G2 INTELLIGENCE
A DIVISION OF PLAIN LANGUAGE MEDIA

# G2 Compliance Advisor

For Clinical and AP Laboratories and Pathology Practices

June 2018

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### Upcoming Events

**Lab Institute 2018**

*Surviving Disruption: Rethinking Business Models, Technologies, and Competitive Strategies in a Changing Lab Market*

Oct. 24-26, Washington, DC
www.labinstitute.com

## Compliance Perspectives: The 12 Things to Include in Your Drug & Alcohol Testing Policy

**MYTH**
*Employee drug testing is illegal in states where it's legal to use recreational or medical marijuana.*

### What's at Stake

No! No! No! The truth is that state laws on marijuana use and possession have little to no direct impact on *workplace* drug policies and the testing methods used to enforce them. After all, alcohol use is legal but that doesn't mean employees can't be tested for alcohol use. All marijuana legalization does is, at least according to studies, is increase use and make testing even more important than it is now. So, if your lab doesn't have an alcohol and drug testing policy, now is the perfect time to create one. And if it does already have a policy, now is the perfect time to vet it.

*Continued on page 2*

## Brief Your CEO: Medicaid Enforcement Trends & Their Impact on Labs

While they do not have to embroil themselves in the day-to-day compliance program details, the C-Suiters do need to be on top of general health care enforcement trends affecting your lab. OIG reports are an excellent source of data necessary to monitor these trends. And, as compliance officer, you can score a whole lot of respect and appreciation points with the lab executives by tracking down and analyzing the OIG data for them so they don't need to do it themselves. The OIG's newly published annual summary of Medicaid Fraud Control Unit (MCFU) activity for FY 2017 should be right at the top of your briefing agenda. Here is a summary of the report's key findings, trends and impact on labs to relay to the executives.

### Background

Start by explaining that the 50 MCFUs are essentially the state arm of the OIG in charge of investigating and prosecuting pro-

*Continued on page 8*

The 12 Things to Include in Your Drug & Alcohol Testing Policy, *from page 1*

## Is Testing Legal?

While testing is highly controversial, there are three things on which all sides agree:

- Workplace drug and alcohol use and impairment is a safety hazard;
- Labs and other employers need clear policies to prevent employees from using or being impaired at work; and
- Testing is one of if not the best ways to enforce those policies.

Another fact that's hard to dispute is that employees and unions hate testing and will go to court or arbitration to contest it. Heading into litigation, unions also have some big legal advantages, including the fact that:

- Testing is highly privacy intrusive;
- Drug and alcohol addiction (although not casual use) is a disability requiring accommodations under the ADA and state discrimination laws; and
- Employers bear the burden of justifying their testing policies as a needed and unavoidable safety measure.

The legality of a particular testing policy depends on a number of factors including:

- What's tested for, i.e., drugs or alcohol;
- Who's tested, e.g., all employees or safety-sensitive ones; and
- What's the basis for performing a test, i.e., pre-employment, post-incident/for cause or at random.

While laws vary by state, the rules follow roughly the same general patterns:

**Legality of Employee Drugs & Alcohol Testing**

| Employee Tested | Post-Incident/For-Cause* | | Random | |
|---|---|---|---|---|
| | Drugs | Alcohol | Drugs | Alcohol |
| Safety-Sensitive | Yes | Yes | Only as necessary safety measure | Only as necessary safety measure |
| Non-Safety-Sensitive | Highly unlikely | Varies by state | No | No |

* Pre-employment testing of safety-sensitive employees typically permitted

## The 12 Things To Include In Your Testing Policy

Knowing how particular types of testing *may be* justified is just the starting point. The windows for justification are extremely tight and your lab won't squeeze into any of them if it doesn't have the right testing policy. Here is a Checklist of general criteria used by courts and arbitrators to evaluate the legality of testing policies:

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Go online to download a Model Drug & Alcohol Testing Policy

Note that while the Model Drug & Alcohol Testing Policy is designed as a standalone, you can also incorporate the testing policy into a larger workplace drug and alcohol use policy. In either case, there are 12 things you should include in the policy.

