G2 INTELLIGENCE
A DIVISION OF PLAIN LANGUAGE MEDIA

G2 Compliance Advisor

For Clinical and AP Laboratories and Pathology Practices

August 2017

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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: Let the C-Suite Know About the Key MACRA Changes on the Table

Ordering physicians aren't just your clients but your business lifeline. So when major changes to physician reimbursements are in the works, you need to be on top of them. And when it comes to physician reimbursements, it doesn't get much bigger than MACRA, the Medicare Access and CHIP Reauthorization Act of 2015. "MACRA is the biggest change in how physicians are paid ... since the creation of DRGs," according to a pathologist who sits on the board of governors for the College of American Pathologists. So you need to be aware that on June 30, the CMS issued a Proposed Rule addressing a key part of implementation: the Quality Payment Program (QPP) for 2018, the second Performance Year. Here's a quick analysis of the Proposed Rule that you can use to prepare a briefing for your lab's CEO or CFO.

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Compliance Perspectives: Private Sector Joins the Battle against Lab Fraud

The crackdown on lab fraud has been going on for decades. But now the dynamics are changing. While federal prosecutors and private whistleblowers continue to supply most of the impetus, they have been joined by a new and powerful ally: the private sector.

Shareholders

One manifestation of this new trend in lab fraud enforcement is the proliferation of securities fraud lawsuits against labs by their own shareholders. The pattern: Investors charge the lab with making misleading statements and omissions about business to inflate stock value. Later, when the truth is revealed, stock prices plunge and investors are left holding the bag.

The most recent example is the class action lawsuit against Foundation Medicine Inc. Established in 2009, Foundation is a molecular diagnostics company known for its next-generation sequencing-based cancer assays including FoundationOne for solid tumors and FoundationACT for circulating tumors. At up

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Brief Your CEO: Let the C-Suite Know About the Key MACRA Changes on the Table, *from page 1*

MACRA, 101

Start out with an overview of what MACRA is all about. Explain that the MACRA system, which won't be fully in place until 2019 at the earliest, eliminates the old sustainable growth rate formula in favor of the QPP system. There are 2 QPP tracks.

1. MIPS

The first is the Merit-Based Incentive Payment System (MIPS), in which value of Part B physician services is based on 4 performance categories:

- **Quality**—physicians must report on 6 measures;
- **Advancing Care Information**—providers can select "customizable measures" for reporting day-to-day use of technology and demonstrate interoperability;
- **Clinical Practice Improvement Activities**—such as care coordination and patient safety;
- **Cost**—based not on physician reporting but on Medicare claims data that use "40 episode-specific measures."

2. Advanced APMs

The second track is incentive payments for participating in certain Advanced Alternative Payment Models (APMs). Providers who participate in Advanced APMs are exempt from MIPS reporting.

The 5 Proposed MIPS Changes

Let your CEO know that the Proposed Rule includes changes to both tracks for the 2018 Performance Year and provide a summary for each one. Start with the 5 key MIPS changes:

1. Raising the Low-Volume Threshold

The first key MIPS change involves a significant hike in the 2018 threshold:

- *2017 Threshold:* $30,000 in Medicare Part B allowed charges or less than or equal to 100 Medicare patients;
- *Proposed 2018 Threshold:* $90,000 in Medicare Part B allowed charges or less than or equal to 200 Medicare patients;

The impact of this increase: More physicians would be exempt from participating in MIPS in 2018. Physicians who fall below the low-volume threshold would be allowed to opt-in to MIPS starting in the 2019 Performance Year.

2. New Virtual Groups Requirement

The second and perhaps most troubling proposed MIPS change is the new requirement that disparate providers who don't belong to a medical group form virtual groups for purposes of aggregating and reporting their MIPS data. Physicians will have to submit a written agreement among members of the virtual group to CMS by December 1, 2018.

Sticking point: Explain that physicians may have a hard time meeting that deadline. Public comments on the Proposed Rule are scheduled to close on August 21. And based on what it did last year, the CMS will likely issue

G2CA

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G2 Compliance Advisor (ISSN 2332-1474) is published by G2 Intelligence, Plain Language Media, LLLP, 15 Shaw Street, New London, CT, 06320.
Phone: 1-888-729-2315
Fax: 1-855-649-1623
Web site: www.G2Intelligence.com.

