

November 2017

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## Upcoming Events

### Lab Reimbursement Summit 2018

December 8, 2017  
Holiday Inn Airport (South)  
Atlanta, GA

[www.lableadershipsommit.com](http://www.lableadershipsommit.com)

## CMS Finalizes Controversial PAMA Fee Schedule

It's official. Brushing aside fierce lab industry opposition, CMS has decided to go forward with its PAMA Clinical Laboratory Fee Schedule (CLFS) in 2018.

### The Flawed Fee Schedule

The intent of the PAMA law is to base Medicare payments for lab tests on actual market rates. While welcoming the concept, the lab industry was appalled at how CMS proposed to implement it, specifically its exclusion of hospital and community labs from the definition of "applicable laboratories" whose data was used to determine market rates for tests. In addition to representing a key segment of the lab market, these labs have the leverage to command higher rates. So excluding their pricing data artificially deflates rates for lab tests.

In [announcing](#) the final 2018 rates, CMS defends the CLFS as incorporating pricing data "from laboratories from every state" accounting for over 96% of Medicare spending on lab tests in 2016. "This strong response gives us confidence that the final payment rates accurately capture the rates paid by private pay-

*Continued on page 2*

## Medicare Reimbursement: CMS Finalizes Hospital Outpatient Prospective Payment Changes for 2018

With all of the PAMA commotion, the 2018 Medicare Hospital and Ambulatory Surgical Outpatient Prospective Payment System (OPPS) [final rule](#) has flown under the radar. In case you don't feel like reading all 1,133 pages, here's a summary of the three items you need to know if your lab provides tests to Medicare patients on an outpatient basis.

### 1. Revised Lab Date of Service Rules

For most labs, the most important part of the new HOPPS rule is CMS's new rules for calculating the date of service (DOS) for outpatient lab tests.

**Current Rules:** The DOS for outpatient lab services is normally the date the specimen is collected, as opposed to date of order, testing or analysis. *Exception:* The date the test is performed is the DOS if:

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### ■ CMS Finalizes Controversial PAMA Fee Schedule, from page 1

ors and allow CMS to utilize the power of the private market to help make sure the CLFS pays accurately for tests.”

### The Final CLFS

The finalized CLFS published on Nov. 17 closely tracks the objectionable preliminary version of Sept. 22 (See [GCA, Oct. 24, 2017](#), for the details) with four adjustments:

#### 1. Phase-In Reduction Cap of Cuts Over 10%

**Situation:** Under the current CLFS, the National Limitation Amount (NLA) for a lab test HCPCS code is based on a percentage of the median of all local fee schedule amounts, including \$0. Medicare pays whichever is lowest among the billed amount, local fee schedule amount or NLA. In most cases, the NLA is the lowest amount. The new CLFS will apply a phase-in reduction cap when comparing the 2017 NLA to the weighted median of the private payor rates would reduce payment for lab tests by over 10%.

**Preliminary CLFS:** The 23 HCPCS codes with a \$0 NLA and a local fee schedule amount of over \$0 in 2017 were slated for the full NLA treatment rather than the 10% reduction cap.

**Final CLFS:** The formula was recalculated to exclude the above \$0 local fee schedule amounts. Result: 16 of the 23 tests will qualify for the phase-in reduction cap.

#### 2. Payment Floor for Diagnostic or Screening Pap Smear Lab Tests

**Situation:** The national minimum payment amount for a diagnostic or screening pap smear lab test (including all cervical cancer screening technologies that the FDA has approved as a primary screening method for detecting cervical cancer) is \$14.60 for tests furnished in 2000. The national minimum payment amount for later years is then annually adjusted. The CY 2017 floor for these tests was \$14.49. The CY 2018 update factor is 1.1%, which yields a CY 2018 floor of \$14.65.

**Preliminary CLFS:** CMS didn't apply the national minimum payment amount floor to the 24 diagnostic or screening pap smear laboratory HCPCS codes for CY 2018.

**Final CLFS:** The minimum applies for eight of these codes; the remaining 16 will be paid the higher private payor rate-based payments, with the phase-in reduction cap where applicable.

#### 3. Payment for Home Use Hemoglobin A1c (HbA1c) Kits

**Situation:** The payment rate for a diagnostic test for HbA1c labeled for home use by the FDA must equal the payment rate for HCPCS Code 83036 glycosylated hemoglobin test (and subsequent codes).