### 1. Policy Statement

Like many employers do, you may want to state that your lab has a zero tolerance drug and alcohol policy. But while "zero tolerance" may be the right principle, just using the phrase doesn't get you over the legal obstacles standing in the way of enforcing a testing policy.

It's also generally advisable to phrase your policy as a workplace safety rather than a moral or even legal imperative (especially in states where marijuana is legalized) [Policy, Sec. 1].

### 2. Statement of Purpose

Acknowledge that testing is intrusive but state that it's essential to enforcing your zero tolerance policy and its workplace safety objective [Policy, Sec. 2].

### 3. Policy Scope

Make sure the policy is balanced in scope. On the one hand, testing should generally be limited to safety-sensitive employees; on the other hand, the policy should apply broadly to any and all individuals that perform safety-sensitive jobs regardless of their employment status, including employees of contractors and applicants for safety-sensitive jobs with your lab [Policy, Sec. 3].

### 4. Employees' Duties

If the testing policy is freestanding, you may want to restate or refer to employees' duties under lab's drug and alcohol use policy, including coming to work sober and fit for duty and remaining in that state at all times while on duty [Policy, Sec. 5].

### 5. Bases for Testing

The meat of the policy are the rules for different bases of drug and alcohol testing, including:

- **Pre-employment testing:** Mandatory for applicants who receive offers for safety-sensitive jobs [Policy, Sec. 6.1];
- **For-cause testing:** Allowed when there are grounds for reasonable suspicion of impairment with such grounds specifically listed [Policy, Sec. 6.2];
- **Post-incident testing:** A form of for-cause testing allowed after safety incidents and near misses [Policy, Sec. 6.3];
- **Random testing:** Permitted only for safety-sensitive employees in narrow safety-related circumstances [Policy, Sec. 6.4];
- **Post-Rehabilitation Testing:** May be required for employees that test positive who are offered the opportunity for rehab in lieu of termination [Policy, Sec. 6.5]; and
- **Scheduled Periodic Testing:** May be required as part of a fitness for duty medical exam [Policy, Sec. 6.6].

### 6. Testing Procedures

There are six crucial procedural issues you need to address in your testing policy:

- How job applicants and employees give their consent to be tested [Policy, Sec. 7.1];
- How samples are collected and who can collect them [Policy, Sec. 7.2];
- The controls in place to ensure the integrity of the sample from collection to transporting for actual testing [Policy, Sec. 7.3];
- The methods used to confirm initial positive test results [Policy, Sec. 7.4];
- The criteria for a positive result—which should generally track the applicable regulatory limit apply to the tested-for substance tested, e.g., BAC for alcohol [Policy, Sec. 7.5]; and
- Procedures for retesting and appeals after positive results [Policy, Sec. 7.6].

### 7. Privacy of Test Results

Acknowledge that test results are privacy-protected information that you'll keep secure and refrain from using except as allowed or required by law. Also indicate that test records are lab property but that you'll make them available for inspection and copying as required by law [Policy, Sec. 8].

### 8. Violations

Explain that violations include not just testing positive but tampering or attempting to tamper with samples and/or improperly refusing to submit to testing in the first place [Policy, Sec. 9].

### 9. Consequences of Violations

Make it clear that employees who commit violations are subject to discipline up to and including termination in accordance with your lab's disciplinary policies and procedures. In addition, reserve your right to revoke job offers to job applicants who test positive or commit violations before starting work [Policy Sec. 10].

### 10. Rehab Rather than Termination

Reserve your right to offer current employees who test positive the opportunity to enter a last chance agreement in lieu of immediate discipline or termination. Typically, the employee is put on administrative leave and allowed to return to work provided they successfully complete a rehab program, which usually involves regular testing [Policy, Sec. 11].