CMS is also asking for comments on a proposal that would allow QPs to receive participation credit for Medicare Advantage as part of the Medicare Option rather than the All-Payer Combination Option.

a Final Rule in November. That may not be enough time for disparate providers to get together and conclude a virtual agreement for the 2018 Performance Year to submit to CMS by December 1, 2108.

3. Allow for Continued Use of 2014 CEHRT
Let the CEO know that the Proposed Rule would allow providers to continue using a 2014 Certified Electronic Health Record Technology in 2018; but providers who implement a 2015 edition product may qualify for a bonus.

4. Cost Performance of Zero Percent
Under the Proposed Rule, the cost performance category of the MIPS score for the 2018 Performance Year would be set at zero percent to give CMS more time to develop and provide feedback to providers on episode-based measures.

5. Facility-Based Performance Evaluation
Explain that the Proposed Rule establishes a method to assess the quality and cost performance of individual providers who carry out their primary responsibilities in a health care facility based on the facility's performance.

The 2 Proposed Advanced APM Changes

Let your CEO know that the Proposed Rule includes changes to both tracks for the 2018 Performance Year and provide a summary for each one. Start with the 5 key MIPS changes:

1. New Qualified Advanced APM (QP) Determination Process
First, explain that under the Proposed Rule, CMS would be permitted to make determinations of a Qualifying APM Participant (QP), i.e., eligible provider participating in an Advanced APM to a sufficient degree for Advanced APMs that start or end during the QPP performance year and which operate continuously for at least 60 days. In those circumstances, CMS will use only data from Advanced APMs where they operated within the QPP performance year to make QP determinations.

CMS is also asking for comments on a proposal that would allow QPs to receive participation credit for Medicare Advantage as part of the Medicare Option rather than the All-Payer Combination Option. Under current rules, providers looking to become QPs have only 2 scoring options based on their participation in Advanced APMs: the Medicare Option (only Medicare as the payer) and/or All-Payer Combination Option (payers other than Medicare).

2. New Other Payer Advanced APM Determination Process
The Proposed Rule would also establish a process allowing payers to request that CMS make a determination about whether a payer's program meets Advanced APM status starting before the 2019 Performance Year. Payers eligible to request such determinations include, among others, Medicaid, Medicare Advantage, Programs of All Inclusive Care for the Elderly plans and Medicare-Medicaid plans.

OIG Work Plan Monthly Review: August 2017

Two months into its new monthly update regime, the OIG added 4 new items to its Work Plan in August, none of which will have a direct impact on laboratory services. However, 3 of the initiatives may have an indirect effect on at least some labs.

1. Part B Payments for Psychotherapy Services

Red Flag: The Work Plan update cites an earlier OIG review finding that Medicare Part B psychotherapy services payments were "particularly problematic" and that Medicare paid for services that were not covered, inadequately documented, or medically unnecessary.

What OIG Will Investigate: The OIG will review Part B payments to determine whether they were allowable under Medicare documentation requirements.

2. Medicare Payments for Ventilation Devices

Red Flag: Ventilation devices aren't competitively bid the way some devices are. And Medicare reimbursement for ventilation devices has risen from $51 million in 2011 to $72 million in 2015.

What OIG Will Investigate: The OIG will determine the reasonableness of the Medicare fee schedule prices for ventilation devices compared to prices on the open market to identify potential wasteful spending.

3. Duplicate Drug Claims for Hospice Beneficiaries

Red Flag: Previous OIG work (A-06-10-00059) found that Medicare may have paid twice for prescription drugs for hospice beneficiaries, once under the Part A per diem rate and again under Part D.

What OIG Will Investigate: The OIG says it intends to follow up on this work and review 2 things:

- Whether Part D drug claims for individuals who receive hospice benefits under Part A are appropriate; and
- Whether Part D is continuing to pay for prescription drugs that should have been covered under the per diem payments made to hospice organizations.

Takeaway: Although none of the new OIG initiatives directly involve lab services, you need to be aware of them if you're involved in providing any of the affected goods and services to Medicare, Medicaid or other government health program beneficiaries.

Decoding Quality Terminology

By Jennifer Dawson

Quality has been defined as fitness for use, conformance to requirements, the pursuit of excellence and a product or service free of deficiencies[1]. There is a lot of talk about quality these days, as there should be, but I find there is confusion around quality terminology. I hear quality assurance and quality control used interchangeably.

