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INSIDE THIS ISSUE

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New Laws: Very Quietly, Congress Doubles Penalties for Medicare Fraud & Abuse

Sneaky may be too strong a word. But what is fair to say is that the new hikes in federal health care fraud violation penalties have flown totally under the radar despite their obvious and immediate ramifications for labs, pathology practices and other providers. Here is the rundown of what you need to know.

How It Happened

As is often the case when significant amendments are made to existing legislation, the new penalty provisions were tacked onto a larger bill addressing a totally different topic—in this case, the new federal budget, aka the *Bipartisan Budget Act of 2018* (BBA) that was officially signed into law on Feb. 9, 2018.

Continued on page 2

Case of the Month: $33.2 Million Alere Settlement Sends Warning Shot Across Bow of LDT & DX Device Makers

One of the reasons Abbott Laboratories got cold feet about consummating the $5.3 billion Alere acquisition was concern over the legal proceedings against the target firm. Now one of those cases involving the Alere Triage point-of-care rapid testing device has settled for a cool $33.2 million. The significance of the case is not simply the price tag but what it may portend for other manufacturers of diagnostic devices and laboratory developed tests.

The Triage Recall...

Alere designed the Triage Device to diagnose acute coronary syndromes, heart failure, drug overdose, and other conditions. In 2012, the FDA investigated and reportedly issued three citations related to defects in the device:

- Significantly significant disparities between the actual cardiac Triage Device coefficient of variation (CV) specifications and the CV specifications listed on the product labeling;

Continued on page 10

New Laws: Very Quietly, Congress Doubles Penalties for Medicare Fraud & Abuse, *from page 1*

Which Laws Were Affected

Of course, funding the federal government is the perfect occasion for tweaking just about any and all activities the budget pays for, including enforcement of health care fraud and abuse laws. Among the laws amended by the BBA are the Civil Monetary Penalties Law (CMPL) and the Anti-Kickback Statute (AKS). (See the related story on page 3 to find out about BBA changes to the Stark Law.) If you want to look them up, the changes are contained in Section 50412 of the BBA.

Higher Civil Penalties Under the CMPL

The CMPL is the foundation of federal health care enforcement because it authorizes the OIG to impose civil monetary penalties and other punishments for Medicare and Medicaid fraud and abuses, including AKS and Stark Law offences. The CMPL lists a schedule of fines for different types of offenses. The BBA doubles (and in some cases more than doubles) those amounts:

New CMPL Civil Penalties

Offense Type	Previous Penalty	New Penalty(1)
Knowingly filing an improper claim for a medical or other item or service	Maximum of $10,000 per claim	Maximum of $20,000 per claim
Knowingly making or causing to be made a false statement, omission or misrepresentation of a material fact in any application, bid or contract to participate or enroll a federal health care program provider or supplier	Maximum $50,000 per false statement	Maximum $100,000 per false statement
AKS violation	$50,000 per violation	$100,000 per violation
Payments made to induce reduction or limitation of services(2)	Maximum $2,000	Maximum $5,000

NOTES:

(1) The numbers are actually less dramatic when you take into account that previous budgets mandated that penalty amounts be indexed for inflation

(2) In addition, some payments to induce reduction or limitation of services that once carried a $5,000 maximum were also increased to a $10,000 maximum

Higher Criminal Penalties Under the AKS

The BBA also jacks up the maximum criminal penalty for an AKS violation from $25,000 to $100,000 while doubling the maximum prison sentence from five to 10 years.

When the New Penalties Take Effect

The penalties went into effect on the same date that the BBA did, Feb. 9, 2018 and apply only to offenses committed on or after that date.

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Physician Referrals: New Rules Offer Some Stark Law Relief but Not Nearly Enough

Like most budget bills, the new federal *Bipartisan Budget Act of 2018* includes a number of changes to Medicare fraud and enforcement requirements. (See the related story on page 1 to find out about the new increases in penalties.) One set of changes affects the current physician referral rules under the Stark Law. So, to the extent you are owned by or do business with physicians (and what lab or pathology practice isn't?), you need to be on top of the changes.

