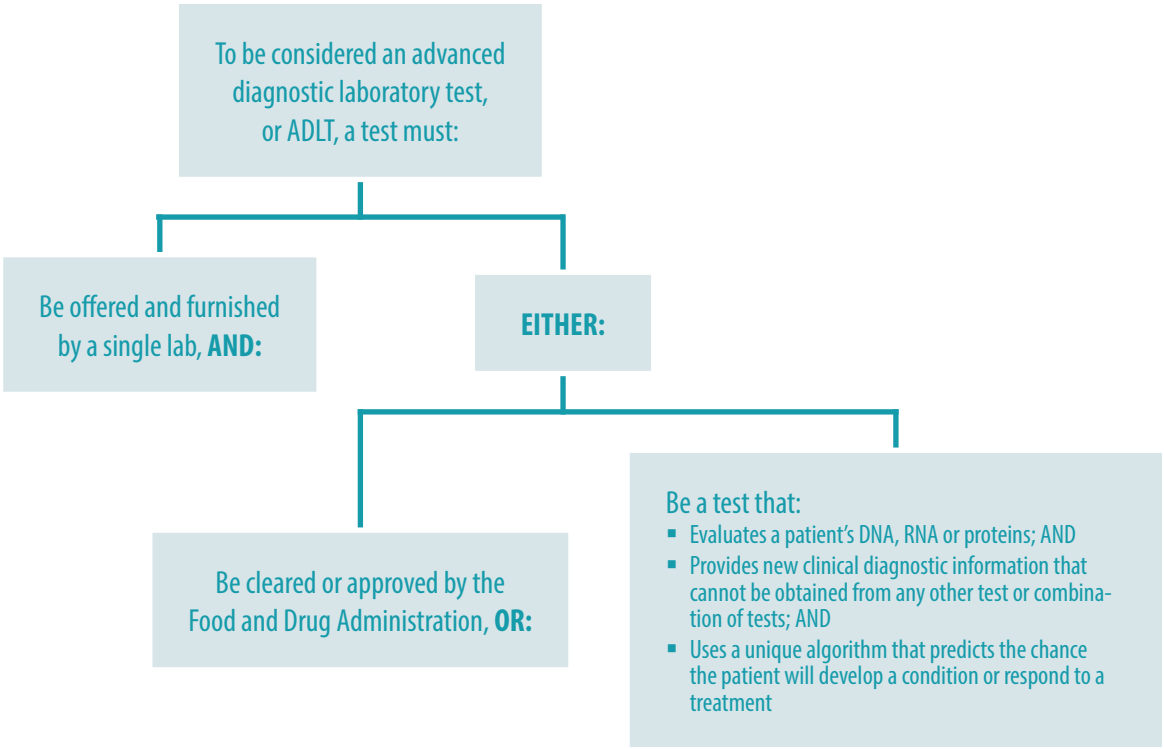
Change: The final rule expands the exemption to all advanced diagnostic lab tests (ADLT) regardless of whether they are molecular pathology lab tests. The same rationale for excluding molecular pathology lab tests from bundled payments applies to all tests that meet ADLT criteria, according to CMS.

Bottom Line: 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 OPPS bundled payment, if:

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



8. Packaging Based on Claim Rather than Date of Service

Whether payment for an outpatient service is bundled or separate 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.

Change: 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."

Bottom Line: 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 OPPS provided during a hospital stay lasting longer than one day.

9. New Fee Schedule for Off-Campus Hospital Outpatient Departments

The most drastic change in the OPPS final rules are those affecting services provided in off-campus hospital outpatient departments that recently began billing under OPPS. From now on these services will be paid not under the OPPS but the physician fee schedule at rates of roughly 50 percent of the OPPS rates.