If you run a Google search for the terms "quality assurance" and "quality control", I am 99% certain your search will return a number of differing definitions. "Quality management", "Total quality management" and "quality improvement" are additional terms that are used frequently, adding to the confusion. Many of these terms are often used interchangeably. You may think these terms are more alike than different as they all contain the word "quality", but they are not synonymous.

Let's explore some definitions to make sense of this alphabet soup.

Quality Control (QC)

- Procedures used in each assay to assure a test run is valid and results are reliable[1]
- A system for verifying and maintaining a desired level of quality in an individual test or process[3]
- A generic term that refers to the monitoring and assessment of laboratory testing processes to identify problems and maintain performance[2,6]
- The operational techniques and activities used to fulfill requirements for quality[8]

Quality Assurance (QA)

- A part of quality management focused on providing confidence that quality requirements will be fulfilled[7]
- A formal and systematic exercise in identifying problems in medical care delivery, designing activities to overcome the problems, and carrying out follow-up monitoring to ensure that no new problems have been introduced and that corrective steps have been effective[11]
- A broad spectrum of evaluation activities aimed at ensuring compliance with minimum quality standards[17]
- All actions taken to establish, protect, and improve the quality of health care[12] NOTE: The author of this definition, Avedis Donabedian, opined that one cannot guarantee or assure quality. Instead, he believed the goal was to increase the probability that the health care delivered would be good or better quality and suggested the term *continuous quality improvement*.[12]

Quality Improvement (QI)

- A formal approach to the analysis of performance and systematic efforts to improve it[4]
- Systematic and continuous actions that lead to measurable improvement in health care services and the health status of targeted patient groups[8]

- Defining standards of care, reassessing those standards periodically, and continuously improving the medical systems that support those standards[10]
- A set of techniques for continuous study and improvement of the processes of delivering health care services and products to meet the needs and expectations of the customers of those services and products. It has three basic elements: customer knowledge, a focus on processes of health care delivery, and statistical approaches that aim to reduce variations in those processes[11]

Quality Management (QM)

- The application of a quality management system in managing a process to achieve maximum customer satisfaction at the lowest overall cost to the organization while continuing to improve the process[8]
- Management activities and functions involved in determination of quality policy and its implementation through means such as quality planning and quality assurance (including quality control)[14]
- Quality management is the act of overseeing all activities and tasks needed to maintain a desired level of excellence. This includes the determination of a quality policy, creating and implementing quality planning and assurance, and quality control and quality improvement[15]
- All activities of the overall management function that determine quality policy objectives and responsibilities; and implement them by means such as quality planning, quality processes, quality control, quality assessment, and quality improvement within the quality system[26]

Quality Management System (QMS)

- Management system to direct and control an organization with regard to quality[5,7]
- A formalized system that documents the structure, responsibilities and procedures required to achieve effective quality management. A QMS helps coordinate and direct an organization's activities to meet customer and regulatory requirements and improve its effectiveness and efficiency on a continuous basis[8]
- The organizational resources, processes and procedures to implement quality management, which is broader than both quality assurance (QA) and quality control (QC). Besides QA, the laboratory quality management system also includes management of equipment, supplies and inventories, management of capital, finances and budgeting, and providing training and continuous support of staff and customer service[16]
- The organizational structure, resources, processes, and procedures needed to implement quality management[26]

Total Quality Management (TQM)

- A management approach to long-term success through customer satisfaction[8]
- A management philosophy that seeks to integrate all organizational functions (finance, production, customer service, etc.) to focus on meeting customer needs and organizational objectives[13]

- A business philosophy that the long-term success of a company comes from customer satisfaction. TQM requires that all stakeholders in a business work together to improve processes, products, services and the culture of the company itself[15]

As laboratory scientists, I think we can all agree with the definition of QC. Historically, we have been very good at controlling quality in the analytical phase and we know what this entails. The definition of QA however is surrounded by a little more controversy within the lab community, healthcare as a whole and amongst quality professionals working in different sectors. Healthcare source include description of QA as being reactive, retrospective, policing, and in many ways punitive[4]. That it often involves determining who is at fault after something went wrong and focuses on finding the culprit. This term is also described as being outdated[4,10]. I'd like to propose that as an industry we adopt the definition that QA is ensuring compliance against necessary standards. This includes QC and regulatory requirements such as CLIA, CAP and TJC. In contrast to QA, the definitions for QI, QM, QMS and TQM are fairly consistent and seem to be accepted even across industries.