**Preliminary CLFS:** CMS didn't apply the national minimum payment amount floor to the 24 diagnostic or screening pap smear laboratory HCPCS codes for CY 2018.

### Application of Phase-In Reduction Cap When NLA is \$0 but Some Locality Rates Are Greater Than \$0

HCPCS	HCPCS Description	Weighted Median	Preliminary Determinations NLA				Final Determinations NLA			
			2017 NLA	2018 Pay w/ Cap	2019 Pay w/ Cap	2020 Pay w/ Cap	2017 New NLA	New 2018 Pay w/ Cap	New 2019 Pay w/ Cap	New 2020 Pay w/ Cap
80061	Lipid panel	\$11.23	\$0.00	\$11.23	\$11.23	\$11.23	\$18.37	\$16.53	\$14.88	\$13.39
80074	Acute hepatitis panel	\$38.79	\$0.00	\$38.79	\$38.79	\$38.79	\$65.34	\$58.81	\$52.93	\$47.63
80400	Acth stimulation panel	\$28.80	\$0.00	\$28.80	\$28.80	\$28.80	\$44.74	\$40.27	\$36.24	\$32.62
80402	Acth stimulation panel	\$76.16	\$0.00	\$76.16	\$76.16	\$76.16	\$119.28	\$107.35	\$96.62	\$86.96
80406	Acth stimulation panel	\$63.49	\$0.00	\$63.49	\$63.49	\$63.49	\$107.35	\$96.62	\$86.95	\$78.26
80408	Aldosterone suppression eval	\$109.94	\$0.00	\$109.94	\$109.94	\$109.94	\$172.15	\$154.94	\$139.44	\$125.50
80412	Crh stimulation panel	\$801.62	\$0.00	\$801.62	\$801.62	\$801.62	\$452.16	\$801.62	\$801.62	\$801.62
80414	Testosterone response	\$42.26	\$0.00	\$42.26	\$42.26	\$42.26	\$70.83	\$63.75	\$57.37	\$51.64
80415	Estradiol response panel	\$40.60	\$0.00	\$40.60	\$40.60	\$40.60	\$76.66	\$68.99	\$62.09	\$55.89
80416	Renin stimulation panel	\$209.32	\$0.00	\$209.32	\$209.32	\$209.32	\$181.02	\$209.32	\$209.32	\$209.32
80417	Renin stimulation panel	\$38.89	\$0.00	\$38.89	\$38.89	\$38.89	\$60.34	\$54.31	\$48.88	\$43.99
80420	Dexamethasone panel	\$161.88	\$0.00	\$161.88	\$161.88	\$161.88	\$98.83	\$161.88	\$161.88	\$161.88
80422	Glucagon tolerance panel	\$40.94	\$0.00	\$40.94	\$40.94	\$40.94	\$63.20	\$56.88	\$51.19	\$46.07
80424	Glucagon tolerance panel	\$34.69	\$0.00	\$34.69	\$34.69	\$34.69	\$69.27	\$62.34	\$56.11	\$50.50
80426	Gonadotropin hormone panel	\$133.40	\$0.00	\$133.40	\$133.40	\$133.40	\$203.58	\$183.22	\$164.90	\$148.41
80428	Growth hormone panel	\$59.53	\$0.00	\$59.53	\$59.53	\$59.53	\$91.50	\$82.35	\$74.12	\$66.70
80430	Growth hormone panel	\$129.33	\$0.00	\$129.33	\$129.33	\$129.33	\$107.66	\$129.33	\$129.33	\$129.33
80432	Insulin suppression panel	\$165.61	\$0.00	\$165.61	\$165.61	\$165.61	\$185.32	\$166.79	\$165.61	\$165.61
80434	Insulin tolerance panel	\$285.03	\$0.00	\$285.03	\$285.03	\$285.03	\$138.78	\$285.03	\$285.03	\$285.03
80436	Metyrapone panel	\$69.35	\$0.00	\$69.35	\$69.35	\$69.35	\$125.05	\$112.55	\$101.29	\$91.16
80438	Trh stimulation panel	\$41.59	\$0.00	\$41.59	\$41.59	\$41.59	\$69.15	\$62.24	\$56.01	\$50.41
80439	Trh stimulation panel	\$33.07	\$0.00	\$33.07	\$33.07	\$33.07	\$92.20	\$82.98	\$74.68	\$67.21
G0471	Ven blood coll snf/hha	\$5.00	\$0.00	\$5.00	\$5.00	\$5.00	\$5.00	\$5.00	\$5.00	\$5.00

