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**Enforcement Trends: Labs Caught Up in Massive National Telemedicine Takedown**

So much for the pandemic’s dulling the momentum of federal fraud enforcement. Dubbed “Operation Rubber Stamp,” the new nationwide enforcement action revealed by the Department of Justice (DOJ) on Sept. 30 is the largest “takedown” in Department history involving 51 federal districts, 345 defendants, including over 100 doctors, nurses and other licensed medical professionals, and \$6 billion in false claims. And, while not necessarily the primary target, medical labs have been pulled in to the “Rubber Stamp” dragnet.

**The Takedown Target**

Of the \$6 billion in false and federal claims submitted to federal health care programs and private insurers involved

*Continued on page 2*

**Compliance Perspectives: How to Create a Legally Sound Substance Abuse Policy**

**Bottom Line on Top:**  
Make it all about fitness for duty,  
rather than zero tolerance

Although it may sound good, zero tolerance may not be the best foundation on which to build a legally enforceable workplace substance abuse policy. This is especially true in states that have legalized recreational marijuana. The reason drug and alcohol use and impairment in the workplace cannot be tolerated isn’t so much that it’s illegal, but because it renders employees unfit to do their job. In addition to undermining the productivity you’re entitled to expect from your employees, this unfitness for duty may pose a health and safety dangers to not only the employee who’s high but others in the lab. Here are 14 things to include in your Substance Abuse and Fitness for Duty Policy, along with a Model Policy you can adapt for your own use.

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■ **Enforcement Trends: Labs Caught Up in Massive National Telemedicine Takedown,**  
from page 1

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in Operation Rubber Stamp, \$4.5 billion is connected to telemedicine. And that makes perfect sense. Long touted as the future of health care, telemedicine utilization has taken off during the public health emergency by enabling care to continue without breaching the walls of social distancing. Public and private payors immediately recognized this and have temporarily expanded coverage of telemedicine services, with the expectation that coverage will become permanent before too long.

But as other segments of the health care industry can attest, with profit and payment comes scrutiny. While it may be the biggest, Operation Rubber Stamp isn't the first major federal enforcement action targeting telemedicine. For example, in April 2019, the DOJ announced the indictments of 24 individuals and telemedicine companies for allegedly accepting kickbacks from durable medical equipment (DME) suppliers and using telemedicine visits to persuade Medicare beneficiaries to accept DME that wasn't medically necessary. Similar charges were filed against other telemedicine providers in August 2019.

As Operation Rubber Stamp reveals, federal and state health care law enforcement has been stepping up the scrutiny of telemedicine since very early in the COVID-19 public health emergency.

### Telemedicine Fraud and Lab Services

Nor is Operation Rubber Stamp the first time that telemedicine abuse has been connected to ordering of lab tests. One notable case concluded on Jan. 10, 2020, when the owner of two genetic testing labs in Pennsylvania pleaded guilty to conspiring with the operator of a Florida-based telemedicine company to carry out schemes to submit false claims to Medicare for cancer genomic testing (CGx) and pharmacogenetic testing (PGx). The labs paid the operator kickback fees based on the percentage of Medicare reimbursement to obtain CGx and PGx prescriptions from physicians who were contracted by the telemedicine company to review the beneficiaries' personal and familial medical histories. According to the DOJ, the contract physicians authorized testing for greater than 95% of beneficiaries even though they didn't conduct a proper telemedicine visit, weren't treating the beneficiaries for cancer or cancer symptoms, didn't use the test results for treatment of the beneficiaries, and generally weren't qualified to understand and interpret the test results.

Not surprisingly, many of the defendants in Operation Rubber Stamp are labs and telemedicine operators charged with paying kickbacks to doctors to order medically unnecessary tests for patients with whom they never actually had televisits.

## The Other Targets of "Rubber Stamp"

Although 75% of the ill-gotten gains came from telemedicine abuses, Operation Rubber Stamp also targeted two other forms of more traditional fraudulent activity:

### Illegal Opioids Distribution and Prescription

The takedown resulted in charges against 240 defendants for allegedly participating in illegal schemes to prescribe and distribute more than 30 million doses of opioids resulting in over \$800 million in false claims. In addition to billing for services that weren't medically necessary or actually provided, in many cases, patient recruiters, beneficiaries and others received cash kickbacks in return for providing beneficiary information to providers, which the providers then used to submit fraudulent claims to Medicare. Urine and other drug testing labs were named as defendants in a number of these cases.

