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Enforcement Trends: OIG Report Suggests that Urine Drug Testing Is Making Labs a Juicy Target Once Again

The Office of Inspector General just published its Semiannual Report to Congress (covering Oct. 1, 2017 through March 31, 2018). Here are the key things labs and lab managers need to know about this year's Report.

Improper Payments to Labs

While, curiously, the OIG did not provide a total, labs featured prominently in improper Medicare and Medicaid payments during the period, specifically specimen validity tests billed in combination with urine drug tests which accounted for $66.3 million in improper payments to physician offices. The OIG cites CMS officials as stating that medically necessary tests for certain conditions billed on the same day as a urine drug test for a single beneficiary should be rare since the former usually can be used for the latter. Yet, such payments were frequently made due to:

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Industry Trends: PAMA Cuts Make Little Dent on Q1 Lab Earnings

PAMA-SHLAMA! The early financial returns suggest that the new PAMA Medicare Part B fee schedule is having only a marginal impact on at least publicly traded labs. That assessment is based on newly published first quarter earnings reports which show that FY 2018 is off to a very strong start despite PAMA reimbursement cuts.

Growth Fueled by Acquisitions

One reason labs are doing better than expected is preparation. Over the past two years, a number of larger labs have made strategic acquisitions to make up for anticipated PAMA losses. The strategy seems to have paid off with large labs like Abbott, Becton Dickinson, PerkinElmer, Quidel and Thermo Fisher Scientific reporting atypically high revenue growth as a result of recently completed acquisitions.

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Enforcement Trends, *from page 1*

- Providers' failure to follow existing Medicare guidance; and
- Flaws in CMS system edits designed to screen out such improper claims.

Even after CMS implemented improved edits, $1.8 million in improper payments still got through over a seven-month rate. On a projected basis, that would amount to $12.1 million over a five-year period. OIG's recommendations with which CMS has concurred:

- Order Medicare contractors to recover those $66.3 million in improper payments from physicians that billed them; and
- Further strengthen CMS's system edits.

Other Problem Areas

Other problem areas resulting in improper payments that the OIG cites include:

- Outpatient physical therapy services—of the 300 claims that OIG randomly reviewed, 61% did not meet Medicare medical necessity, coding or documentation requirements;
- Hospital reporting of cardiac medical device credits associated with recalled devices—none of the 296 hospital payments reviewed complied with Medicare rules for reporting manufacturing credits;
- Payments for Part B drugs—Failure to exclude noncovered versions in average sales prices of two Part B drugs resulted in $366 million in improper payments over a two-year period; and
- Capitation payments for dead patients—while CMS policies and procedures did a good job of preventing them, the agency was less effective in recovering improper payments that had already been made, with $2.4 million for 1,817 capitation payments for 978 beneficiaries still unrecovered.

Enforcement Activities

Year over year, enforcement activities were sharply down in all metrics except for program exclusions. Most startling was the over 25% decline in year to date recoveries compared to FY 2017:

Metric	FY 2017	FY 2018
Total recoveries	$2.04 billion	$1.46 billion
Criminal actions	468	424
Civil actions	461	349
Exclusions	1,422	1,588

Enforcement against Labs

The OIG typically includes at least two or three cases involving labs among its highlighted cases. But the 2018 Semiannual Report calls out just one such case, a settlement of allegations that a services agreement between Primex Clinical Laboratories, LLC and the CEO and owner of lab service firm DNA Stat, LLC (DNA Stat) constituted an illegal kickbacks arrangement. Among other things, Primex and DNA Stat allegedly provided physicians with in-office medical technicians to do work related to a Primex-sponsored study to induce them to order pharmacogenetic tests from Primex. Price tag:

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- Primex agreed to pay $3.5 million and enter a five-year corporate integrity agreement; and
- The CEO agreed to pay $270,000 and a five-year exclusion.

The 5 Takeaways

OIG Semiannual Reports tend to be pretty formulaic and relatively unchanged from year to year. But there are always subtle "tells" to be found, especially when you read them against previous versions. For lab managers, the key points in this year's Report:

1. Overall federal enforcement activity is down compared to the same period last year;
2. Pharmaceuticals, medical devices and opioid drugs are commanding the lion's share of the OIG's attention;
3. But while labs are no longer the focal point they used to be, they remain on the OIG enforcement radar;
4. In fact, attention is shifting back to labs particularly to the extent they play a role in monitoring of patients prescribe legal opioids;
5. The inclusion of an item calling out urine drug testing is both an indication and a harbinger of increased enforcement activity targeting labs that perform opioid related tests.