**Final CLFS:** The CY 2018 payment rate for HCPCS 83037 has been reduced from \$22.50 to \$11.99.

#### 4. Removal of General Health Panel Code (HCPCS 80050)

**Situation:** HCPCS 80050, a bundled code that includes a comprehensive metabolic panel (HCPCS code 80053), thyroid stimulating hormone test (HCPCS code 84443) and a complete blood count (HCPCS code 85025), is not payable under Medicare.

**Preliminary CLFS:** CMS listed 80050 as a payable code.

**Final CLFS:** HCPCS 80050 has been removed from the list of payable codes. 

## CLIA Corner: FDA Moves to Boost CLIA Waiver Transparency

The CLIA standards that a lab must meet are based on the complexity of the *in vitro* diagnostic tests it performs. The FDA's primary role in the CLIA system is to categorize IVDs.

Test Category	Get CLIA Certificate	Meet Quality Standards	Submit to Routine Inspections
Moderate complexity	✓	✓	✓
High complexity	✓	✓	✓
Waived	✓		

Last month, the FDA did two things to enhance the transparency of its CLIA activities.

### 1. Revised Categorization Guidance

The FDA issued updated guidance providing more details about the procedures it will use to categorize IVDs and respond to applications for CLIA waivers. Key details:

- ▶ The FDA will try to notify sponsors of an approved IVD's categorization within two weeks of approval;
- ▶ IVDs approved for home or over-the-counter use will be waived automatically;
- ▶ Makers of IVDs categorized as moderate complexity can apply for a CLIA waiver;
- ▶ To get the waiver, the maker must use clinical and flex studies to show that the test is simple to use and poses "insignificant risk of an erroneous result."

### 2. Publication of CLIA Waivers

The FDA also launched a pilot program to publish summaries of its CLIA Waiver by Application (CW) decisions. In addition to enabling the public to see how the FDA reviewed the data, publishing the decision summaries will help test makers prepare their future CW applications, according to the agency. 

## OIG Work Plan Monthly Review: November 2017

The OIG added four new items to its Work Plan this month, all of which have potential indirect effects on clinical labs involved in providing the targeted services.

### 1. Opioids in Medicaid: Concerns about Extreme Use and Questionable Prescribing

**Concern:** Medicaid beneficiaries are particularly vulnerable to opioid abuse and overdose deaths because they are more likely to have chronic conditions and comorbidities requiring pain relief, especially if they qualify for Medicaid due to a disability.

**What OIG Will Investigate:** The OIG will identify cases in which beneficiaries may have gotten extreme amounts of opioids through Medicaid as a result of shopping for doctors, pharmacies or other prescribers. The agency will use the results as baseline data for identifying both beneficiaries who receive extreme amounts of opioids and providers with questionable opioid prescribing patterns.

The OIG will review selected States' Medicaid payments for tele-services to ensure that they are on the level.

## 2. Medicaid Services Delivered Using Telecommunication Systems

**Concern:** The OIG notes that there has been a “significant increase” in Medicaid claims for telemedicine, telehealth and telemonitoring services.

**What OIG Will Investigate:** The OIG will review selected States' Medicaid payments for tele-services to ensure that they are on the level. Items the agency is likely to check:

- ▶ Qualifications and use of facility site codes by the originating site;
- ▶ Whether all services billed were covered;
- ▶ Use of POS codes and modifiers by the distant site;
- ▶ Whether the rendering provider was an eligible distant site provider;
- ▶ Compliance with geographic location requirements for tele-services; and
- ▶ Whether the technology used met the applicable audio and visual requirements.

## 3. Medicare Claims on Which Hospitals Billed for Severe Malnutrition

**Concern:** There are three Diagnosis Related Groups (DRGs) for hospital inpatient treatment of malnutrition based on the severity of the condition—mild, moderate or severe. Severe malnutrition is classified as a major complication or comorbidity (MCC). And adding an MCC to a Medicare claim can result in a higher Medicare payment because the claim is coded at a higher DRG.

**What OIG Will Investigate:** The OIG will review whether providers are using the proper DRG codes for severe malnutrition to ensure that no up-coding is taking place.