### "Sober Homes" Abuses

More than a dozen criminal defendants were also charged in connection with more than \$845 million of allegedly false and fraudulent claims for tests and treatments for vulnerable patients seeking treatment for drug and/or alcohol addiction. Prosecutors contend that physicians, labs, owners and operators of substance abuse treatment facilities and patient recruiters, aka "body brokers" participated in schemes involving the payment of illegal kickbacks for referring patients to substance abuse treatment facilities, where they were prescribed medically unnecessary opioids and subjected to medically unnecessary drug testing. In many cases, payors were billed thousands of dollars for a single test. The patients were then often discharged and admitted to other treatment facilities, or referred to other labs and clinics, in exchange for further kickbacks.

### Takeaway

*Health care fraud is huge business even in the midst of a global pandemic. Thus, while utilization of routine and non-COVID medical treatment has slowed down, fraudsters have effectively pivoted their business models to take advantage of the newly expanded telemedicine and coverage rules adopted in response to the public health emergency. Operation Rubber Stamp makes it clear that the enforcers are onto the scammers and determined to bring them to justice. It also represents continuation of pre-pandemic patterns of massive joint federal-state takedown campaigns targeting specific forms of fraud. Rubber Stamp is the biggest takedown so far. But don't be surprised if that distinction ends by an even bigger campaign in the months or even weeks ahead. *

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# Labs IN COURT

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

## Michigan Reference Lab Settles False Billing Charges for \$1.2 Million

**Case:** The OIG claimed that Michigan reference lab Great Lakes Medical Laboratory, Inc. ripped off Medicare and United Mine Workers Association (UMWA) health plans by billing for routine urine and blood tests that were already reimbursed for other lab services over a roughly 18-month period. In some cases, the lab billed tests for West Virginia workers that weren't ordered by a physician or even actually performed. Rather than risk a trial, the lab agreed to settle the charges for \$1,200,737.64, exactly twice the actual \$600,368.82 that Medicare and the UMWA paid for the false claims. In addition to the double penalty, the lab in this case had to enter into a three-year Integrity Agreement requiring it to, among other things, implement a compliance program under the OIG's review and hire an Independent Review Organization to review its Medicare and UMWA claims.

**Significant:** Reference labs hired by Medicare providers to perform contracted tests have become a popular target for federal false billing enforcement activity, particularly in drug testing. Earlier this year, a reference lab and pain clinic in Tampa and the executive that ran them had to pay \$41 million to settle charges of billing Medicare for unnecessary urine drug tests.

## Out-of-Network Drug Testing Labs Can Sue UnitedHealthcare for Inadequate Reimbursement

**Case:** A group of out of network labs and substance abuse clinics sued UnitedHealthcare for reimbursing them only 19.5% of covered charges on 1,306 insureds that had already met their annual out-of-pocket maximum even though plan documents and federal law required payment at 100%. UnitedHealthcare contended the labs' claims weren't legally valid and asked the California federal court to dismiss them without a trial. The court rendered a mixed decision, upholding some of the claims while tossing others.

**Significance:** Claims about the terms of the actual health plans under the federal *Employee Retirement Income Security Act* (ERISA) failed because they were based on state insurance laws which ERISA preempts, i.e., supersedes. However, the court went on to find that the labs had valid non-ERISA breach of contract claims and would get the chance to prove them at trial. The breach of good faith and fair dealing claims also ended up on the cutting room floor because they were largely duplicative of the contract claims, the court reasoned [*In re Out of Network Substance Use Disorder Claims Against UnitedHealthcare*, 2020 U.S. Dist. LEXIS 153773].