### 11. Acknowledgment of Employee Accommodation Rights

To insulate against liability risks for discrimination, acknowledge that drug and alcohol addiction are disabilities under the ADA and state discrimination laws and state that you'll provide reasonable accommodations to employees and applicants with addictions up to the point of undue hardship [Policy, Sec. 12].

### 12. Attach Consent Form

Last but not least, attach a copy of the form you require job applicants and employees to sign to consent to testing as an Exhibit to your policy [Policy, Exhibit A]. G2

# Enforcement Trends: Private Insurers Are Cracking Down on the Labs that Scam Them

Watch out billing scammers! The DOJ, OIG and whistleblower have a new ally in their never-ending quest to bring dishonest labs to justice: private insurance companies. And among the insurance companies suing to force labs to cough up their ill-gotten gains, none has been more aggressive than UnitedHealthcare.

Hiding behind the hospital's persona, the suit charges that the two labs inflated claims to 50 times the actual cost of testing, charged for tests not performed or ordered and billed for tests already billed by another provider.

## Don't Mess With UnitedHealthcare

A pair of Texas labs are learning this lesson the hard way. UnitedHealthcare is suing Sun Clinical Laboratories and Mission Toxicology (and their owners) for allegedly "conning" it into paying $44 million worth of bogus toxicology and allergy lab testing claims. Paying physicians kickbacks for referrals is just the tip of the iceberg. The insurance giant is claiming that the labs, who are not part of its network, set up testing centers inside in-network rural hospitals to make it look like the bills came from the hospitals. Then when the United payments came in, the labs allegedly had hospital employees transfer 95% of the money to the labs and their owners. Hiding behind the hospital's persona, the suit charges that the two labs inflated claims to 50 times the actual cost of testing, charged for tests not performed or ordered and billed for tests already billed by another provider.

## The Next Health Case

Aggressive legal action against labs that "con" them is hardly a new policy for UnitedHealthcare. Last January, the insurer filed a massive lawsuit against Next Health LLC claiming that the Dallas-based provider and its subsidiaries scammed it for over $100 million in drug and genetic tests. The allegations sound like they came right out of the DOJ's own script:

- Improper utilization of standing orders for tests administered to patients regardless of actual medical history or conditions;
- Payment of kickbacks to physicians in exchange for referrals;
- Illegal recruitment of insured patients to participate in "wellness studies" in exchange for $50 gift cards;
- Billing for tests that were never actually ordered or performed.

## Other Insurers Join the Fray

Of course, UnitedHealthcare is not the only private insurer to take on labs for improper billing. Last fall, Aetna filed suits against the same two Texas labs that UnitedHealthcare is suing, i.e., Sun Clinical Laboratories and Mission Toxicology, for an alleged fraudulent billing scheme costing Aetna $21 million.

Those same two labs are also at the center of a lawsuit by Blue Cross & Blue Shield of Mississippi. The accusations in both cases follow the same pattern as the alleged violations against UnitedHealthcare—payment of kickbacks and misrepresenting claims as coming from an in-network hospital.

# OIG Work Plan Monthly Review: May 2018

Of the seven new Work Plan items, none directly impact labs and lab services. However, one item on Medicare Part B reimbursement of outpatient cardiac and pulmonary rehab services may have an indirect impact on some of you. The other items may also affect some lab providers but in a much more tenuous way. Here is the complete rundown:

## 1. Medicare Part B Outpatient Cardiac & Pulmonary Rehabilitation Services

**Issue:** Previous OIG work found instances where Medicare Part B was billed for outpatient cardiac and pulmonary rehabilitation services that were not medically necessary or did not meet documentation requirements.

**OIG Action:** The OIG plans to determine whether payments for outpatient cardiac and pulmonary rehabilitation services were allowable and determine whether potential risks of improper billing and payment of these services continue to exist.

## 2. Effectiveness of HHS Hurricane Emergency Preparedness & Response Efforts in 2017

**Issue:** In 2017, HHS was given $5.97 billion in supplemental funds for emergency preparedness and response after Hurricanes Harvey, Irma and Maria, including $1.07 billion in discretionary and $4.9 billion in Medicaid funding.

