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# LAB Compliance Advisor

For Clinical and AP Laboratories and Pathology Practices

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## Enforcement Trends: New Administration Continues OCR HIPAA Right of Access Initiative

Although the Biden administration has signaled its intention to revisit just about every healthcare regulatory initiative of its predecessor, one enforcement undertaking seems to be continuing seamlessly with no interruption: The HHS Office for Civil Rights (OCR) campaign to ensure providers recognize patients' HIPAA access rights.

### The HIPAA Right of Access Initiative

Historically, OCR enforcement of the HIPAA Privacy Rule has focused on unlawful collection, use and disclosure and provider efforts to keep personal health information (PHI) private and secure. But in April 2019, the agency announced that it was broadening its scope to include the part of the HIPAA Privacy Rule that requires labs and other providers to provide persons timely access to their PHI at a reasonable cost. Less than six months later, the OCR handed down its first ever fine to a provider for failing to comply with its right of access obligations.

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## False Claims: The Liability Risks of Failing to Report Tests of Dubious Medical Necessity

What should your lab do if providers order tests that clearly don't meet coverage criteria for medically necessary coverage criteria? A recent settlement involving Cordant Health Solutions charges of falsely billing Medicare for medically unnecessary urine drug tests offers perspective on this question.

### The Case

The allegations stem from events that happened in New England far from Cordant's Denver, Colo., base of operations.

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Enforcement Trends: New Administration Continues OCR HIPAA Right of Access Initiative, *from page 1*

By the time the Trump administration left town, the agency had dished out no fewer than 14 such penalties, the final one at a record-high of $200,000. And, as expected, there would be more to come. Fines number 15 and 16 were announced in early February. To be fair, the latest fines represent the completion of cases started under the old administration; however, unlike some Trump enforcement activities, the HIPAA Right of Access Initiative is a bipartisan, fairly noncontroversial effort that is highly likely to continue without interruption under the new regime.

Here's a Scorecard of all announced settlements to date.

**OCR Right of Access Initiative Settlements Scorecard (as of Feb. 19, 2021)**

| Provider | Settlement Amount* | Allegations |
|---|---|---|
| Banner Health ACE | $200,000 | OCR cites two occasions in which Phoenix-based not-for-profit health system took about 6 months to provide patients their requested PHI |
| 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 |
| Renown Health, P.C. | $75,000 | Nevada private, not-for-profit health system didn't timely honor patient's request to transfer her EHR and billing records to a third party |
| Sharp Rees-Stealy Medical Centers | $70,000 | California hospital and healthcare network didn't timely honor request to transfer patient's EHR to a third party |
| Beth Israel Lahey Health Behavioral Services | $70,000 | Massachusetts provider ignored request of personal representative seeking access to her father's PHI |

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| Provider | Settlement Amount* | Allegations |
|---|---|---|
| University of Cincinnati Medical Center, LLC | $65,000 | Ohio academic medical center failed to respond to patient's request to send an electronic copy of her medical records maintained in its electronic health record EHR to her lawyers |
| Housing Works Inc. | $38,000 | New York City non-profit services provider refused patient's request for a copy of his medical records |
| Peter Wrobel, M.D., P.C., dba Elite Primary Care | $36,000 | Georgia primary care practice failed to provide patient access to his medical records |
| Riverside Psychiatric Medical Group | $25,000 | California medical group didn't provide patient copy of her medical records despite repeated requests and OCR intervention |
| Dr. Rajendra Bhayani | $15,000 | NY physician didn't provide patient her medical records even after OCR intervened and closed the complaint |
| 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

## Compliance Perspectives: How to Create an Enhanced Cleaning and Disinfection Policy

In the age of COVID-19, complying with the rigorous hygiene requirements CLIA, accreditation criteria, OSHA and other standards may not be enough. That's because the U.S. Centers for Disease Control and Prevention (CDC) and public health guidelines mandate that work facilities still in operation undertake special enhanced cleaning and disinfection measures. This is particularly true of lab and other healthcare diagnostic and treatment sites. Here are the rules and how to comply.

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Compliance Perspectives: How to Create an Enhanced Cleaning and Disinfection Policy, *from page 3*

There's also a Model Policy on page 8 that you can adapt for use at your own lab.

### What's at Stake

SARS-CoV-2, the virus that causes coronavirus, spreads by human-to-human contact and can live on a surface or object for up to seven days. The virus can be killed but it takes the right products and procedures. That's why public health agencies are requiring employers to implement special cleaning and disinfection procedures as part of their workplace COVID-19 exposure control plan. In addition to putting workers and others present at your facility at greater risk of infection, failure to comply exposes your lab to the risk of OSHA penalties, loss of CLIA accreditation and even partial or full shut down.

