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INSIDE THIS ISSUE

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Upcoming Events

Lab Institute 2017
October 25-27
Hyatt Regency Washington on Capitol Hill, Washington, DC
www.labinstitute.com

Brief Your CEO: Help Your Lab Brace for Key Medicare Outpatient Reimbursement Changes

With the 2018 Clinical Laboratory Fee Schedule (CLFS) still in the works, CMS proposed changes to the Hospital Outpatient Prospective Payment System (HOPPS) rules on July 13. There are three items affecting laboratories that provide tests to Medicare patients on an outpatient basis that you should bring to the attention of your CEO (or CFO).

1. Revised Lab Date of Service Rules

Start your C-suite briefing with the part of the new HOPPS proposal that will probably have the most impact on your labs: CMS's proposed changes to the 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:

- 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.

Continued on page 10

Case of the Month: Theranos and Walgreens Bury the Hatchet—For Now

It all looked so promising back in 2015. Privately-held Theranos was poised to usher in a new era of diagnostics with its revolutionary fingerprick technology for performing a wide array of tests with just a few drops of blood. Walgreens was (and remains) the nation's largest retail pharmacy chain. So the arrangement to open independent "wellness centers" at Walgreens stores across Arizona and California seemed like a game changer, one that Walgreens hailed as the next step in its

Continued on page 2

Case Of The Month: Theranos and Walgreens Bury the Hatchet—For Now, From Page 1

"efforts to transform community pharmacy." Arizona's enactment of legislation empowering residents to order tests for themselves without a doctor's order was the icing on the cake.

Just 16 months later, it had all come undone. The Theranos Edison platform failed to meet its lofty expectations. Walgreens ended the partnership in July 2016; in November, it sued Theranos for $140 million claiming that it misrepresented the technology's capabilities. Meanwhile, the Centers for Medicare and Medicaid Services slammed Theranos and its CEO Elizabeth Holmes for a series of infractions at its Newark, CA, lab. The Arizona Attorney General joined the fray by bringing a consumer fraud lawsuit.

Theranos on the Settlement Path

After settling with CMS in April and Arizona in April, Theranos has now reached a tentative settlement agreement with Walgreens. Under the deal, which requires official court approval and is also reportedly still subject to negotiation, Theranos would pay Walgreens a sum south of $30 million.

THE THERANOS SETTLEMENT SCORECARD

$30,000: Agreed monetary penalty to CMS for CLIA violations at Newark lab (penalty reduced in exchange for agreement not to operate a lab for at least 2 years);

$4.65 Million: Reimbursement to Arizona residents for blood testing payments for services between 2013 and 2016 to settle state consumer fraud lawsuit;

Under $30 Million: Reported settlement with Walgreens for alleged misrepresentations regarding capabilities of Edison platform (subject to final approval);

Undisclosed: Amount for which Theranos has agreed to pay to settle a pair of securities fraud claims filed by a San Francisco hedge fund in connection with investment financing of $96.1 million.

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NEWS AT A GLANCE

The Latest Medicare Fraud Takedown: New Administration, Same Enforcement Strategy

Although the Obama Justice Department didn't invent coordinated health care fraud enforcement, it did advance the strategy more than any previous administration. So when the Trump crew took over, some wondered what it would portend for the strategy. Not much, as it turns out. The latest takedown the DOJ announced on July 13 is a clear illustration that collective enforcement remains alive and well.

Enforcement Records Broken—Again

Since its inception in March 2007, the Medicare Fraud Strike Force has charged over 3500 defendants for over $12.5 billion worth in false billings to Medicare, Medicaid and TRICARE. The nationwide takedown the DOJ announced at just about this same time last year set a new standard with "the most defendants charged and largest alleged loss amount in Medicare Strike Force history." That record has proven to be short lived. The new takedown results not only break but pulverize the 2016 records.

Metric	2017 Takedown	2016 Takedown
Federal districts participating	41	36
State Medicaid Fraud Control Units participating	30	23
Doctors, nurses and other health professionals charged	115	61
Total individuals charged	412	301
Total false billings involved	$1.3 billion	$900 million

Where Are All the Lab Cases?

For laboratories, the big story of the takedown is not so much the volume of enforcement activity but relative lack of activity targeting labs. Most of the takedown allegations were against providers of home health, mental health, physical/occupational therapy, durable medical equipment and prescription drug-related services. The DOJ report cites only one case specifically involving labs—an alleged fraudulent lab testing scheme involving 10 individuals in Missiouri.