The Context

The Stark Law, aka Physician Self-Referral Law, bans physicians from referring Medicare or Medicaid patients to labs in which the physicians or a family member have a financial relationship unless the transaction meets a specific exception. The Stark Law is what is known as a strict liability law. *Translation:* Just committing the banned action triggers liability regardless of whether you meant to or what your mental state was.

Over the years, many in the health care industry have contended that the law is too strict and that it throttles not only business but critical collaboration between physicians and labs (and, of course, other providers). Two years ago, Congress held hearings to discuss whether Stark should be rolled back to allow for value-based, coordinated health care service business models and arrangements. (To learn more, see *GCA*, Aug. 15, 2016.) On Jan. 17, 2018, CMS Administrator Seema Verma stated that an inter-agency review would tackle the issue of reducing Stark Law burdens.

Unfortunately, while they are intended to make Stark Law compliance simpler, the BBA changes are not the kind of fundamental reforms Congress was talking about back in 2016 or that Ms. Verma was hinting at in January. In fact, the changes are not even new rules so much as codification and clarification of *previous* changes. Still, they could very well have an impact on your current or future physician business arrangements. These are the three changes you need to be on top of:

1. Clarification of How to Meet the Writing Requirement

Several of the Stark Law exceptions allowing for compensation arrangements between physicians and referral sources require that there be a written agreement between the sides. The BBA change clarifies that the written agreement requirement does not necessarily mean a literal contract but may also be satisfied "by a collection of documents, including contemporaneous documents evidencing the course of conduct between the parties involved."

2. Clarification of How to Meet the Signature Requirement

Another common requirement of Stark Law compensation arrangements is the signature of the parties. The BBA change clarifies that the requirement can be satisfied if the parties obtain the necessary signatures "not later than 90 consecutive calendar days following the date on which the compensation arrangement became noncompliant" as long as the arrangement meets all

of the other applicable criteria. The reason this is something of a big deal is that the previous formulation in the Stark legislation was out of whack with the signature requirement language in the regulations. The BBA change fixes the problem so that now both the statute and regulation say the same thing.

3. Clarification of How to Meet Holdover Lease & Personal Service Agreement Exception

Stark Law exceptions allow for physicians to enter into leases (both office and equipment) and/or personal service arrangements with referral sources provided that the terms of the lease/service contract provide for fair, market value rent/compensation not reflecting the value of referrals. There are also provisions allowing for "holdovers," i.e., leases/service arrangements that continue in effect past the term stated in the written agreement, for up to six months. The BBA revokes the six-month limitation and clarifies that indefinite holdovers of office space or equipment leases and/or personal services arrangements are allowed provided that the following four conditions are met:

1. The immediately preceding arrangement expired after a term of at least one year (i.e., indefinite holdovers are not in play for short-term arrangements);
2. The preceding arrangement met all of the requirements of the exception when it expired (i.e., noncompliant arrangements do not qualify for indefinite holdover protection);
3. The holdover arrangement must be on the same terms and conditions as the previous arrangement; and
4. The holdover arrangement must continue to satisfy the applicable conditions of the exception.

Takeaway: The main significance of the BBA Stark Law changes is that they iron out inconsistencies between the Stark legislation and implementing regulations and clarify what the parties must do to meet some of the more problematic requirements of the exceptions. While this is a welcome and favorable development, it is a far cry from the fundamental reform and easing up of the Stark Law that the industry has been craving and that, given the political orientation of the current administration, might actually come to fruition in the not all too distant future.

Emerging Tests: Medicare to Cover Next Gen-Sequencing Tests for Advanced Cancer

In the PAMA era, there are two salient trends in Medicare Part B lab reimbursements:

- Sharply lower prices for traditional tests; and
- Wider coverage of newly emerging tests, including some that the FDA has not yet approved.