Of course, the duty to maintain a clean and sanitary workplace is nothing new. But the COVID-19 public health guidelines go well beyond the normal standards. They require not just regular but frequent and special cleaning and disinfection measures to ensure the virus isn't allowed to linger on workplace surfaces, door knobs and other frequently touched objects. More precisely, they require employers to create and implement specific cleaning and disinfection procedures for all parts of the workplace, including lab-owned vehicles. The best way to comply is to create a policy that provides for at least the following six things:

### 1. Workplace Cleaning and Disinfection Assessment

First, designate a competent person to carry out an assessment of all the areas in your workplace that may contain COVID transmission points. While not expressly required, if your lab has a workplace joint health and safety committee (JHSC) or health and safety representative, it's best practice to enlist it/him/her to participate in the assessment. In the policy, identify the tasks of the assessment, including:

- Identifying all surfaces and objects requiring just routine cleaning;
- Identifying surfaces and objects also requiring disinfection;
- Determining how often the particular surface or object needs to be cleaned and disinfected;
- Determining which materials to use for cleaning and disinfection;
- Listing the health and safety measures needed for each particular cleaning and disinfection operation; and
- Listing personal protective equipment (PPE) necessary for each particular cleaning and disinfection operation.

### 2. Transformation of Assessment into Cleaning and Disinfection Schedule

The next step is to use the data from the assessment to create a schedule for cleaning and disinfection, which can be either: i. a central plan created

by your OHS or safety director for the entire facility, or ii. a set of separate plans for each department created by each department head. In either case, have the person creating the plan systematically listing for each space or area:

- The specific objects and surfaces it contains;
- How frequently those objects and surfaces will be cleaned and, if necessary, disinfected; and
- Who'll be responsible for carrying out those cleaning and disinfection operations.

### 3. General Cleaning Procedures Guidelines

The person who creates the schedule should also establish a cleaning and disinfecting procedure for each item on the schedule. While specifics will vary, in general, cleaning should be performed before disinfection in a well-ventilated area by a properly trained person following manufacturers' instructions with regard to concentration/dilution, required PPE and application methods.

### 4. General Ground Rules for Materials Used

Most routine cleaning operations can be carried out with soap and water. Disinfectants should be used only if they're approved for use against coronavirus (SARS-CoV-2) infection. However, safe alternative disinfectants are okay to use if such products aren't available, such as a mixture of one-third cup of 5.25 percent to 8.25 percent bleach added to one gallon of water, or 70 percent alcohol solutions. But ban mixing bleach together with other cleaning and disinfection products because the mix may emit hazardous fumes.

### 5. Separate Guidelines for Cleaning of Soft (Porous) Surfaces

Procedures for soft (porous) surfaces such as carpeted floor, rugs, and fabric chairs, should provide for removal of any visible contamination present and then cleaning with appropriate cleaners indicated as being safe for use on those surfaces. Those items should be laundered after cleaning using the warmest appropriate water setting in accordance with the manufacturer's instructions and then completely dried. If laundering isn't possible, be sure to use a disinfectant approved for use against SARS-CoV-2.

### 6. Required PPE

Cleaning and disinfection procedures should specify the PPE required to perform the operation safely. In general, that should include:

- Disposable gloves—once the procedure is over, users must immediately discard their gloves and wash their hands;
- Eye protection where there's a risk of splash or splatter to the face; and
- Gowns or aprons for larger scale or frequent cleaning.

# Labs IN COURT

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

## Massachusetts Drug Testing Lab Shells Out $84K to Settle SVT False Billing Charges

**Case:** A urine drug testing lab in Massachusetts is the latest to settle self-disclosed charges of falsely billing Medicare for specimen validity tests (SVTs). While Medicare covers drug testing as part of medically necessary treatment, it doesn't cover SVTs, which are performed as part of a quality control process to catch drug test cheaters by verifying that a urine drug screen sample is consistent with normal human urine and hasn't been adulterated, diluted or substituted. The Massachusetts lab will pay $84,393 to settle the case with the OIG.

**Significance:** In 2018, the OIG issued a report contending that Medicare made $66.3 million in improper SVT payments to nearly 4,500 labs and physician offices. In response, CMS ordered Medicare contractors to take measures to get that money back. Since then, at least a dozen urine drug testing labs have come forward to self-disclose improper SVT billing, generating nearly $3 million in total recoveries. Here's the settlement rundown in order of settlement amount.