Still, while not specifically targeting labs, the takedown focuses on violations that have been associated with labs, including submitting claims for services that weren't medically necessary or even performed, paying kickbacks for beneficiary information used for making false claims and allowing nonqualified individuals to perform services billed to Medicare, Medicaid and TRICARE. Another common pattern: charges against medical professionals for the unlawful distribution of opioids and other prescription narcotics.

Local Results

Here's a rundown of key results from different Strike Force locations participating in the takedown:

- **Southern District of Florida:** Total of 77 defendants charged for $141 million in false billings for home health care, mental health services, pharmacy and other services, including over $58 million for drug treatment services;
- **Middle District of Florida:** 10 individuals charged with participating in schemes involving almost $14 million in fraudulent billing;
- **Eastern District of Michigan:** 32 defendants charged for fraud, kickback, money laundering and drug diversion schemes involving approximately $218 million in false claims for services that were medically unnecessary or never provided;
- **Southern District of Texas:** 26 individuals charged in cases involving over $66 million, including a physician and clinic owner indicted for illegally distributing controlled substances and three substantive counts of distribution of controlled substances from a purported pain management clinic claimed to be the highest prescribing hydrocodone clinic in Houston;
- **Central District of California:** 17 defendants charged in alleged schemes to defraud Medicare out of approximately $147 million;
- **Northern District of Illinois:** 15 individuals charged in six different schemes concerning home health care services and physical therapy fraud, kickbacks, and mail and wire fraud allegedly involving over $12.7 million in false billing;
- **Eastern District of New York:** 10 individuals charged with participating in schemes involving over $151 million in fraudulent billing, roughly $100 million of which involved payment of illegal kickbacks by five health care professionals in exchange for patient referrals to their own clinics.

In addition to the state Strike Force locations, 31 U.S. Attorney's Offices from across the country participated in the takedown, including Alabama (Northern and Southern Districts), Arkansas (Eastern District), California (Northern and Southern), Connecticut, Georgia (Northern and Southern), Illinois (Southern), Indiana (Northern and Southern), Iowa (Southern), Kentucky (Western), Maine, Missouri (Eastern and Western), Nebraska, Nevada, New York (Northern, Southern and Western), Ohio (Southern), Tennessee (Eastern), Texas (Eastern, Northern and Western), Utah, Virginia (Eastern) and Puearge;

Takeaway: The latest takedown is an unambiguous signal that the new administration will continue and even step up coordinated federal and state government enforcement activity. It also reinforces previous patterns indicating that, while not forgotten, labs now share the enforcement bullseye with other providers including prescription drugs, medical equipment and home health.

Enforcement Trends: OIG Switches from Semi-Annual to Monthly Work Plan Strategy

New OIG Work Plans every six months are a thing of the past. In June, the agency announced plans to update its Work Plan website monthly. The self-proclaimed "dynamic," web-based strategy is intended to "enhance transparency" of OIG's enforcement efforts and make it easier for labs and other providers to "respond to emerging [fraud and abuse] issues" more effectively.

Navigating the New OIG Work Plan Website

Under the new regime, the key to staying up to date will be to navigate the OIG Work Plan website, which will now be organized into three categories:

- **Recently Added**, containing new items for the month;
- **Active Work Plan Items**, into which the Recently Added items will be shifted after a month and remain until the OIG deems them "complete"; and
- **Work Plan Archive**, containing Work Plan reports dating back to 1997.

The First New Monthly Updates

Key new enforcement initiatives in the first monthly Work Plan updates of June and July that may affect labs include review of:

- Medicare payments for nonphysician outpatient services provided under the inpatient Prospective Payment System;
- Medicare claims for telehealth services provided at a "distant site," i.e., the practitioner's location, that don't have corresponding claims for the "originating site," i.e., the beneficiary's location; and
- Quality data reported by Accountable Care Organizations that have received earned share savings payments under the Medicare Shared Savings Program to ensure compliance with quality measures data reporting rules.

Takeaway: The need to adjust your lab's fraud and abuse compliance efforts to address new OIG Work Plan enforcement initiatives is nothing new. But from now on, you'll have to assess the need for such adjustments on a monthly rather than semi-annual basis.