FDA Opens Door to Direct-to-Consumer Marketing of Genetic Tests—But Just a Crack

In a notice for public comment issued last November, the FDA raised eyebrows by floating a proposal that would make it easier to bring new genetic health risk (GHR) assessment tests to market. The message to GHR test manufacturers: Once you get first time premarketing authorization, you can sell new GHR tests directly to consumers (DTC) without undergoing additional review. On June 5, the agency made good on its promise by finalizing the proposal.

The New DTC Genetic Tests Exemption

The June 5 notice, (which also says that not even premarket notification is necessary for certain class II (moderate risk) GHR assessment *devices*) is the latest example of the FDA's new "flexible" regulatory approach to genetic risk tests. "As consumer interest in genetic risk information grows, opportunities are also expanding for the detection of additional genetic conditions and diseases that can help inform people of their medical risks," according to the statement.

While acknowledging that these tests pose risks "especially if they provide consumers with incorrect or misleading information that may be used to make health choices without the advice of a medical professional," the agency insisted that one-time premarket authorization would be enough to manage the problems of false negatives and false positives. And, of course, test manufacturers would still be on the hook for making false claims in their DTC advertising.

Doesn't Apply to GHR Tests Used for Treatment Decisions

The notice also makes it clear that the new exemption does not apply to GHR tests used to inform treatment decisions. The four types of tests that cannot be commercialized even with prior premarket approval include:

1. Prenatal testing;
2. Cancer predisposition testing;
3. Pharmacogenomics testing; and
4. Genetic diagnosis of deterministic autosomal dominant variants.

The not-for-treatment-decision limitations are consistent with previous FDA policy. Thus, for example, earlier this year, when the FDA granted first ever premarket authorization to 10 GHR tests from consumer genomics firm 23andMe, it attached strings in the form of "caveats" or controls restricting DTC marketing of GHR tests used to inform treatment decisions, such as hereditary cancer tests analyzing BRCA1 and BRCA2 genetic mutations that may influence women to decide whether to have a prophylactic mastectomy. (For more details, see *NIR*, April 3, 2018.)

ACA: DOJ Won't Defend Individual Mandate in Court—But 16+ States Will

One of the DOJ's principal roles is to defend the federal laws in court cases challenging their constitutionality. But the agency has made it known that it will not be doing that in a lawsuit brought by 20 Republican-led states claiming that the individual mandate and other key provisions of the Affordable Care Act are unconstitutional.

While unusual, the DOJ's decision not to defend a federal law, which has the backing of the President, is not unprecedented.

Constitutionality of ACA Individual Mandate

Legal challenges to the individual mandate requiring individuals to buy insurance or pay a tax penalty are nothing new. In 2012, the U.S. Supreme Court upheld the mandate as a valid exercise of Congress' power to tax. But rather than ending the controversy, the ruling served only to further politicize it. The tax bill Congress enacted last year included a provision repealing the penalty provisions but left the actual mandate to buy insurance in place.

The new lawsuit, which was filed in February, returns the controversy to the judicial level. Now that the tax penalty has been repealed, the 2012 Court ruling is no longer effective, the states contend. And since the mandate's constitutionality is now back in play, the argument goes, another key ACA provision tied to the mandate, namely, the guarantee of coverage for people with pre-existing conditions, is also subject to constitutional challenge.

This is normally the stage where the DOJ jumps in and defends the federal law under attack. But the brief the agency filed on June 7 argues that the challenged ACA provisions actually are unconstitutional and should be overturned.

What It Means

While unusual, the DOJ's decision not to defend a federal law, which has the backing of the President, is not unprecedented. The Obama DOJ took the same approach in calling off its efforts to defend the federal ban on same-sex marriage.

Moreover, the vacuum left by the DOJ has already been filled. As reported by *The Wall Street Journal*, 16 states and the District of Columbia have been granted permission to intervene in the case and defend the ACA.

FOCUS ON:

Feds Target Providers Who Took Free Test Cup Kickbacks from Millennium Labs

Free point-of-care test cups from Millennium Labs have become radioactive. So far, at least six different providers have agreed to fork over significant amounts (ranging from $40K to $186K) to settle kickback charges stemming from accepting those freebies from the now bankrupt lab, including two settlements in just the past six weeks. Fallout from the continuing scandal is an instructive tale of how something as seemingly harmless as a test cup can form the basis of an improper relationship tainting subsequent referrals between a provider and lab.