## Pain Management Network Shells Out \$1 Million to Settle Lab Testing Kickback Charges

**Case:** The DOJ accused a collection of companies owned by Wisconsin-based Advanced Pain Management Holdings, Inc. (APMH) of paying kickbacks in the form of shares of company stock to non-employee physicians who performed pain management procedures at its ambulatory surgical centers. The idea was for the incentive stock to be redeemed upon the sale of AMPH based on the company's profitability, which was calculated on the basis of referrals from those same non-employee physicians. The company shares also represented a reward for previous referrals. To make matters worse, APMH also paid non-employee physicians to serve as medical directors using a formula tied to the volume of procedures performed at the ambulatory surgery centers. APMH agreed to settle the claims for \$1 million.

**Significant:** In addition to the kickback abuses, which came to light as a result of a whistleblower lawsuit, one of APMH's subsidiary labs self-disclosed to HHS that it routinely performed confirmatory urine drug tests without relying on an individualized risk assessment to determine whether confirmatory testing was medically necessary for the particular patient.

## Specimen Collection Fee Scam Costs San Diego Lab \$3+ Million

**Case:** Phamatech, Inc. and its CEO and founder agreed to pay \$3.034 million to settle charges of falsely billing Medicare for drug testing services. The feds claim that the San Diego-based lab and diagnostic device manufacturer paid a to medical practice group kickbacks in the form of specimen collection fees in exchange for referrals of Medicare patients for urine drug tests. By subsequently billing Medicare for those tests, the lab crossed over into the realm of *False Claims Act* violation.

**Significance:** Paying referring physicians specimen processing fees remains a highly risky proposition for labs regardless of how those fee arrangements are structured. The clearest example of this is the HDL and Singulex, Inc. case involving whistleblower allegations of paying physicians processing fees of \$10 to \$17 per test exchange for orders of medically unnecessary blood tests, which were subsequently billed to Medicare and TRICARE. And the risk flows in both directions. Thus, for example, earlier this year, a pair of Colorado physicians and their family medical practice had to fork over \$55,000 for accepting those fees from HDL and Singulex.

## Pennsylvania Medical Assistants Confess to Participating in Genetic Test Fraud Scheme

**Case:** Federal and state enforcers are closing in on a Pennsylvania primary care physician who allegedly ripped off Medicare for genetic tests to the tune of \$755,241. At the center of the scheme is Yitzachok "Barry"

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■ Labs in Court from page 5

Kurtzer and his wife, Robin, who accepted monthly cash kickbacks of up to \$5,000 in exchange for collecting DNA samples from Medicare patients and sending them for genetic tests to clinical labs in New Jersey and Pennsylvania. The Kurtzers were able to keep the scheme going even when the COVID-19 pandemic substantially reduced in-patient visits by accepting payments via wire and mobile phone money-transfer apps.

**Significance:** Prosecutors appear to be building a strong case against the Kurtzer. Three persons have stepped forward and admitted their role in the scheme, including two medical assistants and an employee who helped collect the DNA swabs. 

## TOOL

## Model Substance Abuse and Fitness for Duty Policy

Workplace substance abuse remains a major challenge for labs. Although sound in principle, the traditional zero tolerance policy is ill-suited to the legal complexities of the modern world. This is especially true in states that have legalized marijuana. You can still take a clear and firm line on employee drug and alcohol abuse for the purpose of health and safety. But the policy also has to exhibit finesse and sensitivity to legal subtleties. One of the best ways to create an enforceable policy is to base it not on the morality or even legality of substance abuse but the undisputable fact that it renders employees unfit for duty to the detriment of safety. Here's a Model Policy you can adapt.

### XYZ Laboratories Substance Abuse and Fitness for Duty Policy

#### 1. POLICY STATEMENT

XYZ Laboratories recognizes that employees who use or are impaired by drugs or alcohol while performing work endanger not only themselves but their co-workers and others affected by the work. XYZ Laboratories' policy with regard to such conduct is one of zero tolerance and employees must be aware that any violations they commit may result in disciplinary action up to and including termination.

However, XYZ Laboratories also recognizes that addiction to drugs or alcohol is a serious health problem. The intent of this Policy is to accomplish the health and safety goal in a manner that is fair, humane and consistent with employees' accommodation rights under discrimination laws. The ultimate goal is not to punish but to help employees identify and get help for their substance

abuse issues so that they can return to work healthy, safe, happy and productive.

