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Brief Your CEO: New Penalties Double the Dollar Value of Protecting Your Lab from Liability

You may not realize this, but Congress has just doubled the dollar value of what you do as a compliance manager to keep your lab out of federal health care fraud hot water.

How?

By significantly increasing the penalties for violations. While sneaky may be too strong a word, these new penalty increases have flown under the radar despite their obvious and immediate ramifications for your lab. And even if you are on top of the situation, odds are that your lab executives are totally oblivious. So, it behooves you—and them—to let the C-Suiters know about the higher penalties and how they increase the stakes of compliance.

Look What I Found

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. In addition to making the execs aware of the legal risks your lab is facing, pulling out this bit of critical information from a dense federal budget bill running over 1,000 pages sends them a subtle message: Our compliance officer is really on the ball!

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PAMA Reimbursement: CMS Tells Labs How to Secure ADLT Status for New Tests

Although the 2018 market-based Clinical Laboratory Fee Schedule (CLFS) is officially in effect, implementation of the new PAMA Part B payment rules for lab tests remains a work in progress. On March 23, CMS filled in some of the missing details by issuing new guidance for labs seeking ADLT status for newly developed tests.

What Are ADLTs

ADLTs, or Advanced Diagnostic Laboratory Tests, are a new classification of tests created by PAMA. To qualify as an ADLT, a new test must:

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New Penalties Double the Dollar Value of Protecting Your Lab from Liability, *from page 1*

Which Laws Were Affected

Now you can demonstrate your legal knowledge by pointing out which health care fraud laws the new BBA penalty provisions affect, namely the *Civil Monetary Penalties Law* (CMPL) and the *Anti-Kickback Statute* (AKS). (If you want to look them up and perhaps photocopy them for your briefing, the changes are contained in Section 50412 of the BBA.)

Higher Civil Penalties Under the CMPL

Explain that 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 amendments double (and in some cases more than double) those fine 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

Let your executives know that 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

End the briefing with a sense of urgency by explaining that the new BBA penalties are already in effect—they actually took effect on Feb. 9, 2018, the same date that the BBA did. On a more consoling note, you can point out that the new higher fines are not retroactive but apply only to offenses committed on or after Feb. 9.

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Getting Paid: 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.

OIG Work Plan Monthly Review: April 2018

Four of the six new items that the OIG added to its workplan have an impact—albeit indirect—on labs:

1. CMS Recovery of Medicare Overpayments

Issue: Between Oct. 1, 2014 and Dec. 31, 2016, OIG issued 153 Medicare audit reports listing 193 monetary recommendations. Of the $648 million in overpayment recoveries that OIG recommended, CMS agreed to collect $566 million.

OIG Action: The OIG plans to determine how much of that money CMS collected and whether it took the corrective actions the OIG recommended with regard to its systems and procedures for recording, collecting and reporting overpayments and instructing Medicare contractors on how to document overpayment collections.

2. Mandatory Review of Rules on Dual-Eligible Beneficiary Access to Drugs Under Part D

Issue: Dual-eligible beneficiaries who are enrolled in Medicaid also qualify for Medicare Part D prescription drug coverage. Part D plan sponsors have the discretion to include different Part D drugs and drug utilization tools in their formularies as long as the plan meets certain limitations.

OIG Action: As required by the *Affordable Care Act*, the OIG will perform an annual review to determine the extent to which drug formularies developed by Part D sponsors include drugs commonly used by dual-eligible beneficiaries as required.

3. Personal Use of Government Email by HHS Officials

Issue: Misuse of personal emails by government officials has become a controversial issue of late and Congress has now asked the OIG to conduct a review of internal policies and practices at HHS.

OIG Action: The OIG will determine whether HHS and its operating divisions have controls in place to:

- Ensure officials' use of email is restricted to government business in accordance with federal laws and regulations; and
- Preserve all emails related to government activities.