The Millennium Case

It all started with the notorious Millennium Health case. While the key charges against Millennium Health centered on use of custom profiles to bill Medicare for medically unnecessary tests, prosecutors also claimed that Millennium provided free POCT cups with embedded testing to physicians in exchange for referral of urine specimens in violation of the Anti-Kickback Statute (AKS) and Stark Law. Physicians allegedly agreed not to bill any insurer for the cups and return the specimen samples in each cup to Millennium for additional, often more expensive lab testing. Millennium also charged physicians who did not return the cup for further testing.

Ameritox LTD, a competitor, got the ball rolling by suing in Florida federal court and winning an $11.26 million judgment. Millennium appealed.

Why Free Test Cups Crossed the Kickback Line

The focus of the appeal was whether offering free cups to physicians violated the AKS and Stark Law ban on paying "remuneration" for referrals. The Stark Law specifically says that banned "remuneration" does **not** include "[t]he provision of items, devices or supplies that are used solely to (i) collect, transport, process, or store specimens for the entity providing the item, device, or supply, or (ii) order or communicate the results of tests or procedures for such entity." Although there is no such "carve out" for *de minimus* remuneration in the AKS, the OIG has made clear in starting with its 1994 Laboratory Fraud Alert that provision of supplies and equipment under those limited circumstances will not implicate the AKS.

Accordingly, Millennium argued that it did nothing wrong because the supplies were "used solely to (i) collect, transport, process or store specimens for the entity providing the item, device, or supply, or (ii) order or communicate the result of tests or procedures for such entity."

Although not a party to the case, the DOJ took the unusual step of intervening to counteract what it claimed were Millennium's "erroneous" arguments. In its *amicus curiae* ("friend of the court") brief, the DOJ brief focused on the

FOCUS ON:

word "solely" in the statute. "Solely" means that the freebie may not convey to the receiving physician even a tiny benefit that is not related to permissible collection, transport, and storage purposes. Millennium's actions did not fall within the exception, the DOJ argued, because the test strips embedded in the free POCT cups were not integral to collecting, transporting, processing or storing specimens; they were there to help the physicians make treatment decisions more quickly at no cost. Accepting Millennium's argument would open an "enormous" loophole in the Stark Law enabling labs to attach anything, even five-dollar bills, to cups. According to the DOJ:

> "The 'cup agreements'. . . create exactly the sort of intertwined financial relationships in the health care system that the Stark Law and AKS are designed to prohibit. . . .The purpose and effect of this arrangement was to give doctors a significant financial incentive to obtain laboratory testing of each sample collected in a POCT cup and to obtain such testing from Millennium rather than a competitor. That is precisely the sort of inducement that the Stark Law and the AKS forbid."

Feds Turn Downstream

In October 2016, Millennium tossed in the towel and agreed to settle all claims for $256 million, a record high settlement involving health care fraud by a lab. Almost inevitably, prosecutors then began to target the downstream providers who accepted the free cups from Millennium.

So far, six different providers—mostly pain management and drug treatment centers and in a couple of cases, individual physicians associated with the provider—have been caught up. The latest example is Michigan-based opioid addiction clinic, Recovery Pathways, LLC, which on May 24, agreed to pay $64,555.

Date	Provider(s)	Settlement Amount	Individual Physicians Also Charged?
May 24, 2018	Recovery Pathways, LLC (Michigan)	$64,555	NO
April 5, 2018	Affordable Medical Care f/k/a Andalusia Medical Center (Alabama)	$40,500	YES
Feb. 28, 2018	The Pain Institute, Inc. d/b/a Space Coast Pain Institute (Florida)	$95,302	YES
Dec. 5, 2017	Addiction Medical Care of Norwalk, Practice Management Associates Norwalk, LLC, Addiction Medical Care of Columbus, and Practice Management Associates, LLC (collectively, "AMC") (Ohio)	$79,880	NO

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Date	Provider(s)	Settlement Amount	Individual Physicians Also Charged?
Sept. 27, 2017	Advanced Pain Management (Arizona)	$186,210	NO
Sept. 18, 2017	Parallax Center, Inc. (New York)	$64,203	NO

Takeaway: The moral of the Millennium case is not that free test cups are illegal remuneration but that they can be. Many if not most such arrangements can be justified under the "used solely" exception language referred to above. What made the test cups in Millennium radioactive was the embedding of testing strips. Rightly or wrongly, by adding an extra feature to what would normally have been treated as an item of minimal value raised suspicions that Millennium was trying to using the de minimus *exception as an end-run around AKS and Stark Law referral prohibitions.*

Labs IN COURT

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

Psychiatrist Pays $805K to Settle Urine Drug Test Billing Fraud Claims

Case: The DOJ charged the owner of a Connecticut psychiatric practice of false billing of urine drug screening tests. The practice allegedly tested urine samples collected from patients with substance use disorders for different classes of drugs and billed each class tested for as if it were a separate patient encounter. Under Medicare and Medicaid rules, urine tests screening for multiple classes of drugs are considered one test since they are conducted on a single urine sample. The alleged abuses, which involved Medicare and Connecticut Medicaid, continued over a nearly three-year period.