#### 2. PURPOSE

The purpose of this substance abuse policy is to ensure that all employees report to work fit for duty as part of its duty to ensure the health and safety of persons at or near the workplace under the *Occupational Safety and Health Act (OSHA)* and other applicable laws.

#### 3. SCOPE

This Policy applies to all individuals that work for XYZ Laboratories including but not limited to full-time, part-time, temporary and contract employees, independent contractors, volunteers and employees of third-party contractors or subcontractors that XYZ Laboratories engages to perform work at its facilities.

### 3.1 Union Employees

This Policy applies to both union and non-union employees but is not intended to supersede or circumvent the provisions of any current collective bargaining agreement that XYZ Laboratories has negotiated with an employee's union. In the event of a conflict between this Policy and a collective bargaining agreement, the latter shall control.

### 3.2 Contractor Employees

This Policy applies to individuals employed by contractors and subcontractors that perform work at XYZ Laboratories facilities but is not intended to supersede or circumvent the provisions of any current collective bargaining agreements that those contractors or subcontractors have negotiated with their own workers and their unions. In the event of a conflict between this Policy and a contractor employment agreement or collective bargaining agreement covering the worker, the latter shall control.

## 4. DEFINITIONS

For purposes of this Policy:

**"Drugs"** includes:

- ▶ Narcotics and illegal drugs;
- ▶ Marijuana, whether used or obtained legally or illegally; and
- ▶ Legal prescription and over-the-counter medications and drugs that cause or have the potential to cause impairment and render an employee unfit for duty.

**"Fit for duty"** means a state of physical and mental that allows an individual to perform his or her job duties safely and effectively without impairment due to the use of or after-effects of alcohol, illegal drugs, legal medications or other health conditions.

**"On duty"** includes reporting for and performing work, including:

- ▶ Scheduled work;
- ▶ Unscheduled call-in work;
- ▶ Work performed at XYZ Laboratories facilities;

- ▶ Work performed for XYZ Laboratories away from XYZ facilities, including but not limited to business travel and driving or traveling to and from work.

**"Safety-sensitive job"** means positions that have a direct and substantial impact on the health and safety of the employee, other workers, customers, visitors, the public, property and/or the environment, including but not limited to those involving driving, operation of machinery or equipment, handling of toxic substances and others determined by XYZ Laboratories.

**"Substance abuse"** means the use of alcohol, illegal drugs, legal marijuana and medications and other substances that can impair a person's judgment, clarity and functioning and render him/her unfit for duty.

## 5. EMPLOYEE RESPONSIBILITIES

All employees and workers covered by this Policy are required to:

- ▶ Come to work fit for duty;
- ▶ Take reasonable care to protect the health and safety of themselves and others at the workplace at all times while on duty as required by OSHA;
- ▶ Refrain from using or being impaired by alcohol or drugs while they are on duty;
- ▶ Refrain from possessing, purchasing, selling, distributing or engaging in any other conduct involving alcohol or illegal substances or paraphernalia while they are on duty;
- ▶ Refrain from misusing or being impaired by prescription or non-prescription drugs while they are on duty;
- ▶ Notify their supervisor if they suspect that a co-worker is unfit for duty; and
- ▶ Submit for drug and alcohol testing in accordance with the XYZ Laboratories Testing Policy.

## 6. LEGAL MARIJUANA

### 6.1 No Exemption for Legal Marijuana Use

All employees must understand that marijuana is an impairing drug and that using it at work or coming to work high renders them unfit for duty in violation of this Policy.

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■ Model Substance Abuse and Fitness for Duty Policy, from page 7

**Being impaired at work is NEVER legal regardless of the legality of the impairing substance used or how it was obtained!**

### 6.2 Employee Duty to Notify

Employees must notify their supervisor if they are using legally prescribed medical marijuana or other legal prescription and non-prescription drugs that may cause impairment for the treatment of a medical condition. Off-duty and legal use of such drugs does not violate this Policy as long as employees are fit for duty at all times when they are on duty.

