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OIG Semiannual Report: Opioid Crackdown Is Making Labs a Prime Enforcement Target Once Again

Once the favorite whipping boy of federal enforcers, labs have been demanding less and less of the OIG's attention in recent years. But the newly published OIG Semiannual Report to Congress (covering Oct. 1, 2017 through March 31, 2018) suggests that this trend may be arresting if not reversing as a result of the opioid crackdown. Here are the key things labs and lab managers need to know about the new Report.

Improper Payments to Labs

Labs featured prominently in improper Medicare and Medicaid payments during the period, specifically specimen validity tests

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Compliance Perspectives: How to Implement a Respiratory Protection Program at Your Lab

Worker exposure to infection and hazardous substances is a constant and pressing challenge for lab managers. And if yours is among the many labs where workers are required to use respirators, you face the additional challenge of complying with the OSHA Respiratory Protection Standard (Section 1910.134). The centerpiece of the Standard—and primary source of OSHA respiratory protection citations—is the mandatory implementation of a Respiratory Protection Program (RPP). Here's a look at RPP requirements and the 10 things your own Program must include.

OSHA REQUIREMENTS

Does Your Lab Need an RPP?

One of the hardest parts about keeping lab workers safe and healthy is preventing them from breathing in the substances that can poison them. The ideal solution is to use engineering controls like ventilating systems to eliminate airborne hazards or at least reduce them so that workers' exposure is kept below the permissible exposure limit (PEL) for the particular substance. But where use of engineering controls isn't reasonably practicable, labs must require respirator use to keep workers' exposure below the PEL.

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OIG Semiannual Report: Opioid Crackdown, *from page 1*

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:

- 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

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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.

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:

- 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.

Case of the Month: Jury Socks HDL Blood Test Fraud Principles with $114.1 Million Verdict

Roughly three years ago at this time, mega-scandals 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

Labs IN COURT

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

Insurer Sues Florida Lab and California Hospital for Toxicology Test Billing Scam

Case: Anthem Blue Cross Blue Shield is suing Reliance Laboratory Testing for allegedly conspiring with California hospital Sonoma West Medical Center to create a fraudulent billing organization in a bid to get around Anthem's $32 per test fee cap. By billing toxicology tests through the hospital rather than the Florida Reliance lab that performed them, Sonoma West was able to bill $3,500 per claim, the suit charges. Over a nine-month period, Sonoma West submitted more than 15,000 netting $16 million in payments, according to the complaint.

Significance: This is the latest in a growing line of private insurer suits targeting labs for test billing rip offs. (For more details, see *GCA*, May 23, 2018.) Anthem says it got wise to the scheme after receiving a call from a Missouri health plan member saying she had received a statement from Sonoma West even though she had never been to California. After investigating and finding that patients listed on Sonoma West claims were never patients at the hospital, Anthem put a stop to the scheme by implementing a "zero pay" system edit that implemented Anthem into its toxicology claims software system.

Midwest Lab & Pain Clinics at Center of Massive Opioid Distribution Scheme

Case: The feds filed criminal charges against a CEO and four physicians as part of an investigation into a $200 million health care fraud scheme involving a network of Michigan and Ohio pain clinics, labs and other providers responsible for the distribution of over 4.2 million doses of medically unnecessary opioid injections, many of which were resold on the streets. The CEO and owner of the clinics and labs allegedly conspired with clinic physicians to prescribe oxycodone, hydrocodone, oxymorphone and other controlled substances to Medicare beneficiaries who did not need them, including addicts. Beneficiaries were also required to submit to expensive, medically unnecessary and painful injections to obtain the drugs, the indictment charges.

Significance: This case is typical of the new face of health care fraud enforcement in the opioid epidemic era. It began when Medicare conducted a medical review of the injection claims and determined that 100% of the claims were not eligible for Medicare reimbursement and summarily suspended the billing privileges of the pain clinics involved. The labs allegedly got involved by performing medically unnecessary urine drug tests ordered by clinic physicians. After medical review of lab claims determined that 95% of claims failed to meet Medicare reimbursement criteria, the lab was ordered to repay $6.9 million to Medicare.