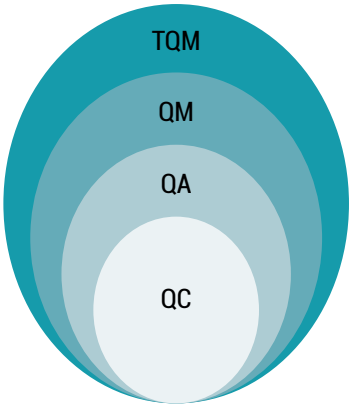

Figure 1: Hierarchy of Quality Concepts

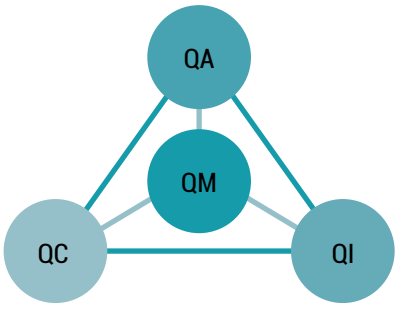

Figure 2: QM = QC + QA + QI

Tying it all together

Now that we've defined the terms, let's examine how they relate to each other. If you examine the definitions, it appears that the terms build on each other and increase in scope. It is widely accepted by quality professionals, particularly those in other industries, that the progression of quality started with QC, followed by QA, QM and finally TQM[5,18-25]. It is also accepted that as you go up the progression, each new phase includes the previous (figure 1). Applying my preferred definition of QM that it is quality planning, assurance, control and improvement and think of QM as an equation, the result is QM = QC + QA + QI (figure 2), where QM includes a QMS. TQM is one step beyond QM where customer, namely patient, satisfaction is the focus.

Conclusion

I remember back to when I was working on the bench. I would hear these terms and had no idea what they meant, just that they were related to quality. Had it not been for my career turning in the direction of quality management, I would still not have a solid understanding of their meanings. It is my sincere hope that the information presented in this article provides some clarity in decoding these often utilized and often confused quality terms and buzzwords.

[Editor's Note: See references for this article at www.g2intelligence.com/decoding-quality-terminology.]

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Labs IN COURT

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

Spine Clinic Owner Indicted for Falsely Billing Quantitative Urinalysis Tests

Case: The co-owner and billing manager of a Louisiana spine and pain management clinic have been charged with falsely billing Medicare and private insurers for $4.4 million worth of medically unnecessary services, including $3.9 million in quantitative urinalysis tests. The clinic was planning to open a urinary testing lab and began storing specimens for unnecessary testing once the lab went on line, the indictment claims.

Significance: The Louisiana spine clinic principals are among the over 400 defendants charged with health care fraud as part of the 2017 National Health Care Fraud Takedown spanning 41 federal enforcement districts and 30 State Medicaid Fraud Control Units. (For more on the Takedown, see GCA, July 2017, page 3.)

Genetic Testing Company Linked to Indiana False Billing Prosecution

Case: Now we know why the FBI raided the HQ of Proove Biosciences in Southern California. The genetic testing company is apparently caught up in a Takedown case targeting illegal dispensing of oxycodone and opioids by Physicians Primary Care (PPC) in Indiana. The indictment claims that 3 individuals affiliated with PPC, including an MD and 2 nurse practitioners, caused Proove to fraudulently bill for genetic tests administered to PPC patients that were medically unnecessary and never interpreted.

Significance: It's important to note that Proove hasn't been formally charged with any offenses. And in a recent statement, the company's founder and CEO emphasized 3 key points, including the fact that Proove:

- Received written and signed medical necessity determinations for the tests in question;
- Cut ties with the indicted PPC physician immediately upon learning of the investigation in 2014; and
- Has cooperated with the FBI and U.S. Attorney's office.