**Urine Drug Testing Lab SVT Billing Settlements**

| Lab | Settlement Amount |
|---|---|
| Ethos Laboratory (Newport, KY) | $1,345,959 |
| American Toxicology Lab, LLC (Johnson City, TN) | $175,889 |
| Northern Kentucky Center for Pain Relief | $126,799 |
| VerraLab JA, LLC (Louisville, KY) | $125,983 |
| Wheelersburg Internal Medicine Group + Mohammad Mouhib Kalo, MD (Ohio) | $111,706 |
| Discover Diagnostic Laboratory, LLC (Oak Ridge, TN) | $95,882 |
| Commonwealth Pain Associates, PLLC (Louisville, KY) | $88,214 |
| New Horizons Medical, Inc. (Framingham, MA) | $84,393 |
| Aeon Global Health (Gainesville, GA) | $75,000 |
| Medical Specialist of Kentuckiana, PLLC (Louisville, KY) | $69,776 |
| American Clinical Solutions, LLC (Boca Raton, FL) | $61,546 |
| Ohio River Laboratories, LLC (Houston, TX) | $49,493 |

## Genetic Test Company Pays Over $2.5 Million for Role in Nursing Home Scam

**Case:** Federal prosecutors accused a molecular testing lab owned by California-based AutoGenomics of carrying out a scheme to generate illegal referrals of tests on residents of 76 nursing homes that were then billed to Medicare. According to the complaint, AutoGenomics agreed to pay marketing firm a specified percentage of Medicare reimbursement for each genetic test patient. The fee was contingent on Medicare's paying for the test. Rather than risk a trial, AutoGenomics agreed to settle the charges for $2,538,000.

**Significance:** Prestige Healthcare, the owners of nursing homes in Wisconsin and other states, allegedly participated in the scheme by helping the marketing firm identify and gain access to their Medicare patients to collect buccal cell samples to send to AutoGenomics for testing. Prestige got off somewhat lighter, having paid about $1 million to settle its role in the scheme, which unfolded before Prescient Medicine acquired AutoGenomics in 2019.

### Patient Recruiter Found Guilty of Running Telemarketing CGx Testing Scheme

**Case:** After a four-day trial, the owner of an Orlando telemarketing call center was found guilty of running a $2.8 million cancer genetics screening test scam (CGx) targeting seniors in Medicare. The firm owned by 34-year-old Ivan Andre Scott called beneficiaries and persuaded them to take CGx tests costing up to $6,000 pop on the assurance that they were covered by Medicare. Scott also paid kickbacks to telemedicine companies to get physicians to order the tests regardless of medical necessity and often without even speaking to the patient. He then submitted invoices to the labs for hourly marketing services to conceal the kickbacks.

**Significance:** The Orlando case is part of the Operation Rubberstamp national takedown initiative targeting telemarketing fraud unveiled by the Justice Department last fall. Many of the schemes in the takedown, the largest in DOJ history, involve payment of kickbacks and false billing of lab tests.

### Talking to Competing Lab Doesn't Violate Marketing Manager's Employment Contract

**Case:** In 2017, S&G lab hired a market manager at a base salary plus 35 percent of net profits generated by his accounts. But then came EKRA in 2018 and S&G felt compelled to redo the deal as a straight salary arrangement as a result of the new law's ban on incentive-based compensation pegged to medical tests volume. But the manager was happy with his current contract and refused to renegotiate. Suspension and a unilateral pay cut didn't change his mind. And when S&G learned that the manager had been talking to a competitor, it served him up a pink slip and summons to a lawsuit.

**Significance:** The Hawaii federal court tossed S&G's case without a trial. There was no case for disclosure of trade secrets because there was no evidence that the manager revealed any confidential information about S&G while discussing employment opportunities with the competitor. While they did talk about how fast the lab turns around tests and the kinds of equipment it uses, S&G doesn't treat that information as secrets and even features it on its website, the court explained. Nor did those discussions violate the manager's non-compete because nothing he divulged gave the competing lab a competitive edge over S&G [*S&G Labs Haw., LLC v. Graves*, 2021 U.S. Dist. LEXIS 29248].

# TOOL MODEL LAB ENHANCED CLEANING AND DISINFECTION POLICY

Complying with the usual CLIA, accreditation and other hygiene standards and requirements may not be adequate to protect workers and others present at your lab facilities against risk of COVID-19 infection. That's because the U.S. Centers for Disease Control and other public health organizations mandate that employers take additional cleaning and hygiene measures during the pandemic. Here's a Model Policy you can adapt for your own use based on your specific circumstances and applicable local and specialty rules.

## ENHANCED LABORATORY FACILITIES CLEANING & DISINFECTION POLICIES & PROCEDURES

### 1. POLICY

XYZ Laboratories is implementing the following routine enhanced cleaning and disinfection policy as part of its COVID-19 Prevention Plan with the goal of ensuring a healthy and safe workplace for all and to ensure compliance with Clinical Laboratory Improvement Amendments (CLIA), Occupational Safety and Health Act (OSHA) and other applicable laws, public health guidelines, accreditation criteria and other standards.