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.

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.

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 word "solely" in the statute. "Solely" means that the freebie may not con-

vey 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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FOCUS ON

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.*

OIG Work Plan Monthly Review: June 2018

None of the eight new Work Plan items for June directly address labs and lab testing. However, five of the items may indirectly labs that are part of larger health networks participating in the activities and programs covered.

1. Medicare Part B Payments for ESRD Dialysis Services

Issue: Previous OIG review found problems with Medicare payments for outpatient end-stage renal disease treatments including payments for services:

- For services not furnished or documented;
- For which there was insufficient medical necessity documentation;
- That were not ordered by a physician; and
- That were ordered by a physician not treating the particular patient.

OIG Action: The OIG plans to review Part B ESRD dialysis claims to see if the billed services met all Medicare requirements.

2. Medicare Part D Denials & Appeals

Issue: The Medicare Part D capitated payment model may give insurers an incentive to deny beneficiaries access to services or payment. But there is also a multi-layered appeals system that beneficiaries can use if they are denied Part D prescriptions and payments.

OIG Action: The OIG will review national trends and CMS's oversight of prescription drug denials in Part D during 2014-2016 to determine the

extent to which denials that have been appealed to each level of review were overturned. The agency will also look at variations in appeals and overturned denials across Part D contracts and evaluate CMS's efforts to monitor and address inappropriate denials in Part D.

3. Inappropriate Medicare Advantage Denials of Services & Payment

Issue: The capitated payment model that Medicare Advantage uses may give managed care plans an incentive to inappropriately deny access to, or reimbursement for, health care services.

OIG Action: The OIG will conduct medical record reviews to determine the extent to which beneficiaries and providers were denied preauthorization or payment for medically necessary services covered by Medicare and try to determine the reasons for any inappropriate denials and the types of services involved.

4. Review of Home Health Claims for Services with 5 to 10 Skilled Visits

Issue: Home health agencies receive Low Utilization Payment Adjustments (LUPAs) if they provide four or fewer covered skilled service provider visits in an episode. But after a fifth visit is provided, the HHA instead gets a full 60-day payment based on episode of care.

OIG Action: Since the OIG has not reviewed payments for LUPA, it will review supporting documentation to determine whether home health claims with 5 to 10 skilled visits in a payment episode in which the beneficiary was discharged home met the conditions for coverage and were adequately supported as required by federal guidance.

5. ACO Strategies for Reducing Spending and Improving Quality

Issue: The Medicare Shared Savings Program (MSSP) introduced accountable care organizations into Medicare to promote accountability of hospitals, physicians and other providers responsible for a patient population, coordinate items and services, encourage investment in infrastructure and redesign care processes for high-quality and efficient service delivery.

OIG Action: The OIG will identify ACO strategies aimed at:

- Reducing spending and improving care in different service areas, such as hospitals and nursing homes;
- Working with physicians and engaging beneficiaries;
- Managing the care of beneficiaries needing high-cost, complex care;
- Addressing behavioral health and social needs; and
- Using data and technology.

Compliance Perspectives: Respiratory Protection Program, From Page 1

The OSHA Occupational Exposure to Hazardous Chemicals in Laboratories Standard (Section 1910.1450(i)) stipulates that in this situation where respirator use is required, the lab must furnish and pay for the necessary equipment and follow the OSHA Respiratory Protection Standard, including the requirement to implement a written RPP run by a "suitably trained program administrator" that sets out specific safety measures for respirator use in the workplace (Sec. 1910.134(c)).

10 Elements to Include in Your RPP

1. Respirator Selection

There are many different types of respirators, each of which has its own specific capabilities and limitations. The RPP must set out your procedures and criteria for selecting the appropriate respirator. Respirators must be NIOSH-certified and meet Standard requirements. There are two sets of respirator selection criteria:

- One for use in atmospheres that are IDLH (immediately dangerous to life or health); and
- Another for non-IDLH atmospheres.