GCA to Provide Regular OIG Work Plan Updates

GCA will begin including regular OIG Work Plan reports in each monthly issue to help you track the latest twists and turns in OIG enforcement strategy without having to navigate the OIG's website.

Do No Harm: Diagnostic Errors and the Lab

By Jennifer (McMahon) Dawson, MHA, DLM (ASCP)

"Do no harm" is the mantra that health care providers live by. Doctors, nurses and laboratory professionals alike enter into the business of health care because they are motivated to help people.

We can all agree that the identification of diagnostic errors in medicine is critical to improving patient safety; however, that's easier said than done.

Why Mistakes Happen

Why then do 5% of adults in the U.S. experience diagnostic error annually in outpatient settings at the hands of these well-meaning providers?[1] Humans work in health care. Where humans are involved, there will be mistakes.

There's also a certain level of trial-and-error that's acceptable in the diagnosis of patients. Lab professionals often feel removed from the actual diagnosis of the patients that they serve.

The Role of Labs

Labs play a critical role as lab testing is often used to confirm initial impressions or rule out differential diagnoses. An estimated 70% of all health care decisions affecting diagnosis or treatment involve lab testing[2] and at least 10% of all diagnoses are not considered final until lab testing is complete.[3,4]

We can all agree that the identification of diagnostic errors in medicine is critical to improving patient safety; however, that's easier said than done. Historically, the lab industry has focused its quality improvement efforts within boundaries of the lab. We have been lab-centric in this respect and have not focused on collaboration with other members of the care team or patient outcomes.

The lab has been very good at detecting and eliminating errors in the analytical phase. Less focus has been placed on identifying and remedying errors outside of the analytical phase, particularly those that occur outside the boundaries of the lab (pre-pre and post-post-analytical).

For the lab to have a positive impact on diagnostic errors, it must become part of the interdisciplinary patient-centered care team. Lab professionals need to view their services as contributing to patient outcomes, not just generating results.

Research on diagnostic errors and the lab's role has found that failure to order appropriate diagnostic tests, including lab tests, makes up 55% of missed and delayed diagnoses in the ambulatory setting and 58% of errors in emergency departments.[5] We know that health care providers don't understand our tests as well as we do. This statistic underscores the need for Clinical Lab Scientists to interact with and provide education to ordering providers on the proper use of the testing we provide.

Ways Labs Can Reduce Dx Errors

One way that clinical lab professionals can affect positive change is by collaborating with other health care providers to establish evidence-based decision-making guidance for ordering tests. Providing feedback to providers detailing improper test utilization patterns, both over- and under-utilization, is another way that lab professionals can help to reduce diagnostic errors. Other ways the labs can help reduce diagnostic errors include reflexive testing, consultative services and improved test reporting.

The identification of diagnostic errors to which the lab has contributed is a crucial piece of the puzzle in our effort to improve patient safety and outcomes.

Unfortunately, standardized feedback systems and reliable evidence-based decision support mechanisms do not yet exist on a large scale. In the meantime, we are reliant largely on our non-conforming event management systems to capture diagnostic errors. The success of these systems, whether you choose a manual or electronic option, is contingent on the establishment of a reporting culture.

A reporting culture is a culture of trust where employees feel safe, supported and comfortable pointing out errors, which may include their own, in the interest of patient safety and continuous improvement. The types of errors captured will include lab errors, errors generated outside the confines of the lab and near misses. A near miss is "any event that could have had an adverse patient consequence, but did not, and was indistinguishable from a full-fledged adverse event in all but outcome." [6] A near miss is the perfect quality improvement opportunity, as we have the opportunity to eliminate the root cause before a patient is harmed. It is only after we are made aware of an event or near miss that a root cause analysis and corrective action can be formulated to prevent the event's recurrence.

The identification of diagnostic errors to which the lab has contributed is a crucial piece of the puzzle in our effort to improve patient safety and outcomes. The lack of comprehensive information on the incidence of diagnostic errors should not prompt us to conclude that these errors are uncommon or unavoidable.[7]

In addition to the patient safety benefits, the shift from fee-for-service to value-based purchasing is already requiring us to become more patient-centric and outcomes-focused. This way of thinking is in line with the way we will be reimbursed in the future. The lab can help to reduce diagnostic errors by focusing on becoming more patient-centered, educating providers on lab testing, providing consultative services, initiating feedback loops that extend beyond the walls of the lab and ensuring that we have an effective non-conformity management system.