## 4. Use of Funds by Medicaid Managed Care Organizations

**Concern:** Managed care accounted for over 40% of total Medicaid payments in 2015 and that rate continues to grow. Capitation in which Managed Care Organizations (MCOs) receive a pre-determined rate for each enrollee regardless of actual services rendered is one of the methods Medicaid uses to control Medicaid costs.

**What OIG Will Investigate:** The OIG will review whether Medicaid MCOs are spending their capitation payments to provide quality medical services, including lab tests, to enrollees. 

## The 10 Assumptions NOT to Make when Doing Your OSHA 300s

**D**ecember is here and it's time for the logs. No, not the yule logs—the OSHA 300 logs! It's time to get the year's injury and illness records in order and start getting the OSHA 300A ready for the Feb. 1 filing deadline—that is, of course, unless yours is among the labs exempt from OSHA reporting requirements. As you set about your task, here are 10 OSHA 300 assumptions you want to avoid at all costs.

### Bad Assumption #1: We Should Record *Everything* Just to Be Safe

**The Truth:** Although underreporting can lead to citations, over-reporting can also get you into trouble because it artificially inflates your illness and injury rates. In addition to higher workers' comp premiums, that may make your lab a target for OSHA enforcement programs aimed at facilities with above-industry average rates.

**What to Do:** Erring on the side of caution is all well and good. But make sure you record only illnesses and injuries that meet the OSHA criteria, i.e., that:

- ▶ Are work-related; and
- ▶ Are new cases you haven't reported before; and
- ▶ Result in at least one of the following:
  - Death;
  - Days away from work;
  - Restricted work or transfer to another job;
  - Medical treatment *beyond* first aid;
  - Loss of consciousness; or
  - Significant injury or illness diagnosed by a physician or licensed healthcare professional.

### Bad Assumption #2. We Don't Have to Record Injuries that Aren't Our Fault

**The Truth:** OSHA 300 recordability is no-fault. *Translation:* Illnesses/injuries may be recordable even if they're sustained in bizarre accidents, result from deliberate misconduct on the part of an employee, or are otherwise “not your fault.”

**What to Do:** Record *all* illnesses and injuries that meet OSHA criteria, i.e., see list above.

### Bad Assumption #3: We Don't Have to Record Injuries Not Covered by Workers' Comp

**The Truth:** OSHA and workers' comp follow different rules for recording injuries and illnesses.

**What to Do:** It's okay to use the workers' comp reporting form instead of the OSHA 300 as your template the way many labs do. Just be sure that the criteria for recordability listed on the form come from OSHA and not your state's workers' comp board.

### Bad Assumption #4: We Don't Have to Record Injuries to Temps

**The Truth:** Temps *are* “covered employees” for whom illness/injury records must be kept under [Sec. 1904.31](#) of the OSHA Recordkeeping standard.

**What to Do:** The real issue is not if a temp’s injury/illness is recordable but who is responsible for recording it—the host lab or temp agency that placed the temp at the lab. Rule: You must do the reporting if you supervise the temp’s work on a day-to-day basis, i.e., exercise control over the details, means, methods and processes by which work is carried out.

### Bad Assumption #5: We Don’t Have to Record Aggravation of Injury that a Doctor Says Is Non-Work-Related

**The Truth:** Aggravation at work of a non-work injury/illness is recordable if it’s “significant.” But problems can arise because of the disconnect between doctors and OSHA on what “work-related” means. To a doctor, an injury primarily caused by something outside work may not be “work-related” just because it gets tweaked at work. But for OSHA, such tweaking *would be* deemed “significant” enough to make it work-related to the extent it occurs as a result of a discrete work event.

**What to Do:** When asking doctors for an opinion, make sure they consider aggravation on the basis of the OSHA definition of work-relatedness.