4. Medicaid Nursing Home Supplemental Payments

Issue: CMS makes supplemental payments to nursing homes covering the difference between Medicare and Medicaid rates for nursing home services in some states. Under some of these programs, local governments fund the states' share of the supplemental payments through intergovernmental transfers.

OIG Action: OIG will review the nursing home supplemental payment program's flow of funding and determine how the funds are being used bearing in mind the fact that previous OIG and GAO audits have found that federal supplemental payments often benefit the state and local governments more than the nursing homes.

Labs IN COURT

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

Lab Accused of Inflating Specimen Travel Mileage Pays $525K to Settle

Case: The feds accused a Missouri lab of submitting false claims to Medicare for travel fees in transporting specimens from April 2011 to December 2014. In addition to a $525K fine, the lab had to sign a five-year corporate integrity agreement to settle the case.

Significance: The lab allegedly committed two violations of Medicare travel allowance billing rules that caused its mileage claims to be deemed false:

- Logging mileage for specimens transported collectively in a single trip separately rather than prorating the miles among each specimen; and
- Charging for mileage traveled by a non-medical driver rather than by a lab technician.

Cancer Genetics Sued by Its Own Shareholders

Case: Personalized cancer treatment firm Cancer Genetics has been struggling with cash flow since acquiring Personal Genetics for $14 million in 2015. Just how tough the situation is became clear on April 3, when Cancer Genetics issued its 2017 fourth quarter financial report. In response, two different groups of shareholders have filed class action lawsuits in federal court charging the New Jersey-based firm with making false and misleading statements and omissions to investors and failing to disclose that it "had ineffective disclosure controls and internal controls over financial reporting."

Significance: Shareholder lawsuits against labs with disappointing financial results is hardly a new phenomenon. Theranos, Alere and NantHealth are just a few recent examples of firms staving facing securities fraud cases from their own shareholders. (For more on the trend and its role in health care fraud and enforcement, see *GCA*, Aug. 30, 2017.)

Self-Disclosed Sleep Study Billing Violations Cost Hospital $252K+

Case: A North Carolina hospital has agreed to fork over $252,455 for improper billing of Medicare and TRICARE for sleep testing and treatment services committed by its sleep center, an amount that might have been higher had the hospital not self-disclosed the violations.

Significance: The OIG does not provide any details about the case or what the hospital did wrong. However, sleep testing by independent and hospital labs has become a high priority of OIG enforcement in recent months, particularly polysomnography, a sleep study in which patients sleep overnight while connected to sensors measuring brain waves, blood oxygen flow and other parameters. The study is commonly used to diagnose obstructive sleep apnea and evaluate the effectiveness of using positive airway pressure (PAP) devices to manage the condition and PAP titration may also be done when the test indicates that a patient has a sleep disorder. (To find out about the billing pitfalls of polysomnography and how to avoid them, see *GCA*, Jan. 6, 2017.)

BLS Scandal Takes Down Another Physician

Case: 38 and counting. . . 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 more than $1.3 million's worth of illegal test referrals to BLS labs. *His sentence:* 18 months in prison, one year of supervised release and a relatively modest $7,500 in fines. 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.

New Stark Rules Offer Some Physician Kickback Relief but Not Nearly Enough

As a lab compliance officer, you have better things to do with your time than read government budget bills. But what you do need to know is that the new federal *Bipartisan Budget Act of 2018* includes some Medicare fraud changes that may affect your lab concerning the Stark Law. And to the extent doing business with physicians is an integral part of your lab's business model, you need to be on top of the changes.

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).

What's At Stake

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.

PAMA Reimbursement: CMS Tells Labs How to Secure ADLT Status for New Tests, From Page 1

- Be covered under Medicare Part B;
- Be offered, furnished and sold only by the single lab that develops the test (or a successor owner); and
- Meet either of the following:
  - **Criterion A:** The test is an analysis of multiple biomarkers of DNA, RNA or protein combined with a unique algorithm to yield a single patient-specific result predicting if a patient will develop a condition(s), how the patient will respond to a therapy(ies) or providing new clinical diagnostic information that cannot be obtained from another test(s); or
  - **Criterion B:** The test receives FDA clearance or approval.