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The 5 Things You Should Never Say to an OSHA Inspector

The way you handle an OSHA inspection can have as much impact on the outcome as the actual health and safety condition of your lab. More precisely, the things your front line employees do and say when they cross paths with the OSHA inspector can have unexpected and disastrous liability consequences. This is especially true when the inspector points out a potential problem. Here are five statements you never want your staffers to utter to an OSHA inspector.

1. "I warned management about that problem"

Passing the buck to the higher-ups is a natural first instinct, especially if employees actually did try to sound the warning bells. But in the OSHA realm, violations are a lot worse when they are "willful." And violations are considered willful when you are aware of them but don't take steps to fix them. So if employees let OSHA inspectors know that management was warned, it significantly increases your lab's liability risks.

2. "We have a procedure to prevent the problem but nobody ever follows it"

A safety procedure that's not enforced can be just as damning as not having a policy at all because it suggests that your safety program is a charade that isn't taken seriously. And that makes your lab more likely to receive a willful citation.

3. "We tried to fix the problem but it didn't work"

To an OSHA inspector's highly attuned ears, the message of this statement is that you recognized that there was a safety problem and took it seriously enough to try and correct it. But you failed to determine whether that measure was effective. It's a serious compliance issue.

4. "We just can't afford to fix the problem"

OSHA rules tend to be prescriptive but not specific. They list the hazards you need to control but do not specify the exact methods how. They also give you leeway to consider costs in deciding on measures as long as you reasonably determine that less expensive controls will work just as well. But what you cannot do is ignore a problem on the basis of costs.

5. "That's the way all the labs do it"

Industry standards may be relevant in deciding how to handle particular hazards. But following an industry standard in lieu of an OSHA requirement is never an option. Never. Suggesting that it is the most surefire way to get under the skin of an OSHA inspector.

Brief Your CEO: Help Your Lab Brace for Key Medicare Outpatient Reimbursement Changes, *from page 1*

Explain that the "14-day rule" is significant because when it applies, the test is paid separately under Part B. If the rule doesn't apply, the test is bundled into the payment for the hospital stay.

Proposed Change: Let your CEO know that CMS is proposing to carve out exceptions to the 14-day rule that would allow labs to bill Medicare directly under the CLFS for certain molecular pathology tests and advanced diagnostic laboratory tests (ADLTs), towit tests that are:

i. Excluded from OPPS packaging rules; and
ii. Ordered *less than* 14 days after a patient's hospital discharge.

The DOS for the excepted tests would be the date of testing rather than specimen collection. Explain that the change is just a proposal at this point and that CMS will issue final rules after collecting public comments.

2. 2.0 Percent OPPS Rate Hike

The other two issues worth covering in the briefing are the proposed HOPPS fee increases. First, let the CEO know that CMS is proposing a 2018 OPPS fee schedule rate increase of 1.75 percent. Explain that the increase is based on a projected 2.9 percent increase in the hospital market basket, minus two other adjustment factors:

- 0.4 percent adjustment for multi-factor productivity; and
- 0.75 percent adjustment required by the Affordable Care Act (ACA).

Bottom Line: When combined with other proposed policy changes, hospitals would receive overall OPPS pay increases of 2.0 percent in 2018, according to CMS estimates.

3. 1.9 Percent ASC Rate Hike

Finally, tell the CEO that CMS has also proposed a similar increase in Ambulatory Surgical Center (ASC) payments based on a CPI urban consumers update of 2.3 percent minus both the 0.4 percent multi-factor productivity adjustment factor and mandatory ACA 0.75 percent adjustment.

Bottom Line: When combined with other proposed policy changes, ambulatory surgical centers would receive overall 1.9 percent ASC pay increases for lab and other covered outpatient services in 2018.

Takeaway: Most of the proposed HOPPS changes are positive ones for labs. But pathologists didn't make out as well. CMS specifically rejected an industry recommendation to create a pathology composite to pay claims with only multiple pathology services and no other separable payable services such as a clinic visit or surgical procedure. Accordingly, where multiple conditionally packaged services billed on the same claim, paying services will continue to be bundled and payment made on the basis of the highest single paying service.