The second trend continued on March 16, when CMS finalized its draft National Coverage determination (NCD) expanding Medicare coverage of next-generation sequencing (NGS) cancer panels.

Coverage of Non-Approved NGS Cancer Tests

The NCD covers certain NGS tests for certain cancer patients for use in limited situations. Let's go through the basic coverage requirements one by one.

1. Patient Must Have "Advanced Cancer"

Under the NCD, NGS tests are approved only for patients with "advanced cancer," i.e., cancer that is:

- Recurrent;
- Metastatic;
- Relapsed;
- Refractory;
- Stage III; or
- Stage IV.

2. Two Approved Uses

The NCD approves NGS testing for advanced cancer for only two kinds of uses:

- As a companion diagnostic "to identify patients with certain genetic mutations that may benefit from" FDA-approved treatments. "These tests can assist patients and their oncologists in making more informed treatment decisions," the NCD explains; and/or
- To determine a patient's eligibility for cancer clinical trials when the patient doesn't have a cancer mutation that matches to an NGS treatment.

3. Tests Must Qualify

The third condition relates to the NGS test itself. Under the NCD, tests currently or subsequently approved or cleared by the FDA as an *in vitro* cancer companion diagnostic are fully covered (provided, of course, that the other NCD conditions are met). Currently available tests with the requisite FDA approval include two assays from Foundation Medicine (whose stock price increased 3% after the NCD was published):

Test	Manufacturer
FoundationOne CDx (F1CDx)	Foundation Medicine
FoundationFocus CDxBRCA	Foundation Medicine
Praxis Extended RAS Panel	Illumina
Oncomine Dx Target Test	Thermo Fisher Scientific

The NCD also expands automatic coverage for FDA-approved tests for repeat testing when a patient has a new primary diagnosis. In addition, tests that have not been FDA cleared or approved may be covered if the local Medicare Administrative Contractor decides to cover them.

Enforcement Trends: Feds Turn Up the Heat on False Billing of Nuclear Stress Tests

While the federal enforcement community has made urine drug testing of opioid drug patients its number one target for lab-related *False Claims Act* (FCA) charges for the time being, nuclear stress tests (NSTs) ordered by cardiologists have also been garnering increasing attention. There are three things about NSTs, which use radioactive dyes to measure blood flow to the heart both when the patient is resting and stressed either via exercise or chemical inducement, that put them high on the list of FCA enforcement priorities in the diagnostics sphere:

1. NSTs are very expensive;
2. They expose patients to significant doses of radiation; and
3. They can generate false positives resulting in the ordering of medically unnecessary invasive procedures.

NST coding irregularities were at the center of one of the largest diagnostic fraud cases of 2017—the $50+ million scam allegedly perpetrated by a cardiologist, neurologist and four others associated with a New York City medical practice this spring.

Routine Ordering of NSTs: The CVC Case

For these reasons, NSTs are deemed medically necessary for Medicare purposes only in very limited circumstances. So the ordering of NSTs at abnormally high rates routine raises a bright red flag.

CVC Heart Center, a California cardiology clinic, and its physician owners just learned this lesson the hard way. The U.S. Attorney charged the defendants with falsely billing Medicare and Medicaid for medically unnecessary NSTs over a five-year period beginning in 2010. According to the indictment, CVC physicians automatically scheduled annual NSTs for patients without actually seeing them to determine whether the test was actually needed in violation of Medicare medical necessity rules and a CMS Local Coverage Determination banning use of NSTs as a screening procedure. Last December, the physicians agreed to settle the case for $1.2 million rather than risk a trial.