Labs must apply to CMS to secure ADLT status for their tests. The significance of the new guidance is that it explains the application process in specific detail.

What's At Stake

Securing ADLT status for a new test is a big deal because it means the test is subject to separate pricing rules. Specifically, prices of new ADLTs are the actual list charge for the test over the first three quarters that the test is available on the market.

Labs are required to report the prices of their ADLTs during that period. When the initial period ends, CMS will use this pricing data to determine the test's weighted median rate. If the list charge turns out to be more than 130% of the median, CMS can make the lab repay the difference.

By contrast, pricing of new tests that are not ADLTs is based on current CMS cross-walking or gap-filling methods:

- Cross-walking to an existing HCPCS code is used if CMS determines that the new test is comparable to an existing test, multiple existing test codes or a portion of an existing test code;
- Gap-filling is used for tests that have no existing HCPCS analog and is based not on a HCPCS code but charges for the test, routine discounts, resources required to perform the test, payment amount set by other payors, input from the clinical lab payment advisory committee and other factors.

What the Guidance Says

Labs must apply to CMS to secure ADLT status for their tests. The significance of the new guidance is that it explains the application process in specific detail.

Information Required to Apply for ADLT Status

First, the guidance specifies the information the lab must furnish to show that the test meets each element of the ADLT definition explained above.

The lab must also agree to notify CMS of any changes to the information in the application it submits within 30 days of the change.

Information Labs Must Submit to CMS to Get ADLT Approval

Element of ADLT Definition	Required Documentation to Prove
Test is covered by Medicare Part B	Evidence of coverage includes (but isn't limited to): ■ Payment for test by a Medicare Administrative Contractor (MAC) based on a reasonable and necessary determination, e.g., MAC remittance notice for test ■ Molecular Diagnostic Services program coverage determination for test ■ Local coverage determination (LCD) for test ■ National coverage determination (NCD) for test
Test is furnished, sold and offered by single lab that develops (or successor)	Information that may be required includes: ■ Name & address of all lab components furnishing test ■ Name, address & role of entity(ies) that owns lab which may offer, sell or design test ■ Name, address & role of entity(ies) that lab owns which may offer, sell or design test ■ Indication of whether applying lab is a successor owner ■ All of single lab's Tax Identification Number(s), NPI(s) and CMS Certification Number(s)
Pricing and payment information	Current coding payment info for test which may include (for all payors to which test is billed): ■ Any existing HCPCS code or identifier used to bill test ■ Descriptor used to bill test ■ MAC's local payment amount for test and date of payment determination
Pricing information about new ADLTs to be paid at actual list charge over initial period	If test hasn't been paid under CLFS before Jan. 1, 2018: ■ First date on which test is obtainable by patient or marketed to public ■ All amounts charged covered by private insurance or listed in marketing on such first date ■ Actual list charge for test based on publicly available rate ■ If available, publicly available source(s) that report actual list charge & all other amounts charged on such first date
Test meets Criterion A (described above)	■ Identification of DNA, RNA or protein biomarkers analyzed by test ■ Description of test's unique algorithm ■ Summary showing that analysis of biomarkers combined with unique algorithm yields result predicting patient condition, response to therapy and delivers new info not obtainable from existing tests on market ■ List of potential comparative tests ■ Comparison between test & other similar tests
Test meets Criterion B, i.e., has received FDA clearance or approval	Documentation must include: ■ FDA premarket approval or notification number ■ Date of FDA clearance or approval ■ Name and branch of FDA reviewer

Additional Information Required If Lab Is Also Applying for Unique HCPCS Code

Each ADLT must have a "unique" HCPCS code, i.e., a code that describes that particular test and only that particular test. If the would-be ADLT does not have a unique HCPCS, the lab must tell CMS if it has applied (or is in the process of applying) to the AMA for a unique level 1 HCPCS code for the test along with the date and status of the application. If not, the lab must include in its ADLT application a request for CMS to assign the test a unique level II HCPCS code when and if it okays ADLT status for the test.