**OIG Action:** The OIG will audit and assess the effectiveness of these efforts starting with the initiatives financed by the discretionary funding. Key question: Did the internal controls over emergency response and preparedness that were in place function effectively?

## 3. Healthcare Coalition (HCC) Partnerships with Non-Hospital-Based Facilities in Community Preparedness Efforts

**Issue:** HCCs, i.e., groups of public and private health care organizations, emergency preparedness planners, responders and other health officials in specified jurisdictions that receive funding through the Hospital Preparedness Program (HPP), are supposed to create emergency response plans addressing the needs of vulnerable populations, including persons with mental illnesses. But after the OIG found that non-hospital-based health care facilities commonly lacked comprehensive emergency response plans, CMS implemented new emergency preparedness requirements covering *all* facilities receiving Medicare or Medicaid reimbursement.

**OIG Action:** The OIG will examine the extent to which HCCs ensure "a successful whole community response" by integrating non-hospital-based facilities into their emergency preparedness activities and technological strategies. It will also assess Assistant Secretary for Preparedness and Response oversight and support, including coordination with CMS, of HCCs' integration of non-hospital-based facilities.

## 4. Impact of Authorized Generics on Medicaid Drug Rebates

**Issue:** In implementing the Medicaid Drug Rebate Program provisions of the *Affordable Care Act*, CMS instructed primary manufacturers to include in their calculation of average manufacturer price (AMP) the sale of autho-

rized generic drugs to secondary manufacturers in certain circumstances. Earlier OIG work has shown that including these sales in AMP calculations may significantly reduce the AMP, resulting in lower Medicaid rebates.

**OIG Action:** The OIG will examine selected drugs with authorized generics and determine how including the sales of authorized generic drugs to secondary manufacturers affects Medicaid drug rebates.

### 5. Noninvasive Home Ventilators (NHVs) - Compliance with Medicare Requirements

**Issue:** The OIG has noticed significant growth in Medicare billing for NHVs in the years since they reached the market.

**OIG Action:** The OIG will determine whether claims for NHVs were medically necessary for treatment of beneficiaries' diagnosed illnesses and whether the claims complied with Medicare payment and documentation requirements.

### 6. Recommendation Follow-up: 2014 OIG Report: Vulnerabilities in the HHS Small Business Innovation Research (SBIR) Program

**Issue:** In 2011, the OIG found that 31% of HHS SBIR fund awardees had questionable or unverified eligibility for at least one requirement and that only of the four SBIR Operating Divisions did the required check for duplicative funding within HHS. None of the OpDivs cross-checked for duplicative awards across other federal agencies. In 2014, it made two recommendations to HHS:

- Ensure compliance with SBIR eligibility requirements; and
- Improve procedures to check for duplicative awards.

**OIG Action:** The OIG will review whether HHS has implemented these recommendations and achieved improvements in its OpDivs oversight operations.

### 7. States' Procurement of Private Contracting Services for the Medicaid Management Information System (MMIS)

**Issue:** States have reportedly had issues with private MMIS contractors, including with initial procurements.

**OIG Action:** The OIG will determine if selected states followed applicable federal and state requirements for procuring private MMIS contracting services and claiming federal Medicaid reimbursement.