NST Bundling: The NYC Case

Coding of NSTs may also raise FCA red flags. There are three possible CPT codes for billing the imaging part of the test:

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

NST coding irregularities were at the center of one of the largest diagnostic fraud cases of 2017—the $50+ million scam allegedly perpetrated by a cardiologist, neurologist and four others associated with a New York City medical practice this spring. Among other things, the defendants have been charged with NST coding abuses, specifically listing only one code for

"Nuclear Studies" in the practice's superbill: 78452. As a result, physicians were forced to indicate that they performed both a resting *and* stress study, even if they actually performed only one part of the study. (See *NIR*, June 19, 2017, for more details about the case.)

Takeaway: For clinical labs, none of this is new. Routine ordering, medical necessity and bundling of costly tests have been fundamental compliance challenges to labs for decades. However, now these same enforcement principles are being applied with increasing regularity to target not just NSTs but other elaborate diagnostic procedures.

Genetic Testing: Natera Settles Prenatal DNA Testing False Billing Claims for $11.4 Million

Before the opioid crackdown, false billing of genetic tests was the hottest thing in federal fraud enforcement against clinical labs. But while drug testing related to prescription opioids has stolen the spotlight (See *GCA* March 2018, for more), the recent case involving one of the nation's leading firms serves as a reminder that genetic testing remains very much on the radar of the DOJ and whistleblowers.

Natera's billing of Panorama was at the center of a significant new fraud case

Sequencing-Based Prenatal Screening

Current treatment guidelines recommend offering prenatal screening to *all* pregnant women in the early stages of gestation to detect fetal aneuploidy, i.e., the presence of an abnormal number of chromosomes in a cell. Two types of noninvasive, sequencing-based testing are commercially available for detecting fetal cell-free DNA fragments in maternal serum:

- Next-generation sequencing-based quantitative tests; and
- Targeted amplification tests capable of detecting single nucleotide polymorphisms (SNP), i.e., variations in a single base pair in one DNA sequence on targeted chromosomes in a single reaction.

The Suit against Natera

One of the leading SNP prenatal tests is Panorama, an assay produced by Silicon Valley-based Natera capable of detecting not only relatively common conditions involving extra genes associated with disorders like Down's Syndrome but microdeletions which are harder to detect and much rarer.

Natera's billing of Panorama was at the center of a significant new fraud case. It began when a pair of ex-Natera employees who worked with providers in administering follow-up tests detected by screening with Panorama filed a qui tam whistleblower lawsuit. Among other things, they claimed that Natera used a CPT code for DNA and chromosome analysis which the Medicaid, TRICARE and the Federal Employee Health Benefits cover instead of an SNP-based testing code which they do not cover to bill for the screenings. The government decided to intervene, charging Natera with $80 million in false billings over a four-year period.

The Settlement

Natera vigorously denied the allegations. But rather than risk a trial, Natera decided to settle the suit for $11.4 million, 19.6% of which will go to the whistleblowers. The terms:

- $5.3 million upfront;
- $5.3 million plus interest in four quarterly installments; and
- $756,183 to state Medicaid programs.

The settlement is also notable for what it did not include, namely an admission of guilt or a corporate integrity agreement. The absence of the latter is an indication that the government considered the alleged wrongdoing to be more mistake than malice.

Takeaway: False billing of genetic testing will remain a significant area of concern for lab compliance going forward (See the SCORECARD below). Adding to the challenge is that testing moves faster than billing and coding. Indeed, after the settlement Natera officials offered a plausible explanation of what went wrong, noting that when it first launched Panorama it had sought the advice of a "nationally recognized coding expert" for billing advice since there was no assay-specific code for the test at the time. (Now such a code does exist—CPT 81420.) And to the extent your lab bills for a newly emerging test that does not have its own CPT code, you face the same conundrum.