Five More Doctors Convicted in BLS Bribery Scheme

Case: The biggest medical bribery scandal of all time continues to grow with 5 more doctors pleading guilty to taking bribes from now defunct Biodiagnostic Laboratory Services LLC (BLS) in Parsippany, New Jersey. Here's the Scorecard for the latest defendants:

Name	Practice	Allegations
Jorge J. Figueroa	Internal medicine, Fair Lawn, NJ	Accepted $200K from BLS employees for roughly $1.4 million in illegal lab business between May 2007 and April 2013
George & Nicholas Roussis (brothers)	Pediatrician and OBGYN (respectively) Staten Island, NY	Accepted $175K in BLS cash payments for roughly $1.7 million in lab referrals from Oct. 2010-April 2013; BLS also paid for strip club trips, lap dances and sexual favors

Name	Practice	Allegations
Basel Batarseh	Internal medicine, Wayne, NJ	Accepted monthly bribe checks of $3.2K ($104K in total) for generating roughly $1.3 million in lab business from Nov. 2007 to Aug. 2010
Yousef Zibdie	Internal medicine, Woodland, NJ	Accepted $80K worth of monthly bribe checks for generating roughly $930K in illegal lab business for BLS

Significance: In a sneak preview of what the future may hold for these five when sentence is handed down in December, the very same day the above convictions were announced, a 79-year-old Bergen County (NJ) family physician was sentenced to 41 months in prison for taking $200,000 in bribes for approximately $3 million's worth of illegal lab business to BLS. The latest BLS "body count" is 50 convictions, 36 of them doctors.

Labs Keep Up the Pressure to Delay PAMA & Add Hospital Lab to CLFS Formula

The lab industry continues to wait nervously for word from CMS regarding PAMA.

Demand 1: Fix the Fee Schedule Methodology

The industry's paramount concern remains the formula CMS proposes to use to calculate market rates for lab tests in setting the Clinical Laboratory Fee Schedule (CLFS) under PAMA, specifically the omission of hospital outreach labs from the definition of "applicable labs." In addition to pressing CMS, representatives of the American Clinical Laboratory Association (ACLA) met with members of Congress last month to "reiterate our belief that the current PAMA regulation effectively excludes hospital outreach labs, which are a significant segment of the laboratory marketplace."

The big labs have made it clear that they are fully behind the ACLA's lobbying efforts. In a conference call following the release of its recent earnings report, Quest President and CEO Steve Rusckowski stated that "while we support reform of the Medicare payment system, we believe any modification should be market-based and appropriately include all applicable independent and hospital outreach laboratories." Meanwhile, LabCorp Chairman and CEO David King complained that the current dataset CMS is reviewing in establishing CLFS reimbursement rates as part of the PAMA process represents only 5 percent of hospital lab-based testing volume.

Demand 2: Delay PAMA Implementation

Meanwhile, the industry wants CMS to postpone the new PAMA-based CLFS pending resolution of the "applicable labs" issue. The ACLA has asked the agency to delay CLFS implementation for at least 6 months. Quest's Rusckowski also indicated that he is recommending that CMS publish the new CLFS no earlier than July 1, 2018.

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to $7,200 per test, Foundation is heavily reliant on major insurance coverage. So when the Cambridge, Mass.-based company made statements suggesting imminent Medicare coverage of the tumor tests, its common stock took off.

But in July 2015, after nearly 18 months of optimism, the bubble burst. The company disclosed that the expected Medicare approval wouldn't be forthcoming any time soon and slashed its financial guidance for the year. The immediate response was a 24% ($7 per share) stock decline. More bad coverage news and deeper guidance cuts in caused further stock losses in November.

Foundation's investors have now filed a class action lawsuit in Massachusetts federal court claiming that the officers knew all along that the representations about Medicare coverage of the tumor tests were false. From now through Sept. 26, the trial lawyers are looking for investors who bought Foundation stock during the affected period (February 2014 to November 2015) to participate in the suit, including those willing to serve as the lead plaintiff.

Other Notable Securities Fraud Cases against Labs

While it may be the most recent, Foundation is hardly the only lab to be sued by its shareholders for securities fraud. Others include:

Theranos: In November 2016, investors filed a series of class action lawsuits alleging that the privately held blood testing firm and its CEO made false claims about its relatively bloodless finger-prick technology to inflate the value of its securities. "Thousands of investors were spoon-fed continuous lies touting the company's 'world-changing' technology that would 'revolutionize' the industry," according to an attorney representing one group of plaintiffs. In April 2017, a California federal judge refused to dismiss the case against Theranos.