### 7. SUPPORT FOR EMPLOYEES WITH SUBSTANCE ABUSE ISSUES

Although XYZ Laboratories reserves the right to discipline, it also recognizes that addiction and substance abuse is a health problem. XYZ Laboratories is prepared to help employees get the counselling, treatment, rehabilitation and support they need to overcome those problems. *[Describe your lab's Employee Assistance Program or other resources or programs for helping employees with substance abuse issues.]*

### 8. SELF-REPORTING

XYZ Laboratories strongly encourages employees with substance abuse problems to step forward and request help voluntarily. *[Describe your lab's procedures for responding to self-report requests for help.]* Employees who do self-report will not be subject to discipline as long as they have complied with their obligation to be fit for duty under this Policy.

### 9. FITNESS FOR DUTY MEDICAL ASSESSMENT

Employees must undergo medical assessments to ensure they are fit for duty before being placed in a safety-sensitive job. Assessments will address substance abuse and be performed:

- ▶ Prior to employment when individuals are applying for safety-sensitive jobs;
- ▶ Before current employees are transferred from non-safety-sensitive to safety-sensitive jobs; and
- ▶ Periodically for as long as the employee remains in a safety-sensitive job.

Medical assessments will be performed by qualified healthcare professionals following appropriate medical practices and results will be kept confidential to the extent required by HIPAA and other applicable personal privacy laws.

### 10. DISCIPLINARY INVESTIGATIONS

XYZ Laboratories may open a disciplinary investigation to check whether an employee is engaged in substance abuse or otherwise in violation of his/her fitness for duty obligations under this Policy in response to:

- ▶ Complaints or concerns by co-workers, supervisors, etc.;
- ▶ Declining performance;
- ▶ Erratic behavior;
- ▶ Involvement in safety incidents including near misses;
- ▶ Arrests for impaired driving, drug offenses and similar violations; and
- ▶ Other indications that the employee has substance abuse issues or is otherwise unfit for duty.

Investigations will be carried out in accordance with XYZ Laboratories' Disciplinary Investigation Procedures.

### 11. DRUGS & ALCOHOL TESTING

Employees may be tested for alcohol and drugs in accordance with XYZ Laboratories' testing policies. *[List the conditions for testing under your lab's own testing policies. Be sure to address: i. Alcohol and drug testing; ii. Safety-sensitive and non-safety-sensitive employees; and iii. Random and for-cause/post-incident testing.]* Supervisors will escort employees to the screening site for testing. Refusal to submit to testing will be grounds for immediate termination under this Policy.

### 12. EMPLOYEE PRIVACY RIGHTS

XYZ Laboratories recognizes that test results and related information is protected personal information under privacy laws and will keep it confidential and secure and refrain from using or disclosing it except as permitted or required by law.

### 13. CONSEQUENCES OF VIOLATIONS

Violation of this Policy is grounds for discipline up to and including termination in accordance with the XYZ Laboratories Progressive Discipline Policy. Employees with substance abuse issues on administrative leave may also be referred for counselling or assistance through the XYZ Laboratories Employee Assistance Program or outside agencies.

### 14. ASSISTANCE & REINSTATEMENT

XYZ Laboratories reserves the right to place employees with substance abuse issues on administrative leave and enter into Last Chance Agreements offering them the opportunity to return to work if they successfully complete the terms of their treatment and rehabilitation program, pass drug and alcohol tests and meet other conditions of reinstatement. 

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## FDA Watch: FDA Pulls the Plug on EUA Review of COVID-19 LDTs

Companies like Quest, LabCorp and others have been in the forefront of pandemic response by creating innovative new laboratory diagnostic tests (LDTs) for detecting the SARS-CoV-2 virus. The FDA has also played a vital role in making these molecular, antibody and antigen tests available to the public by granting Emergency Use Authorization (EUA) to these products. But now the FDA has left the industry and patients in the cold by abdicating its EUA review function for LDTs targeting coronavirus.

### The Controversy and Context

The FDA's authority to perform premarket review of LDTs has been a sore spot since well before the pandemic. Particularly nettlesome is the agency's reliance on regulating via informal guidance instead of submitting his rules to public comment and review under the rulemaking process required to establish new federal regulations.