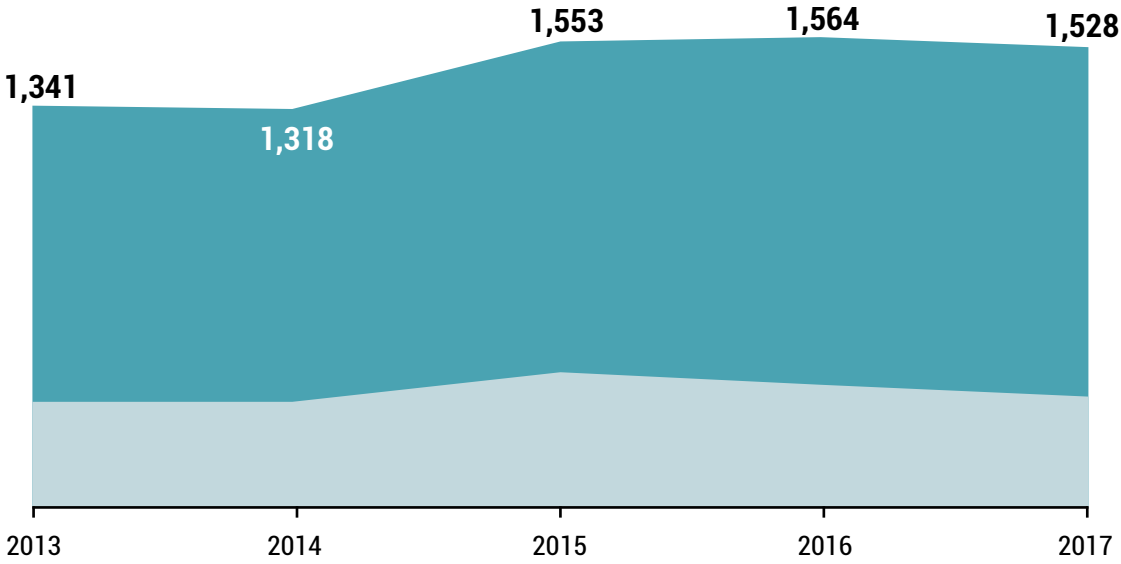
Brief Your CEO: Medicaid Enforcement Trends & Their Impact on Labs, From Page 1

vider Medicaid fraud and patient abuse violations. Each year, the OIG issues a report documenting aggregate MCFU case outcomes for the prior year including convictions, civil settlements, judgments and recoveries. The April report summarizes the results of FY 2017.

## Criminal Convictions

Start with any executive's biggest fear: the risk of criminal conviction. Note that at 1,528, total MCFU convictions have remained flat not just year-to-year but over a five-year period. Acknowledge that, like the other outcomes, criminal convictions include both fraud and patient abuse but point out that the former generally outnumber the latter at a 3-to-1 clip. Thus, fraud accounted for 73% of all convictions in 2017. Use Table 1 as a visual.