### Bad Assumption #6: Treatment Is “First Aid” because It’s Advertised as Such

**The Truth:** Under the OSHA Standard, injuries/illnesses are recordable if the victim gets medical treatment “beyond first aid.” Sec. 1904.7(b)(5) lists the treatments defined as “first aid”:

#### First Aid Treatments

- ▶ Using a non-prescription medication at nonprescription strength (for medications available in both prescription and non-prescription form, a recommendation by a physician or other licensed health care professional to use a non-prescription medication at prescription strength is considered medical treatment for recordkeeping purposes);
- ▶ Administering tetanus immunizations (other immunizations, such as Hepatitis B vaccine or rabies vaccine, are considered medical treatment);
- ▶ Cleaning, flushing or soaking wounds on the surface of the skin;
- ▶ Using wound coverings such as bandages, Band-Aids™, gauze pads, etc.; or using butterfly bandages or Steri-Strips™ (other wound closing devices such as sutures, staples, etc., are considered medical treatment);
- ▶ Using hot or cold therapy;
- ▶ Using any non-rigid means of support, such as elastic bandages, wraps, non-rigid back belts, etc. (devices with rigid stays or other systems designed to immobilize parts of the body are considered medical treatment for recordkeeping purposes);
- ▶ Using temporary immobilization devices while transporting an accident victim (e.g., splints, slings, neck collars, back boards, etc.);
- ▶ Drilling of a fingernail or toenail to relieve pressure, or draining fluid from a blister;
- ▶ Using eye patches;
- ▶ Removing foreign bodies from the eye using only irrigation or a cotton swab;
- ▶ Removing splinters or foreign material from areas other than the eye by irrigation, tweezers, cotton swabs or other simple means;
- ▶ Using finger guards;
- ▶ Using massages (physical therapy or chiropractic treatment are considered medical treatment for recordkeeping purposes); or
- ▶ Drinking fluids for relief of heat stress.

**What to Do:** Note that treatments advertised as “first aid” are not on the list and that the above treatments aren’t just examples of “first aid”—they’re the *entire list*.

### Bad Assumption #7: Injuries Aren't Recordable as a Work Restriction If Employee Can Still Do Useful Work

**The Truth:** Injuries/illnesses result in a “work restriction” where your lab keeps or a licensed health care professional recommends that employee not perform one or more of the “routine functions” of their job, a work activity regularly performed at least once a week.

**What To Do:** Recognize that work restrictions aren't defined by the usefulness of the injured employee's post-injury work but how it compares to his/her pre-injury job functions. So, for example, assigning office work to a warehouse employee who can no longer lift materials as he did every day before he got hurt won't get you out of recording the injury as a work restriction.

### Bad Assumption #8: Light Duty Doesn't Count as a Work Restriction

**The Truth:** According to OSHA, light duty not only *can be* but is *presumed to be* a work restriction that must be recorded.

**What To Do:** If a doctor recommends light duty, treat the case as a work restriction unless you can get the doctor to expressly state that the employee *can* perform all his/her routine job functions. Or, if you're not clear exactly what the doctor is recommending, follow up and ask about what the restriction means. *The best approach:* Ask the doctor directly which, if any, of the employee's routine tasks he/she shouldn't perform. Treat the injury as a recordable restricted work case if:

- ▶ At least one of the employee's routine job functions is on the list; or
- ▶ You can't get specific information from the doctor on the tasks the routine tasks the employee can't perform.

### Bad Assumption #9: The Day the Employee Gets Hurt Counts as a Restricted Work/Lost Day

**The Truth:** Lost/restricted work days are counted from the day *after* the employee gets hurt.

**What To Do:** When an employee suffers a work-related injury leading to lost or restricted work, start the lost/restricted days count on the day following the injury. *Exception:* If an employee is placed on restrictions or lost days for the first time several days *after* the injury occurs, start the count immediately starting with the day the orders were written.

### Bad Assumption #10: Lab Shutdown Days Don't Count as Lost/Restricted Work Days

**The Truth:** They sure do. The OSHA rules for counting restricted/lost work days make no exception for days a company is shut down.

**What To Do:** Be sure to count shutdown days toward the employee's lost/restricted work day total.

*Takeaway: In addition to the usual travails that come with annual OSHA 300 obligations, this year you'll also have to do with the new electronic reporting/recording rules that just took effect. See [GCA, May 15, 2017](#), for the details.* 

# Labs IN COURT

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

## Opioid-Subscribing Doctor Convicted for Lab Referral Kickbacks

**Case:** Two doctors at a Maryland pain management clinic took kickbacks to prescribed pain relief medications and referral of urine tests to a New Jersey lab. Six defendants were charged in the scheme: four pled guilty; one, a doctor, committed suicide, and the other, also a doctor, decided to take his chances with a jury. It turned out to be a bad decision. He was convicted of 26 felony charges and now faces up to 99 years in prison.