In August, HHS suddenly intervened by requiring the FDA to use the rulemaking process for regulating LDTs as part of a broader administration policy to cut government regulation over business. The lab industry supported the move. But on Oct. 7, the FDA dropped a bomb shell by announcing that it was getting out of the business of performing EUA review for coronavirus LDTs altogether.

### The Aftershocks

The FDA decision to stop reviewing LDTs may thwart development of innovative tests. Specifically, it gives test makers three good reasons not to launch new COVID-19 LDTs:

*Continued on page 10*

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### 1. Reimbursement Uncertainty

One problem is the new uncertainty it creates over reimbursement. That's because the *Family First Coronavirus Act* (FFCRA) requires commercial payors to cover medically necessary SARS-CoV-2 testing without cost sharing, but only if they have EUA from the FDA. Consequently, labs developing new SARS-CoV-2 LDTs face the prospect of not being reimbursed for their tests.

### 2. Liability Risks

In addition to reimbursement risk, taking EUA off the table heightens test makers' liability exposure by stripping away the immunity protections afforded by the Public Readiness and Emergency Preparedness (PREP) Act. Like reimbursement under FFCRA, immunity from claims for use of tests during the public health emergency under PREP applies only to tests with EUA. And because of the urgency of the situation and need to get tests out faster than normal, test makers need these liability protections in case things go wrong. COVID-19 litigation has already become big business for trial lawyers and labs that develop inaccurate or faulty LDTs will be a sitting duck.

### 3. Harm to Competitiveness

While it's not full FDA approval, EUA status raises the credibility of a lab test product in the eyes of payors, clinicians and even patients. So, taking EUA off the table may make it harder for new LDTs to compete in the market, particularly against tests that have EUA.

### Takeaway

*The FDA's justification for no longer performing EUA review on COVID-19 LDTs is the need to prioritize its scarce review resources on more innovative tests needed to respond to the pandemic. Of course, this rationale overlooks the fact that many of the LDTs that have already received EUA are just the kind of innovative tests the agency's new policy is purported to promote.* 

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## HIPAA: OCR Cracks Down on Providers Who Don't Provide Individuals Timely Access to PHI

The HIPAA Privacy Rule requires labs and other health care providers to provide persons on whom they keep health records and other protected health information (PHI) timely access to that information at a reasonable cost. But while the access rules have been on the books for decades, they've

historically received less attention from enforcers than other parts of the law. But suddenly that has all changed. Once unheard of, fines against providers for failing to meet their PHI access responsibilities under HIPAA are becoming a common occurrence.

### The OCR Right of Access Initiative

It all began in April 2019, when the Office of Civil Rights (OCR), the HHS agency that's responsible for enforcing HIPAA, announced its intention to make enforcement of individual access rights a priority for the coming year and beyond. Lest anybody thought it was just a bluff, in September 2019, the OCR announced its first ever monetary settlement with a provider for a HIPAA right of access claim—\$85,000 against Florida's Bayfront Hospital for allegedly denying an expectant mother timely access to the PHI of her unborn child.

Before the year was out, the agency would do it again, announcing another settlement with a Florida provider, Korunda Medical, accused of failing to send a patient's PHI to a third party in a timely manner despite repeated requests. When it finally did transmit the information, the primary care and interventional pain management services provider allegedly didn't do so in the requested electronic format and charged the patient excessive fees. Only after the OCR intervened for the second time did Korunda adequately fulfill the request. As in the Bayfront Hospital case, the settlement amount was \$85,000. And like Bayfront, Korunda also had to implement a burdensome corrective action plan as part of the settlement.

### Act 2 of the Access Initiative

Not surprisingly, OCR access enforcement activity slowed considerably with the onset of the COVID-19 public health emergency. However, the interlude—if that's what it was—is apparently over. During the month of September, the OCR announced no fewer than five new settlements under the Right of Access Initiative, with settlement amounts ranging from \$3,500 to \$70,000. In each case, the provider also had to implement a corrective action plan and submit to one to two years of close OCR monitoring.