**Table 1: MCFU Convictions FY 2013-2017**



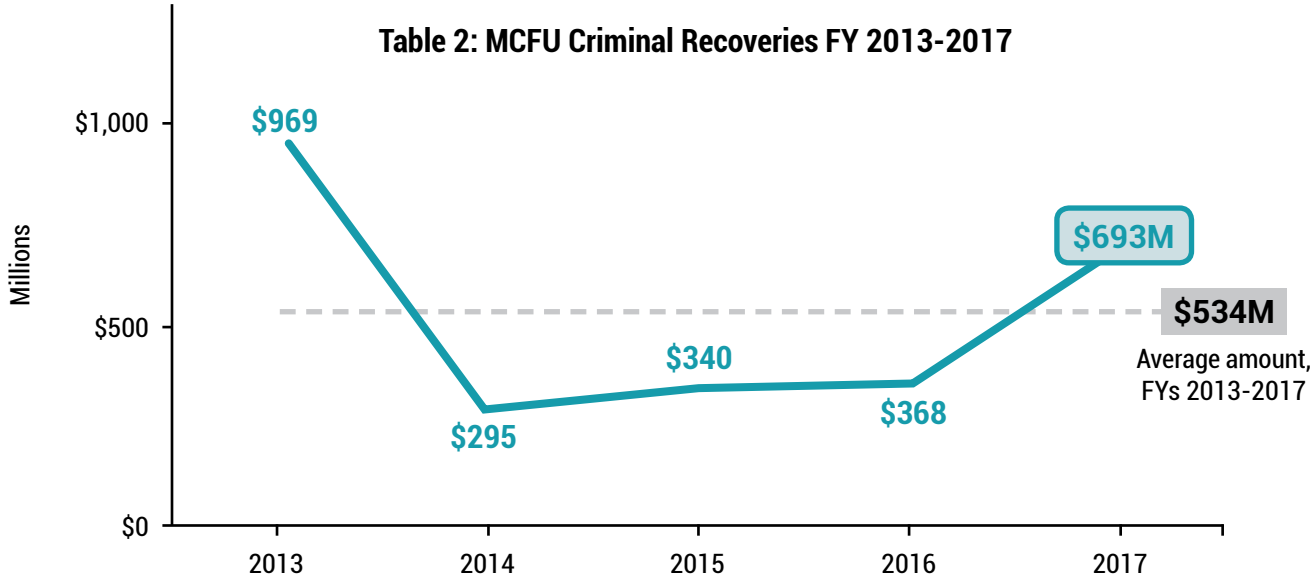

Source: OIG analysis of Quarterly Statistical Reports for FYs 2013-2014 and Annual Statistical Reports for FYs 2015-2017.

Of course, your executives will want a breakdown for the labs segment. So point out that of last year's 1,157 fraud convictions, 523 (45%) involved personal care service (PSC) attendants and agencies, by far the highest of any provider group, followed by nurses (88), home health agencies (54) and family practice physicians (36).

**Labs** were down on the list, accounting for only 12 convictions (8 clinical labs and 4 radiology and physiology labs).

## Criminal Recoveries

While the number of convictions was consistent with previous years, *criminal recoveries* were $693 million, nearly double FY 2016 levels. The point, i.e., that criminal penalties are increasing at a scary level, is one you need to ensure is not lost on your own executives.



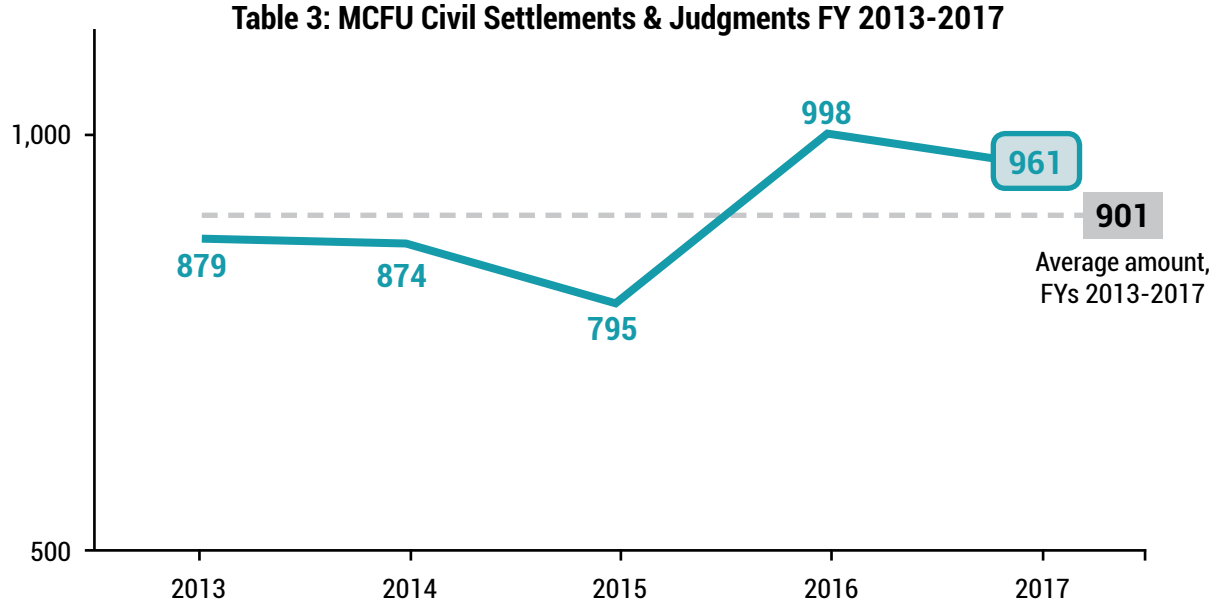

Source: OIG analysis of Quarterly Statistical Reports for FYs 2013-2014 and Annual Statistical Reports for FYs 2015-2017.