Significance: The case, the latest in a string of urine drug test abuse actions against physicians, was originally brought by a whistleblower, a former employee of the practice, who will get $99,113 of the settlement.

Connecticut Hospital Settles Self-Disclosed Stark Violations for $423K

Case: There was more action in Connecticut this month. Another major settlement in the Nutmeg State was authored by Hartford Hospital after it made the mistake of leasing office space to a physician practice (and Medicare referral source) at below fair market value rents. Facing the prospect of trial for violating the Stark law as well as the Civil Monetary Penalties Law for subsequently billing services provided to Medicare beneficiaries as a result of those poison referrals, the hospital has agreed to fork over $423,017 to settle.

Significance: Unfortunately, we do not know any of the details of the arrangement because the hospital self-disclosed the violation to the OIG. Along with a lower fine,

shielding potentially embarrassing details is one of the advantages of self-disclosure and something you need to consider if your lab ever unearths a violation before the OIG does.

Health Care CEO Charged with Paying Kickbacks to Pill Mill Doctor

Case: The former owner and CEO of Alabama chronic care management provider MyPractice24, Inc. has been indicted for an alleged kickback scam involving what has become Public Enemy Number One: abuses involving opioid drugs. The feds claim the CEO offered not only cash bribes but also free chronic care management and medical billing services to a Montgomery physician and his staff for referring patients to MyPractice24. The CEO also allegedly waived Medicare co-pays to recruit patients to enroll in its chronic care management program.

Significance: The physician who allegedly took this bundle of freebies from MyPractice24 has since pleaded guilty to illegal drug distribution, health care fraud and money laundering. And once one domino falls, others typically follow. Thus, it seems highly likely that once they are done with the CEO, the prosecutors will focus on lower level staff managers within both MyPractice24 and the Montgomery practice.

Ohio Hospital System Settles Kickback Claims for $14.25 Million

Case: Mercy Health has agreed to pay $14.25 million to settle charges of having improper financial relationships with six referring staff physicians. The feds accused the Cincinnati-based nonprofit system of providing above fair market value employment compensation to five internists and one oncologist in violation of the *False Claims Act*.

Significance: The size of the settlement is somewhat surprising given the mitigating circumstances. Mercy Health self-disclosed the violations after discovering "errors in the administration of a small number of physician arrangements" during an internal audit and fully cooperated with the investigation, according to a company statement. By the same token, this is not the first time Mercy Health has been in hot water with the feds for false billing. Recently, Mercy hospitals in Missouri and Maine have faced—and ultimately settled—charges of paying oncologists and other physicians for referrals.

Shareholders Sue Myriad Genetics Over Alleged myRisk Billing Improprieties

Case: Last March, Myriad Genetics disclosed that it had received an OIG subpoena related to an investigation into possible false claims stemming from the firm's billing of Medicare and Medicaid for its myRisk genetic cancer test over a four-year period. At issue, specifically, is Myriad's use of CPT codes 81211 and 81213—full sequencing analysis of BRCA 1/2 and duplication and detection analysis of the genes—to bill for myRisk. Now, two different groups of shareholders have filed class action lawsuits charging Myriad with failing to disclose its improper billing practices to investors and making misleading financial claims about the company to the extent those representations were based on false information about myRisk revenues.

Significance: Keep in mind that Myriad has not been charged, let alone convicted of any fraud offense. But the moral of this case is how in the current litigious environment, the mere suspicion of fraud and improper billing may be enough to create ancillary legal problems for labs. This is especially true for publicly traded labs that face the specific risk of being sued by their own shareholders for securities fraud.

Case of the Month: Individual Principles Hit with $114.1 Million Verdict for Role in HDL Blood Test Fraud

Roughly three years ago at this time, mega-scandals were in the news featuring diagnostic giants like Millennium, Health Diagnostic Laboratory (HDL), Biodiagnostic Laboratory Service and the like. But now that the labs themselves have settled, the focus has shifted to the individuals and associated firms involved. (See the related article on Millennium Labs and free test cups on page 6). Many of these spinoff lawsuits have also settled. And if the recent South Carolina ruling involving the former principles of HDL is any indication, the defendants who chose settlement over trial made a prudent decision.