SCORECARD

Leading Whistleblower Suits for False Billing of Genetic Tests

CASE	STATUS/OUTCOME	ALLEGATIONS
Millennium Laboratories	$256 million settlement, 2015	False billing and paying kickbacks for referrals of medically unnecessary genetic tests provided to pain management patients
21st Century Oncology	$24.86 million settlement, 2015	False billing of medically unnecessary FISH tests to detect genetic abnormalities associated with bladder cancer
Bostwick Laboratories	$6 million+ settlement, 2015	False billing of medically unnecessary FISH tests to detect genetic abnormalities associated with bladder cancer
Pathway Genomics	$4.036 million settlement, 2016	Paying kickbacks for referrals of genetic tests
Prestige Healthcare	$1 million settlement, 2017	False billing genetic tests for nursing home patients that were not medically necessary or without a physician's order
Proove Biosciences	Still pending	False billing and paying kickbacks for referrals of medically unnecessary genetic tests provided to pain management patients

Tech Wars: Guardant & Foundation Make Sweet Lemonade Out of False Advertising Lemons

In June 2017, Guardant Health sued Foundation Medicine for making false statements about the Guardant360 test in its advertisements for the FoundationACT liquid biopsy genomic profiling test. Foundation denied the allegations and countersued, claiming that Guardant was the one making false statements about the tests in its advertising materials. But now cooler heads have prevailed with news that the sides have settled the case by asking that both claims be dismissed.

But what makes the settlement worthy of inclusion in this column are the proactive measures the sides agreed to take to turn an ugly situation into a positive, including the creation of:

- A process to quickly resolve any future advertising-related disputes between the companies; and
- A working group to study development of standard definitions and formulas validating genomic profiling assays.

Case of the Month: $33.2 Million Alere Settlement Sends Warning Shot, *from page 1*

- Unacceptably high variability in performing quality control testing of the device; and
- Changes to the manufacturing and release specifications for toxicology Triage Devices resulting in the market release of product lots containing products with potentially significant decreases in precision.

After the inspection the FDA issued a mandatory nationwide recall. Alere then implemented corrective actions.

Faced with the risks of a trial and the compulsion to resolve its legal issues to make way for the October closing of the Abbott deal, Alere agreed to settle the case.

…Spawns a Whistleblower Suit

A typical case involving recall and correction of a faulty product generally ends right there. But the FDA was unhappy with what it perceived to be Alere's foot dragging during the incident and suspected that Alere knew more about Triage's problems than it had let on. The FDA apparently questioned not just the pace but adequacy of the corrective actions. And this set the stage for the case to escalate in an unusual and unanticipated direction.

The second stage began when a former senior quality control analyst named Amanda Wu filed a qui tam whistleblower lawsuit accusing Alere and its San Diego subsidiary of "knowingly selling materially unreliable point-of-care diagnostic testing devices" from 2006 to 2012. The suit claimed that Alere knew the device was unreliable because customers complained that Triage was generating erroneous results, including false positives and negatives. The DOJ decided to join the suit.

Faced with the risks of a trial and the compulsion to resolve its legal issues to make way for the October closing of the Abbott deal, Alere agreed to settle the case. The $33.2 million settlement was announced on March 30. As qui tam relator, Ms. Wu will pocket roughly $5.6 million of the settlement.

Takeaway—3 Ways to Protect Yourself

While not unheard of, DOJ *False Claims Act* cases against diagnostics companies stemming from false test results generated by a recalled product are highly rare. "The DOJ doesn't typically move against companies that have already recalled the product in question," according to former assistant US Attorney Jason Mehta (quoted in the Gray Sheet). The three key lessons for device and test makers:

1. Pay attention to and perform root cause analyses of customer complaints, particularly when they form a pattern pointing to a particular problem or product feature—Alere apparently failed to do this;
2. Take immediate action to correct the problems you identify—Alere's slow response was clearly a factor leading to qui tam litigation and DOJ intervention in this case; and
3. To the extent problems cannot be prevented, self-disclosure may be an advisable strategy for avoiding DOJ prosecution and/or whistleblower lawsuits.