Then, on Oct. 9, the OCR unveiled its biggest Right of Access Initiative settlement yet, a \$160,000 agreement with Phoenix-based St. Joseph's Hospital and Medical Center (SJHMC). The case began when a mother complained to OCR about SJHMC's repeated refusals to provide her access to the PHI of her son despite her legal status as his personal representative. Only after OCR intervened did SJHMC provide all the requested PHI, more than 22 months after her initial request. In addition to the hefty settlement price, SJHMC had to agree to implement a corrective action plan and undergo OCR monitoring for two years.

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■ HIPAA: OCR Cracks Down on Providers Who Don't Provide Individuals Timely Access to PHI, from page 11

### OCR Right of Access Initiative Settlements Scorecard

Provider	Settlement Amount*	Allegations
St. Joseph's Hospital and Medical Center	\$160,000	Phoenix hospital refused to provide PHI to patient's mother even though she was his legal representative
NY Spine Medicine	\$100,000	Neurology practice refuses patient's multiple requests for copies of specific diagnostic films
Bayfront Hospital	\$85,000	Florida hospital didn't provide expectant mother timely access to the PHI of her unborn child
Korunda Medical	\$85,000	After first refusing to provide it at all, Florida primary care and interventional pain management services provider sent patient's PHI to third party in the wrong format and charged him excessive fees
Beth Israel Lahey Health Behavioral Services	\$70,000	Massachusetts provider ignored request of personal representative seeking access to her father's PHI
Housing Works Inc.	\$38,000	New York City non-profit services provider refused patient's request for a copy of his medical records
All Inclusive Medical Services, Inc.	\$15,000	California multi-specialty family medicine clinic refused patient's requests to inspect and receive a copy of her records
Wise Psychiatry, PC	\$10,000	Colorado psychiatric firm refused to provide personal representative access to his minor son's medical record
King MD	\$3,500	Virginia psychiatric practice didn't provide patient access to her medical records even after OCR intervened, provided technical assistance and closed the complaint

\*In addition to the monetary settlement, each accused provider had to agree to implement a corrective action plan and allow the OCR to conduct close monitoring for one to two years

#### How OCR Determines Settlement Amounts

As with other HIPAA violations, the OCR considers a variety of factors in determining the amount of a settlement for a failure to comply with PHI access rules, including:

- ▶ The nature and extent of the potential violation;
- ▶ The nature and extent of the harm resulting from the potential violation;
- ▶ The provider's history of compliance with the HIPAA Rules, or lack thereof;
- ▶ The provider's financial condition, including its size and the impact of the COVID-19 public health emergency; and
- ▶ "Other matters as justice may require."

## Takeaway

*The OCR Right of Access Initiative has become a significant compliance factor and an incentive for ensuring that labs respond to PHI access request within the required 30 days. Delaying action on the request beyond the deadline raises the risk of complaints to the OCR, followed by investigations and potentially costly settlements. Labs incur the same risks if they send requested PHI in the wrong format or charge excessive fees for processing PHI access requests. “For too long, healthcare providers have slow-walked their duty to provide patients their medical records out of a sleepy bureaucratic inertia,” declared OCR Director **Roger Severino**. “We hope our shift to the imposition of corrective actions and settlements under our Right of Access Initiative will finally wake up healthcare providers to their obligations under the law.”* 

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■ Compliance Perspectives: How to Create a Legally Sound Substance Abuse Policy, from page 1

### 1. Policy Statement

Set the tone by stating that workplace substance abuse creates a safety risk and won't be tolerated. But while laying the legal groundwork for discipline, you should also acknowledge that substance abuse is a health issue and that getting employees the help they need is your ultimate goal [Policy, Sec. 1].

### 2. Statement of Purpose

Clarify that the policy is all about ensuring employees are fit for duty at all times (as opposed to ensuring they behave morally and obey the law) [Policy, Sec. 2].

### 3. Policy Scope

Explain that the policy applies to all individuals working for your lab regardless of employment status or physical location of the work. But also indicate that the policy is subject to the terms of applicable collective bargaining agreements and employment contracts [Policy, Sec. 3].