Note that the numbers are a bit anomalous to the extent that most of this money—about $519 million—came from one big case in Texas involving a doctor and other codefendants who defrauded Medicaid and Medicare by improperly recruiting individuals and falsifying medical documents.

**Labs** contributed roughly $5.443 million to total criminal recoveries with $3.396 coming from the 8 convicted clinical labs and the remaining $2.047 million from the 4 convicted radiology and physiology labs.

## Civil Settlements & Judgments

Next, move over to the civil side of enforcement. Note that in 2017, the number of civil settlements and judgments was slightly down at 961 and that these totals are very much in line with recent trends, as illustrated by Table 3.




Source: OIG analysis of Quarterly Statistical Reports for FYs 2013-2014 and Annual Statistical Reports for FYs 2015-2017.

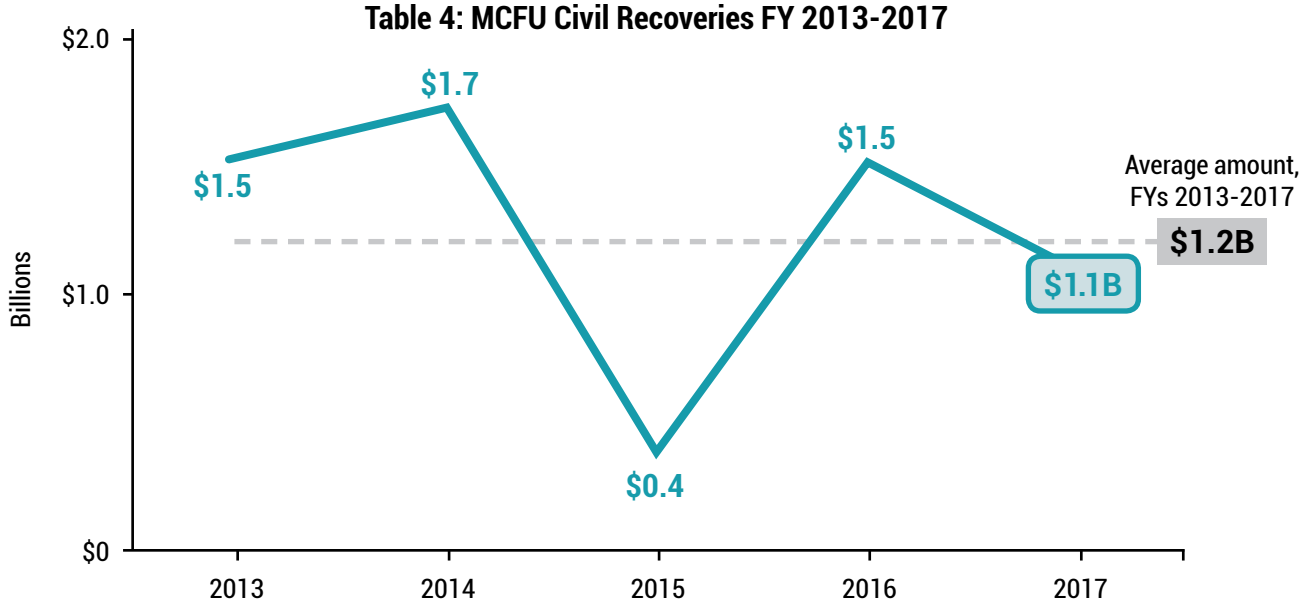
Point out that pharmaceutical makers was the segment with the most settlements and judgements in with 426 (44%) followed by pharmacies (137), DME suppliers (37), PCS attendants and agencies (34) and medical device makers (28).

**Labs** accounted for 10 settlements and judgments, 8 involving clinical labs and 2 involving radiology and physiology labs.