Labs IN COURT

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

Theranos & Its CEO Settle Stock Fraud Charges with SEC

Case: Having settled with CMS, Walgreen's and the Arizona State Attorney General, Theranos has made peace with what may be the scariest of all its legal adversaries: the US Securities Exchange Commission. On March 14, it was announced that Theranos and its founder and CEO, Elizabeth Holmes, agreed to settle securities fraud charges for making false claims about its prickless blood analyzing technology to raise over $700 million in investment capital. False claims cited included predictions that the analyzer would generate over $100 million in 2014 revenues (actual revenues came in just $99.9 million short of those projections) and falsely stating that the product was used on the battlefield in Afghanistan and in medevac helicopters.

Significance: Under the settlement, Holmes will pay a $500,000 penalty, disgorge the 18.9 million shares in Theranos stock allegedly acquired via the fraud and give up her voting control over the company. Holmes has also been barred for serving as an officer or director of a publicly traded company for 10 years. Not included in the settlement is Theranos's former President Ramesh Balwani who will get the chance to prove his innocence in a US California District Court.

Pain Management Doc Gets Jail + $8.7 Million Fine for Opioid Pill Mill Scam

Case: Another month, another physician busted for opioid prescription abuses. The 62-year-old physician caught up in this case ran his pain clinic as a pill mill to pay for a Florida condo, squash court and other accoutrements of his lavish lifestyle. One of Massachusetts's leading oxycodone prescribers, the doctor falsely billed Medicare and private insurers for millions of dollars in opioid-related services, including urine drug tests, that were not provided, medically necessary, reliable or even safe over a three-year period. In addition to 27 counts of health care fraud, the doctor pleaded guilty to16 counts of money laundering and one count of mail fraud for good measure. He will have to pay restitution of $8.725 million and spend eight years in a presumably squash court-less prison.

Significance: While not necessarily the central part of the case, the urine drug testing abuses the doctor pleaded guilty to committing are particularly lurid, including causing urine samples to be stored for weeks and up to three months in an unrefrigerated sunlit space in his lab. Beyond the stench, the practice left the samples degraded and worthless. But the doctor still made his staff test the samples—and then billed Medicare for the test results. And questionable sample storage was just the tip of the iceberg. His other testing and Medicare billing violations included:

- Ordering staff to run every patients' urine sample on two machines, each of which used the same scientific testing methodology;
- Causing every sample to be chemically confirmed even when he did not even know the results of the *initial* screening test;
- Running tests on chemical analyzers that had not been properly calibrated and validated.

Precipio Inc. Settles Shareholders' Suit for $1.9 Million

Case: Crede Capital Group invested $5 million in Transgenomic in exchange for stocks and warrants. In June 2017, Transgenomic merged with molecular DX firm Precipio

and the surviving company, Precipio Inc., assumed Transgenomic's debts. Crede then exercised its Transgenomic warrants. But when Precipio Inc. allegedly did not make the required cash payments and Crede sued for $2 million in damages. Rather than fight it out in court, the parties have agreed to settle the case for $1.925 million in cash, stock or a combination of both to be paid out over a 15-month period.

Significance: The settlement is just one of the things the newly merged firm has done to reduce Transgenomic's roughly $19+ million pre-merger debt to $7 million. News of the debt reduction, which was included as part of Precipio Inc.'s most recent Securities Exchange Commission public filing, sent shares up nearly 30% to $.66.

38 and Counting… BLS Scandal Takes Down Another Physician

Case: A New Jersey internist is the latest physician convicted in the massive Biodiagnostic Laboratory Service (BLS) bribery scheme. The 57-year-old physician pleaded guilty to accepting over $104K in bribes from BLS employees over a three-year span in return for generating more than $1.3 million in illegal test referrals to BLS labs. The sentence: 18 months in prison, one year of supervised release and a relatively modest $7,500 in fines. Of course, he will also have to forfeit the $104,611 in bribes he took.

Significance: The most recent BLS "body count": 53 convictions, including 38 physicians and $13+ million recovered via forfeiture. The latter total gains perspective when you consider that the BLS scandal resulted in over $100 million in illegal payments to Medicare and private insurers.