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

The bad news: However, the new "OPPS-lite" physician fee schedule will cover pathology and other services not listed on the CLFS (or subject to an OPPS bundling exemption) provided by entities that meet the criteria for being an off-campus hospital

outpatient provider-based department (PBD) that started billing under OPPS on or after Nov. 2, 2015. Exceptions: You will not be covered by the new physician fee schedule if:

- You are a dedicated emergency department;
- You began billing for OPPS services before Nov. 2, 2015 and have not impermissibly relocated or changed ownership; and/or
- You are "on the campus," i.e., within 250 yards of the hospital or a hospital remote location.

Takeaway: 4 Things to Do about OPPS Changes—If you receive payment from Medicare for hospital outpatient lab services under the OPPS, 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 OPPS rate if: i. you qualify as an off-campus hospital outpatient department; and ii. you began OPPS billing on or after Nov. 2, 2015.*

G2 Compliance Corner

Is Billing Medicare for Tests a False Claim If Your Lab Has Committed a CLIA Violation?

SITUATION

XYZ Labs knows that it is currently committing quality control and other *Clinical Laboratory Improvement Amendment* (CLIA) violations. But it continues to bill Medicare for tests. A medical technician claims the CLIA violations are compromising testing accuracy and files a *qui tam* suit against XYZ under the False Claims Act (FCA):

QUESTION

Was billing Medicare for tests when it knew it was violating CLIA an FCA violation?

A. Yes, because CLIA compliance is mandatory for billing lab tests

B. Yes, because it made XYZ's certification of compliance false

C. No, because CLIA non-compliance is not grounds for FCA liability

D. No, because CLIA compliance is irrelevant to FCA liability

ANSWER

C. XYZ did not violate the FCA because CLIA violations do not make a lab liable for false claims.

EXPLANATION

The FCA bans providers from knowingly submitting false or fraudulent claims to Medicare. For labs, this typically means billing for tests that were not medically necessary or not provided at all. But recent years have seen the rise of a new false claim: billing for tests when you know you are not in compliance with *other* laws, most notably CLIA. The theory is that in billing Medicare, providers certify (usually by implication) that they comply with all "material" laws. So, knowing failure to disclose material violations renders not just the certification but the underlying claim false.

This scenario illustrates how courts have applied the theory. *Basic rule:* Breach of implied certification *may* be grounds for FCA liability if the violation is "material" to the government's decision to pay the claim. The few courts to address the issue have ruled that CLIA violations are not material to paying lab claims. So C is the right answer.

WHY WRONG ANSWERS ARE WRONG

A is wrong because in deciding what is and is not "material," courts distinguish between the kind of law or rule violated: **conditions of participation**, i.e., health and safety standards for participating in government medical programs, such as CLIA, are not material; **conditions of payment**, i.e., requirements governing if payment is made for particular services are material.

B is wrong because only "material" violations render certification of compliance false. And since they violate a condition of participation rather than a condition of payment, CLIA violations are not material.

D is wrong because the issue is materiality, not relevance.

What Happens Next: Is a Trump Presidency Really the End for ACA?

Obamacare and the Affordable Care Act (ACA) are challenges you have been wrestling with for years. Now that Donald Trump has been elected president, was it all for naught? The short answer: No. While ACA as we know it is going away, change is likely to be slow and incremental rather than sudden and dramatic.

Even if his intent was full and utter repeal, making the ACA disappear will not be so simple. Obstacles include:

- **Filibuster.** The first set of challenges are the legislative barriers. According to Bill Hoagland, senior vice president of the Bipartisan Policy Center, while the Republicans control the House and Senate, there are fewer than 60 Republicans in the Senate which is the "critical number to overcome a filibuster."
- **Unpopularity.** President-elect Trump enters office with a low popularity rating as do the members of Congress with a November Gallup poll finding that only 11 percent of Americans approve of Congress.
- **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.
- **Packed agenda.** "Congress has a lot on its 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.

There is an alternate route to make change more swift and easy for the new administration: the budget reconciliation act process, which Hoagland notes requires only a simple majority. 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.

Another key question for laboratories and other providers is the 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," says Hoagland. He does not 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.

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