**Significance:** This case is very typical of what we have seen all year and why 2017 will be remembered as the year that the opioid drug crusade took over federal health care fraud enforcement. This summer, the Department of Justice unleashed a potent nationwide crackdown on opioid drug abuse,

both illegal and prescription. While labs and physicians are not necessarily the primary target, they are well within the range of potential suspects to the extent that urine testing plays a key role in detecting prescription opioid abuse.

## Unnecessary Lab Drug Testing of Opioid Addicts Focus of \$2.2 Million Scam

**Case:** The year of the opioid crackdown continues. The most recent scheme involves a South Florida network that offered free rent and other kickbacks to physicians in exchange for referrals of insured drug addicts to reside in their sober homes. Residents were then subjected to regular drug testing. Four defendants were involved, including the network medical director who was sentenced to 48 months in prison and one year of supervised release. And as is becoming increasingly common in these cases, the doctor had to pay \$2.198 million to make restitution for the money he stole.

**Significance:** While opioid scams involving drug tests have become common fare, this one seems to have been particularly egregious. The medical director created a drug testing regimen for each resident, including many he never actually examined, based on the bribes he got from the testing lab. He then used higher paying codes to bill Medicare for the exams. Adding insult to injury, residents were allowed to continue doping as long as they kept their mouths shut. 

## Medicare Exclusions: One Week, Two Different Labs Get the Boot

**E**xclusion of a clinical lab from participating in Medicare or other government health programs is a relatively rare penalty. But last month, there were two of them reported in the span of less than a week.

### The Prohealth Exclusion

On Oct. 24, an independent lab in Southern California called Prohealth Neurodiagnostic, Inc. and its owner agreed to a five-year exclusion. *The allegation:* Prohealth allegedly billed for nerve conduction studies that the medical necessity provisions of its Local Coverage Determination listed as screening exams and thus not covered by Medicare.

### The Total Lab Care Exclusion

Five days earlier, Total Lab Care, LLC accepted permanent exclusion from all federal health programs. *The allegation:* The Jacksonville, Florida lab billed for testing urine toxicology samples referred by a physician to whom it paid improper financial remuneration. 

■ **CMS Finalizes Hospital Outpatient Prospective Payment Changes for 2018, From Page 1**

- ▶ The doctor orders the test at least 14 days after a patient is discharged from the hospital;
- ▶ The specimen is collected during a hospital surgical procedure;
- ▶ Collecting the sample at another time would be medically inappropriate;
- ▶ Test results don't guide treatment provided during the hospital stay; and
- ▶ The test is reasonable and necessary for treating an illness.

**Practical Impact:** This so-called “14-day rule” is a big deal because when it applies, the test must be paid separately under Part B. If the rule doesn't apply, the test is bundled into the payment for the hospital stay. All of this poses big problems for labs when testing takes place after tests are ordered and specimens collected but before the 14-day window closes, which is a very common scenario with molecular and genomic panel and cancer testing.

**Change:** Responding to concerns that the 14-day rule is overly confusing and chills hospitals from billing for tests provided by outside labs, CMS has carved out exceptions that would allow labs to bill Medicare directly under the CLFS for certain molecular pathology tests and advanced diagnostic laboratory tests (ADLTs—aka multianalyte algorithm assays (MAAAs)), i.e., advanced tests performed at a single lab that use a proprietary algorithm to analyze multiple markers, and molecular pathology tests. The exclusion will not lead to unbundling abuses, CMS reasons, because these tests “can legitimately be distinguished from the care the patient receives in the hospital.”

**What It Means:** The problem will be figuring out exactly what qualifies as an ADLT. Part of the confusion is that there are different tests for ADLTs, one for PAMA and the other for the new DOS rules:

- i. *Under PAMA*, tests are subject to separate reimbursement as ADLTs if:
  - ▶ They are offered and furnished by a single lab; AND EITHER
    - Are approved by the FDA; or
    - Evaluate a patient's DNA, RNA or proteins; AND provide new clinical diagnostic information that cannot be obtained from any other test or combination of tests; AND Use a unique algorithm that predicts the chance the patient will develop a condition or respond to a treatment condition or respond to a treatment.
- ii. *Under the DOS exemption*, tests qualify as ADLTs exempt from the 14-day rule if:
  - ▶ They are offered and furnished by a single lab; AND
  - ▶ Evaluate a patient's DNA, RNA or proteins; AND provide new clinical diagnostic information that cannot be obtained from any other test or combination of tests; AND Use a unique algorithm that predicts the chance the patient will develop a condition or respond to a treatment condition or respond to a treatment.