The $114.1 Million Verdict

The case against HDL and its lab business associate Singulex, Inc. began as a *qui tam* whistleblower lawsuit alleging payments of kickbacks disguised as processing fees of $10 to $17 per test to physicians in exchange for orders of medically unnecessary blood tests; then, by billing Medicare and TRICARE for tests provided under the arrangement, the labs violated the False Claims Act (FCA). In April 2015, the case settled with HDL agreeing to pay $47 million and Singulex $1.5 million. Both labs also entered into Corporate Integrity Agreements with the government.

The current case also started as a whistleblower suit targeting HDL's former CEO and a pair of individuals involved in marketing HDL and Singulex tests for their role in the scheme. The defendants decided to fight it out in court.

It turned out to be a bad move. After a two-week trial, the jury found all three jointly and severally liable for kickback and FCA violations. The numbers were staggering:

- **35,074:** False claims by HDL the defendants were responsible for submitting to Medicare and TRICARE;
- **$16,601,591:** The value of those claims;
- **3,813:** False claims by Singulex the two marketing defendants were responsible for submitting to Medicare and TRICARE;
- **$467,953:** The value of those claims.

The Bill

Having established liability, the court then had to determine the damage award. The formula:

Treble the damage amounts (something courts are allowed to do under the FCA)
+
Offset of settlement payments HDL and Singulex received for the claims
+
$63.8 million in damages the DOJ requested

Total: $114,148,661.86

Genomic Tests: Two New Assays Win FDA Breakthrough Device Designation

Earlier this month, the FDA finalized new rules designed to relax the regulatory obstacles faced by manufacturers in commercializing new genetic health risk assessment tests. (See the related story on page 3.) And now an earlier liberalization program called the Breakthrough Devices program is starting to have an impact on diagnostics test makers.

According to the company, if the assay is ultimately approved, it would become the first FDA-approved liquid biopsy to incorporate multiple companion diagnostics and biomarkers to inform the use of targeted therapies, including immunotherapies.

The Breakthrough Device Designation

For decades, the FDA has been criticized for blocking patient access to new treatment technologies. Adopted as part of the 2016 *21st Century Cures Act* legislation addressing those concerns by, the Breakthrough Device program is an expansion of the Expedited Access Pathways program that enables test makers to work together with the FDA to cut development costs and approval lead time.

In the past six weeks, a pair of test makers announced Breakthrough designations for new assays.

FoundationACT Assay

On April 26, Foundation Medicine announced that the FDA had granted Breakthrough Device designation to the new liquid biopsy assay the company is developing as an expanded version of its FoundationACT assay. The NGS-based IVD for detecting substitutions, indels, copy number alterations and gene rearrangements in 70 genes as well as genome signatures in circulating cell-free DNA isolated from plasma, is being created as a companion diagnostic to identify patients who may benefit from certain cancer therapies. According to the company, if the assay is ultimately approved, it would become the first FDA-approved liquid biopsy to incorporate multiple companion diagnostics and biomarkers to inform the use of targeted therapies, including immunotherapies. However, other firms, including Guardant Health, are developing similar products.

AutoGenomics Opioid Dependency Panel

On June 6, AutoGenomics said that it had gained Breakthrough Device designation for its Infiniti Neural Response Panel, a genomic test for assessing opioid dependency to be used by physicians in prescribing pain medications. "We believe that this multi-variant addiction panel with its predictive algorithm represents a significant tool for healthcare practitioners to identify and better manage patients at risk of opioid dependency," noted AutoGenomics President and CEO Fareed Kureshy in a statement.

Industry Trends: PAMA Cuts Make Little Dent on Q1 Lab Earnings, *from page 1*

Organic Revenues & Core Products Also Up

While revenue boosts from outside acquisitions were foreseen, the strong growth in organic revenues and core lab products and services was much more surprising. Gains were not only widespread but significant. Thus, among the gainers, only three failed to make their Wall Street targets:

- Quest Diagnostics which posted 3% growth but came up just $2 million shy of its $1.90 billion target;
- NantHealth which missed its $23.3 million target by $1 million despite 17% growth; and
- Struggling Waters whose $498 million in Q1 revenues were up 7% year over year but nowhere close to the $535.3 million target.

Fueled by better than expected earnings, no fewer than eight firms raised their 2018 revenues and/or Earnings Per Share guidance during the quarter.

The Flu Factor

The intense flu season was another key factor of success in the first quarter, lifting firms that offer respiratory and influenza products, e.g., BioMérieux, Danaher, GenMark Diagnostics and Meridian Bioscience, but harming just about everybody else by keeping would-be patients home. The terrible weather of January, February and March also exercised a negative impact on most.