## Civil Recoveries

Unlike the criminal side where the decline in convictions belied the spike in recoveries, civil recoveries actually mirrored the decrease in settlements and judgments dipping to $1.1 billion, as compared to $1.5 billion in FY 2016 and below the annual $1.2 billion average during the overall five-year period.

**Table 4: MCFU Civil Recoveries FY 2013-2017**




Source: OIG analysis of Quarterly Statistical Reports for FYs 2013-2014 and Annual Statistical Reports for FYs 2015-2017.

**Labs** paid out just over $13 million in civil recoveries, with 8 clinical labs contributing roughly $6.268 million and 2 radiology and physiology labs another $6.750 million.

*Takeaway: Sum up by explaining that Medicaid fraud enforcement at the MCFU level remains steady and even in modest decline. And while labs are still drawing attention, they appear to be becoming a relatively marginal target as MCFUs focus more on the PCS and pharmaceutical sector. However, you might want to suggest that the opioid imperative is likely to turn those trends around given the lab's role in urine drug testing.*

# Labs IN COURT

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

## 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.

## Ohio Hospital System Settles Kickback Claims for $14.25 Million

**Case:** Rather than risk a trial, Mercy Health will pay $14.25 million to settle charges of entering into improper financial relationships with six referring staff physicians. The Cincinnati-based nonprofit system allegedly violated the *False Claims Act* by providing above fair market value employment compensation to five internists and one oncologist.

**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.

## Breast Cancer Recurrence Test Billing Case Ends in $2 Million Settlement

**Case:** BioTheranostics has agreed to shell out $2 million to settle claims of falsely billing Medicare for its molecular Breast Cancer Index (BCI) test. BCI, which determines the risk of breast cancer recurrence beyond five years, is used to guide treatment decisions regarding the value of extended endocrine therapy. But the DOJ claimed that BioTheranostics promoted and performed BCI on breast cancer patients who had not been in remission for five years and who had not been taking tamoxifen. In so doing, the San Diego-based company flew in the face of not only Medicare coverage rules but published practice guidelines and clinical trial data finding BCI medically unnecessary for such patients.

**Significance:** So far, FCA cases targeting billing of medically unnecessary gene expression tests have been relatively rare. Of course, that is bound to change as Medicare broadens its coverage rules for such tests. The BCI case may thus prove to be a harbinger of things to come.

## Pennsylvania Drug Testing Lab at Center of Alleged Stark Scam

**Case:** What do Dr. Robert Fetchero of Jeannette, Pennsylvania, Dr. Sridhar Pinnamaneni of Windermere, Florida, and Dr. Thelma Green-Mack of Zionsville, Indiana, have in common—other than being physicians? Answer: All three settled charges of accepting payments for Medicare referrals to Universal Oral Fluid Laboratories (UFOL), a Pennsylvania drug testing

lab with which they had an improper financial relationship in violation of the Stark and anti-kickback laws. The price of settlement:

- Dr. Fetchero: $200K;
- Dr. Pinnamaneni: $370K; and
- Dr. Green-Mack.

UFOL's medical director also pled guilty to charges for his role in the scheme which unfolded over a roughly three-year period.

**Significance:** While drug testing has been the hottest trend in lab enforcement, this case is an old-fashioned kickback scheme rather than the opioid-related abuses that have become so common over the past 18 months.

## BLS Scandal Convicted Physicians Count Reaches 38

**Case:** The latest doctor swallowed up in the Biodiagnostic Laboratory Service (BLS) bribery scheme is a 56-year-old physician from Monmouth County, NJ, who was sentenced to 24 months in prison after pleading guilty to accepting $3,000 per month in bribes for referring at least $828K worth of blood testing business to BLS labs. The judge also added two years of supervised release and a $4,000 fine.

**Significance:** The BLS scandal has become a Bermuda Triangle for physicians, with 38 convicted so far—which may be a record not just for lab but any kind of health care services bribery case. And as we approach the June 2016 anniversary of BLS's guilty plea and subsequent asset forfeiture and shutdown, the crackdown against the individual physicians involved in the scheme is still a long way from over.