Criteria for Direct Billing of Outpatient ADLTs

Under the CMS's proposal, labs could directly bill Medicare under the CLFS for ADLTs delivered to outpatients less than 14 days after hospital discharge if either of the following criteria applies:

Criterion 1: The test:

- Analyzes multiple biomarkers of DNA, RNA or proteins;
- When combined with an empirically derived algorithm, yields a result predicting the probability of an individual patient's development of a certain condition(s) or response to a particular therapy(ies);
- Provides new clinical diagnostic information that can't be obtained from any other test or combination of tests; and
- May include other assays

Criterion 2: The test is cleared or approved by the FDA.

Labs IN COURT

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

$115 Million Anthem Settlement Is Highest Ever for a Data Breach Lawsuit

Case: Anthem, the nation's second largest health insurer, has agreed to shell out $115 million to settle a class action lawsuit over a massive 2015 cyberattack in which hackers stole the names, addresses, birthdates, Social Security numbers and other personal information of roughly 78.8 million plan members and employees. Under the deal, the biggest settlement ever for a data breach, Anthem will furnish two additional years of credit protection monitoring to the individuals affected and set aside a $15 million fund to cover victims' out of pocket costs.

Significance: The settlement isn't just about money. It also requires Anthem to make specific improvements to its data security systems over a three-year period, including:

- Strict access requirements;
- Data retention periods;
- Mandatory information security training for associates; and
- Annual IT security risk assessments.

Health System Pays $6.5 Million to Settle Urine Test Upcoding Charges

Case: A lab director filed a whistleblower suit claiming that Carolinas Healthcare System upcoded what should have been "moderate complexity" urine screens to "high complexity" tests, resulting in overpayments of $80 per test. Carolinas denied the claims but when the government took over the case decided to settle for $6.5 million, $1.365 million of which will go to the whistleblower.

Significance: The damages could have been much higher but for the fact that Carolinas cooperated in the investigation. Another mitigating factor was that Carolinas had enlisted a pair of separate outside consultants to review its coding process, each of which gave the thumbs up. Accordingly, most of the $6.5 million was for restitution of the overcharges rather than penalties.

LabCorp Agrees to $45.4K CMP for Hiring Excluded Individual

Case: Laboratory Corporation of America agreed to pay $45,466 in Civil Monetary Penalties for allegedly hiring an employee that it knew or should have known had been excluded from participating in federal health care programs. The alleged offense, which LabCorp self-disclosed, took place at one of its Florida labs.

Significance: This is the third fine against a major lab in 2017 for a self-disclosed violation to the OIG:

- In February, Quest Diagnostics agreed to pay $315,093 for alleged kickbacks to a referral source in the form of above fair market rent payments by one of its New Jersey labs to a medical practice; and
- In March, Quest settled a trio of CMP offenses, two of which were Electronic Health Records-related for $1.151 million.

Lab Tech and Account Rep Face Jail for Test Fee and Commissions Scheme

Case: A pair of Texans face criminal charges for allegedly conspiring to cheat Medicare of nearly $837,000 over a 6-month period in 2015. The feds contend that the lab technician at a medical clinic misappropriated patient urine samples and secretly sent them to a toxicology testing

company at which his co-conspirator was the account representative to pocket commissions and testing fees. The two allegedly forged physician signatures and medical records to carry out the scheme.

Significance: The defendants have been charged with 8 counts of healthcare fraud each of which carries a maximum penalty of 10 years in prison and a $250,000 fine. They also face 9 counts of aggravated identity theft, at up to 2 years of prison a pop. And those latter years would have to be served consecutively to any jail time for healthcare fraud.

MD Practice Manager Fined, Jailed for Testing Ripoff

Case: The manager of an Oregon ophthalmology practice was fined $2.519 million and sentenced to a year and a day in prison for his role in a six-year scam targeting Medicare, private health insurers and even the IRS. The ophthalmologist, since deceased, who also happened to be the manager's father, performed medically unnecessary diagnostic tests and the manager sent out the invoices, often billing for tests that cost more than were actually performed and double billing insurers for the same test. As icing on the cake, the two concocted a scheme involving a straw company to conceal nearly $8 million in business revenue from the IRS and finance personal expenses including the construction of a posh home.

Significance: The manager was actually hit with a pair of fines--$1.702 million in restitution to Medicare, Care Oregon and several private health insurers and $817,378 to the IRS. And once he gets out of jail, he'll be subject to three years of supervised release.