2. Medical Evaluation of Prospective Respirator Users

Lab workers required to use respirators must undergo medical testing by a doctor or other licensed health care professional before they're fit tested and use the respirator for the first time. Stage 1 of medical evaluation is a baseline exam in which the worker fills out an OSHA questionnaire or provides equivalent information. Follow-up testing is required for workers who report medical conditions that could make respirator use dangerous. Re-evaluation is required if users show certain symptoms or after changes in work conditions affecting respirator use.

3. Fit Testing of Tight-Fitting Respirators

The RPP must provide for mandatory fit testing of workers required to use respirators that include a tight-fitting facepiece to ensure a proper fit and prevent leakage. Fit testing must be done before first use and at least once a year thereafter. The two test methods you can use:

- Quantitative Fit Testing, which uses a numerical measure to assess fit; and
- Qualitative Fit Testing, which involves a pass/fail test.

4. Respirator Use Procedures

The RPP must include procedures for proper use of respirators in both routine and emergency situations, including procedures to:

- Prevent leaks in the respirator facepiece seal;
- Prevent workers from removing respirators in hazardous environments;
- Ensure that respirators operate effectively throughout the work shift;
- Protect workers entering IDLH atmospheres; and
- Protect workers engaged in structural firefighting.

Go online to download a checklist for respirator fit testing

5. Respirator Cleaning, Maintenance & Repair Procedures
You must furnish respirator users equipment that's clean, sanitary and in good working order. The RPP must incorporate a system for ensuring proper care and maintenance of respiratory equipment, including procedures for proper:

- Cleaning and disinfecting;
- Storage;
- Inspection; and
- Removal or repair of defective equipment.

6. Atmosphere-Supplying Respirator Breathing Air Requirements
If you require workers to use atmosphere-supplying respirators that provide breathing air from an independent source so that the user doesn't breathe the air in the work area (supplied-air respirators (SARs) or self-contained breathing apparatus (SCBA)) you must take measures to ensure that the breathing air supplied is safe, including ensuring:

- Breathing air meets quality standards;
- Oxygen use restrictions are in place to limit fire and explosion risks;
- Measures are in place to ensure safe use of cylinders, compressors and couplings; and
- Breathing gas containers are appropriately labeled.

7. NIOSH Labeling of Filters, Cartridges & Canisters
Your RPP must require all respirator filters, cartridges and canisters to have a proper NIOSH label and color coding and ban anybody from removing, defacing, obscuring or doing anything else that makes the label illegible.

8. Respirator Safety Training
The RPP must ensure that all workers required to use a respirator receive the proper training before first use. The Standard doesn't prescribe any particular training program but does list specific things workers must be able to "demonstrate knowledge" of before you can consider their training complete. It also explains when and how training must be provided.

9. Ongoing Program Evaluation
You must periodically monitor your RPP to evaluate its effectiveness. Monitoring involves consulting with workers required to wear respirators to get their feedback on how respirators are working, identifying problems and taking corrective actions.

10. Recordkeeping
Finally, you must retain and make available to workers, their representatives and OSHA officials upon request for inspection and copying certain RPP related records, including:

- A copy of the RPP itself;
- Medical evaluation records; and
- Respirator fit testing records.

The End May Be Near for Theranos & Elizabeth Holmes

Four years ago, Theranos was a $10 billion company poised to turn a breakthrough blood testing technology into a diagnostics dynamo to the tune of $70 billion in annual sales. Today, the company and its founding CEO are on the brink of ruin.

The latest and most devastating blow came last week when a federal grand jury indicted Theranos CEO Elizabeth Holmes and former COO Sunny Balwani on nine counts of wire fraud and two counts of conspiracy, charges carrying a potential sentence of 20 years in prison, fines of $250,000 per count and restitution.

According to prosecutors, "Holmes and Balwani used advertisements and solicitations to encourage and induce doctors and patients to use Theranos' blood testing laboratory services," all the while knowing that its touted finger-prick blood tests could not consistently produce accurate and reliable results.

Meanwhile, *The Wall Street Journal* reports that Theranos is headed for bankruptcy.

Three months ago, it appeared that Holmes and the company she founded in 2013 might be out of the woods when they settled stock fraud charges with the Securities and Exchange Commission.