ADLT Application Process

CMS will make ADLT status determinations (and, if necessary, accompanying HCPCS code assignments) on a quarterly basis based on the following calendar:

Quarterly ADLT Application Filing Window

	Quarter 1	Quarter 2	Quarter 3	Quarter 4
Dates on which CMS must Receive ADLT Application	Jan. 1 to Jan. 31	April 1 to April 30	July 1 to July 31	Oct. 1 to Oct. 31

CMS' review of ADLT applications will result in one of three possible outcomes:

- Approval of the test for ADLT status (which may include assignment of a unique level II HCPCS code;
- Denial of ADLT status for test via email notification to the lab contact person; or
- Request for lab to supply additional information.

Takeaway: Along with the new guidance, CMS published the actual form that labs are supposed to use when applying for ADLT status. The good news is that breezing through this overview and carefully following the instructions set out in the application should spare you the agony of having to read all 30 pages of the guidance.

You Make the Call: Do Cost-Savings Payments to Referring Physician Violate Kickback Laws?

SITUATION

XYZ Consultants recommends that a hospital client cut costs by making 34 changes to its OR spinal fusion surgeries procedures. The recommendations fall into two broad categories, including getting neurosurgeons to agree to:

- Use Bone Morphogenetic Protein only on an as-needed basis for surgeries on three specific regions of the spine; and
- Use standardized devices and supplies for spinal fusion surgeries.

To implement the recommendations, XYZ proposes a three-year arrangement among itself as administrator, the hospital and the medical group of the neurosurgeons that perform the procedures under which the hospital will pay the neurosurgeons a share of the cost savings achieved as a result of the changes they make in selecting and using products during spinal fusion surgeries.

QUESTION

Is the proposed arrangement legal?

ANSWER

Yes, according to recently issued OIG Advisory Opinion (No. 17-09), as long as the safeguards described in the proposal are actually implemented.

EXPLANATION

The OIG analysis addresses two specific legal issues raised by the proposed arrangement and concludes that the safeguards would be adequate to address each concern.

1. Gainsharing Risks

Concern: The cost-reduction payments to the neurosurgeons could violate Section 1128A(b)(1) of the *Social Security Act*, which bans hospitals from paying physicians, directly or indirectly, to induce them to reduce or limit medically necessary services to Medicare or Medicaid patients.

Safeguards: The proposed safeguards would adequately control risk of improper service reductions, including:

- Monitoring via oversight by a specially designated Program Committee;
- Strict documentation requirements;
- Making neurosurgeons disclose the arrangement to patients before getting their consent to the surgery.

2. Kickback Risks

Concern: Cost-reduction payments to neurosurgeons could be deemed kickbacks for referrals to the hospital.

Safeguards: The safeguards in place eased the OIG's *Anti-Kickback Statute* concerns:

- Distributing payments to neurosurgeons on a per capita basis reduced the risk of incentivizing any individual neurosurgeon to generate disproportionate costs savings;
- Capping potential savings based on the number of spinal fusion surgeries performed by the neurosurgeons on Medicare/Medicaid patients in a designated base year;
- Certification that aggregate payments to the group would not exceed 50% of the projected cost savings at the start of the arrangement; and
- Program Committee review to verify historically consistent selection of patients for the surgeries covered by the arrangement in terms of age, severity and payor.

Takeaway: Although the arrangement in this case involved spinal surgery, the principles also apply to arrangements involving physicians and labs—both hospital-based and freestanding. The bottom line: Cost-reduction arrangements in which providers pay referring physicians a portion of savings yielded as a result of accepting changes to medical procedures do raise significant liability concerns under kickback and gainsharing laws and should not be undertaken unless strict and effective safeguards are in place to monitor and prevent abuses.