Alere: In October 2016, shareholders sued Alere and its officers for making misstatements and omissions about the company's sales in Latin America, Africa and China and overall financial condition to inflate share value and attract acquisition suitors ahead of announcing its $5.8 billion merger deal with Abbott in February 2016. When the truth about the company's finances came to light in the spring, share prices plunged and Abbott tried to pull out of the deal before eventually agreeing to go through with the acquisition at a reduced price.

NantHealth: A series of March 2017 securities fraud class action suit by shareholders accuse the California-based precision medicine company of making misleading statements about a $12 million contract with the University of Utah and overstating the number of reported test orders to inflate share value ahead of the company's initial public offering.

Consumers—Overbilling

Consumer lawsuits represent another form of private sector fraud action against labs. Perhaps the most notable examples are the current patient suits charging Quest and LabCorp with overbilling lab tests. Separate federal court complaints, each of which may become a class action, in New Jersey (vs. Quest) and North Carolina (vs. LabCorp) contend that the labs billed "fees far in excess of the market rates negotiated at arm's length with third party payers such as insurance companies." According to one of the plaintiffs' lawyers, the patients "had no agreement with the respective labs, and when their insurance companies did not pay their claims, the labs unilaterally charged them excessive, nonmarket-based rates."

The Quest lawsuit cites the example of a couple who were each billed $328.85 for an MTHFR genetic test done in November 2013. Aetna denied coverage, saying the tests were "experimental or investigational." If Aetna *had* paid for the tests, Quest would have received much less than the $328.85 it billed the patients, the complaint alleges.

The plaintiff's attorney in the LabCorp case cites the example of a patient who was charged $616 for a vitamin D test. Horizon BlueCross Blue Shield refused to pay for the test. But it did pay LabCorp for the 6 other tests the patient received. Payment amount: $63.65, or just 17 percent of the aggregate rack rate of $370. LabCorp then billed the patient for the vitamin D test at the full rack rate of $616, the attorney claims.

Consumers—Misrepresentation

Consumers have also sued labs for misrepresenting their products. Once more, Theranos has been in the eye of the storm. Those same bloated statements by the company about the capabilities of its finger-pricking technology cited in the shareholders' lawsuits spurred consumers to bring a class action lawsuit in Arizona.

But this time, the strategy didn't work. In June 2017, a federal judge tossed out most of the claims against Theranos. For one thing, there was no proof that the consumers ever actually used the product. Thus, for example, at least 3 consumers said that multiple vials of blood were drawn. The problem with that contention is that vials aren't part of the finger-pricking technology.

Note: The private consumer fraud case should not be confused for the consumer fraud case brought by Arizona that Theranos settled with the State Attorney General in April. (For more on the case, see Theranos Announces Settlement Agreements with CMS and Arizona Attorney General, NIR, April 26, 2017.)

Creditors

The massive Health Diagnostics Laboratory, Inc. (HDL) case spawned a new form of private sector action against lab fraud: creditor lawsuits against bankrupt labs. In April 2015, HDL agreed to pay $47 million to settle False Claims Act claims involving alleged kickbacks and medically unnecessary testing. The DOJ accused HDL (and another lab called Singulex) of induc-

ing physicians to refer to them for blood testing, including medically unnecessary large multi-assay panels, by paying them sham specimen processing and handling fees of between $10 to $17 per referral and routinely waiving copayments and deductibles. The government also contended that the labs had an illegal sales contract with a marketing firm named Blue Wave.

In June 2015, roughly two months after the settlement, HDL filed for Chapter 11. But bankruptcy would not bring closure. HDL's creditors sued HDL and Blue Wave for $600 million. The creditors also targeted the physicians who accepted kickbacks for referring patients to HDL.

Private Insurers

Perhaps the biggest private sector threat to labs that cheat are private insurers seeking to recover falsely billed lab services. Cigna's $84 million lawsuit against HDL is a notable example, as is the current case by UnitedHealthcare against Dallas-based Next Health LLC and its genetic lab testing subsidiaries for allegedly fraudulent billing of over $100 million in services generated by illegal kickbacks for physician referrals.

Takeaway: While most labs are honest, lab fraud is still big business. And so is recovering the money paid out as a result of fraud. For decades, the government and private whistleblowers have cornered the market in fraud recovery. But now the private sector has gotten into the act, including private insurers, investors, consumers and even bankruptcy creditors.