In other words, ADLTs that are FDA approved may meet the PAMA exemption for separate billing but not the HOPPS DOS exemption.

## TAKEAWAY: SCOPE OF NEW EXEMPTION FOR ADLTs, MAAAs

### Tests that Can Be Billed Separately

- ▶ ADLTs approved by the FDA and provided by a single lab (under PAMA but not necessarily separately billable under HOPPS)
- ▶ Molecular pathology tests

### Tests that Must Be Bundled

- ▶ ADLTs that are not FDA-approved
- ▶ Protein-based MAAAs that are not deemed molecular pathology tests
- ▶ Genomic sequencing procedures (GSPs)
- ▶ Tests with Proprietary Laboratory Analyses (PLA) codes

## 2. 2018 OPSS Payment Rates

After last year's 1.65% increase, CMS is hiking overall OPSS rates for 2018 by 1.35% based on the following factors:

- ▶ Market basket update of +2.7%;
- ▶ Productivity adjustment of -0.6%;
- ▶ Update for ACA payment cuts of -0.75%.

Overall, CMS estimates that OPSS payments will increase by 1.4% during CY 2018.

## 3. 2018 ASC Payment Rates

The final rule increases Ambulatory Surgical Center (ASC) payment rates an average of 1.2% based on:

- ▶ Consumer Price Index update factor of +1.7%; and
- ▶ Multi-factor productivity adjustment of -0.5%.

Overall, CMS estimates that ASC payments will increase by 3.0% during CY 2018.

*Takeaway: The term "final rule" is a bit of a misnomer since CMS is legally required to take comments for 60 days after the rule's Nov. 1, 2017 publication.* 



## GET THE LATEST ON COMPLIANCE

### Lab Compliance Essentials 2017: Managing Medicare Fraud & Abuse Liability Risk

Avoid catastrophic financial fines and penalties! Whether you're a large laboratory with a robust compliance program and legal counsel on staff, or a small-to-mid size pathology group faced with navigating these murky waters alone, this guide delivers exclusive market intelligence and insight into compliance risks faced by labs and pathologists, while providing direction and guidance on how to minimize these risks.

Contact Jen at **1-888-729-2315** or [Jen@PlainLanguageMedia.com](mailto:Jen@PlainLanguageMedia.com) for details on this special offer.

COMPLIANCE CORNER

## Big Drop in Improper Medicare Payments

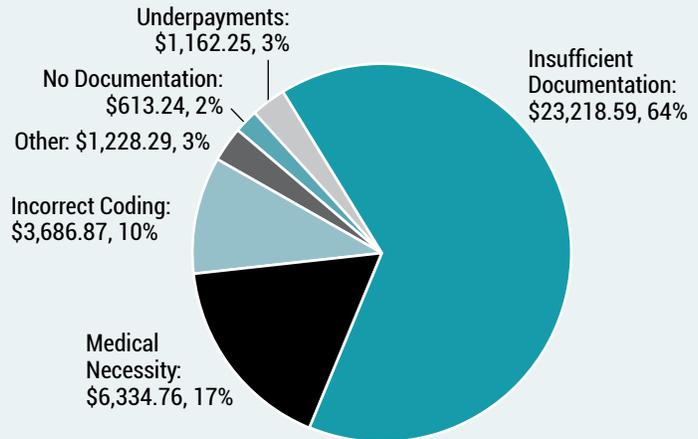
The rate of improper Medicare Fee-For-Service (FFS) payments dipped below the 10% threshold for the first time since 2013. Here are the key findings listed in the [Nov. 15 CMS report](#):

- ▶ **9.5%:** 2017 Medicare FFS improper payment rate;
- ▶ **11%:** 2016 Medicare FFS improper payment rate;
- ▶ **\$36.2 billion:** Total amount of 2017 Medicare FFS payments;
- ▶ **\$4.9 billion:** Total amount of 2017 improper payment decrease;

### Reasons for Improper Payments

Here are the reasons for improper FFS payments by percentage and dollar value:

Improper FFS Medicare FY 2017 Payments by Monetary Loss & Type of Error (in millions)



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