### 4. Definition of “Fit for Duty”

Define exactly what you mean by being fit for duty. Other key terms to define include “substance abuse,” “safety-sensitive job” and “drugs,” the latter of which you should define as including:

- ▶ Narcotics and illegal drugs;
- ▶ Marijuana, whether used or obtained legally or illegally; and
- ▶ Legal prescription and over-the-counter medications and drugs that cause or have the potential to cause impairment and render an employee unfit for duty

[Policy, Sec. 4].

*Continued on page 14*

## ■ Compliance Perspectives: How to Create a Legally Sound Substance Abuse Policy, From Page 13

### 5. Employees' Duties

The heart of the policy is the list of employee requirements, including being fit for duty at all times, refraining from using, buying, selling or distributing drugs/alcohol, notifying supervisors of violations and submitting to testing required by lab policies [Policy, Sec. 5].

### 6. No Exemption for Legal Marijuana

Employees might assume that they're allowed to use or be high on medical or recreational marijuana if it's been legalized in the state. Debunk this popular misconception by expressly saying that impairment at work is never justified regardless of whether the marijuana or other substance that causes it is legal [Policy, Sec. 6].

### 7. Statement of Support

Restate your commitment to helping employees with substance abuse issues and describe your lab's employee assistance program and other resources for providing support, counseling, treatment, rehab, etc. [Policy, Sec. 7].

### 8. Encourage Self-Reporting

Encourage employees to step forward voluntarily if they have substance abuse issues; indicate that those who do self-report won't be subject to discipline as long as they were and are fit for duty when they do their job [Policy, Sec. 8].

### 9. Fitness for Duty Medical Assessments for Safety-Sensitive Jobs

Establish your right to perform proactive medical assessments before workers are assigned to safety-sensitive jobs. Indicate that assessments will be performed by qualified medical or substance abuse professionals and that you'll keep the results confidential as required by HIPAA and other applicable privacy laws [Policy, Sec. 9].

### 10. Investigation Procedures

Explain how you investigate suspected violations. List investigation triggers, which should include:

- ▶ Complaints, concerns or reports of substance abuse;
- ▶ Declining performance;
- ▶ Erratic behavior;
- ▶ Involvement in safety incidents including near misses;
- ▶ Arrests for impaired driving, drug offenses and similar violations; and
- ▶ Other indications of substance abuse issues or unfitness for duty

[Policy, Sec. 10].

### 11. Alcohol & Drug Testing Procedures

Explain your use of testing to enforce the policy. Testing is a complex issue that most organizations address in a separate policy. But however you do

it, be sure to address both the testing involved, i.e., whether for alcohol and/or drugs, and the basis for each kind of testing, including:

- ▶ Pre-employment testing;
- ▶ Random testing; and
- ▶ For-cause testing, e.g., after safety infractions or incidents.

Be sure that your testing procedure aren't overly privacy intrusive and that you limit the strictest testing to employees with safety-sensitive jobs [Policy, Sec. 11].

### 12. Privacy of Test Results

Acknowledge that testing results are privacy-protected information and that you'll keep them secure and confidential to the extent allowed by the law [Policy, Sec. 12].

### 13. Response to Violations

Make it clear that employees found to be unfit for duty will be subject to discipline up to and including termination. Describe your lab's disciplinary procedures. Although zero tolerance is fine as a principle, you need to give yourself the flexibility to deal with each employee on an individual basis which typically includes entering into Last Chance agreements offering reemployment if the employee successfully completes treatment, rehab and other reinstatement conditions [Policy Secs. 13 and 14].

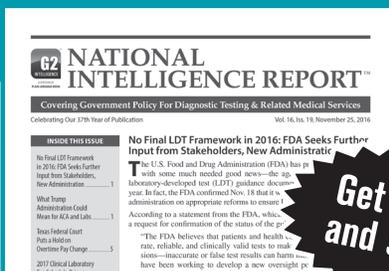
### 14. Acknowledgment of Employees' Accommodation Rights

Last but not least, include a provision acknowledging that addiction and disabling conditions for which legally authorized medical marijuana are used are used are disabilities under federal EEO and state anti-discrimination laws and that you'll provide reasonable accommodations up to the point of undue hardship [Policy, Sec. 15]. **G2**



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