### 2. SCOPE

This Policy applies to all XYZ Laboratories facilities and workplaces, including XYZ-owned vehicles, as well as to all XYZ employees, volunteers, contractors, patients, customers, clients and visitors. Failure to comply with it will be grounds for denial or entrance or immediate removal from the premises.

### 3. WORKPLACE ASSESSMENT

A competent person and member of the workplace joint health and safety committee (JHSC) or health and safety representative (HSR), as the case may be, will perform an assessment of XYZ Laboratories facilities and workplaces, including XYZ-owned vehicles, to:

- Identify all surfaces and objects that require normal routine cleaning with soap and water;
- Identify which surfaces and objects also require disinfection;
- Determine how often cleaning and disinfection must be performed on the particular surface and object;
- Determine which materials must be used for cleaning and disinfection;
- Determine which health and safety measures must be followed for each particular cleaning and disinfection operation; and
- Determine which personal protective equipment (PPE) and health and safety equipment is required for each particular cleaning and disinfection operation.

### 4. CLEANING AND DISINFECTION PLAN DEVELOPMENT

On the basis of the above assessment, [*the XYZ Laboratories EHS Director/each department area/ other*] will create a cleaning and disinfecting plan using the following template:

| Space | Scope | Responsible Party | Instructions/Frequency |
|---|---|---|---|
| Restrooms | All surfaces, objects and sinks, faucets, toilets, door handles, hand dryers and other fixtures | Custodial Department | Full daily cleaning and disinfection 5 times per week at night or early morning with high touch points cleaned a second time. |

### 5. CLEANING AND DISINFECTION PRINCIPLES

In developing the above schedule, [*the XYZ Laboratories EHS Director/each department area/ other*] will ensure more frequent cleaning and regular disinfection of surfaces and objects that are frequently touched, including but not limited

to doors in entrance/exiting areas, counters and shelves, desk surfaces, chairs and arm rests, tables, phones, computer keyboards (especially if shared), counters, light switches, lavatory surfaces, kitchen surfaces and appliances, doorknobs, elevators buttons, handrails, floors and other horizontal surfaces, shared tools and equipment, machinery and truck cabin (clean and disinfect the steering wheel, door handles, and frequently used levers and buttons. Outdoor areas generally require normal routine cleaning and do not require disinfection. In assigning responsibility for cleaning and disinfection, [*the XYZ Laboratories EHS Director/each department area/other*] will, wherever practicable, rely on employees to clean their own areas and adjacent spaces so as not to overwhelm cleaning staff.

### 6. CLEANING AND DISINFECTION PROCEDURES

The [*the XYZ Laboratories EHS Director/each department area/other*] who creates the above schedule will ensure that a specific procedure is created and implemented for carrying out the listed cleaning and disinfection procedure. Before disinfection, surfaces and objects should first be cleaned using a detergent, or soap and water. Disinfectants must be prepared in well-ventilated areas and handled safely by persons using appropriate PPE.

### 7. CLEANING AND DISINFECTION PRODUCTS

Disinfection must be performed using a disinfectant approved for use against the coronavirus (SARS-CoV-2). Disinfection must be performed using a disinfectant approved for use against coronavirus infection. When such products are not available, alternative disinfectants may be used, such as a mixture of 1/3 cup of 5.25%–8.25% bleach added to one gallon of water, or 70% alcohol solutions). Bleach solutions will be effective for disinfection up to 24 hours. Bleach may not be mixed together with other cleaning and disinfection products due to the risk of hazardous vapors. All cleaning and disinfection products must be used in accordance with manufacturers' instructions, including with regard to:

Dilution and concentration;

- Application method and contact time;
- Required ventilation; and
- Use of PPE.

Disinfectants must be stored safely and away from food in closed containers that have proper OSHA Hazardous Communication (Hazcom) labels. Where disinfectants are dispensed into a secondary container, e.g., spray bottles, the secondary container must also have a proper Hazcom label identifying its contents.

### 8. CLEANING OF SOFT, POROUS SURFACES

Cleaning procedures for soft (porous) surfaces such as carpeted floor, rugs, and fabric chairs, must provide for removing visible contamination (if present) and cleaning with appropriate cleaners indicated for use on these surfaces. After cleaning, such items should be laundered using the warmest appropriate water setting in accordance with the manufacturer's instructions and then completely dried. iii. If laundering is not possible, a disinfectant approved for use against SARS-CoV-2 must be used.

### 9. PPE

Cleaning and disinfection procedures must specify the PPE required to ensure the procedure is carried out safely, which may include:

Disposable gloves—once the procedure is over, users must immediately discard their gloves and wash their hands;

- Eye protection where there is a potential for splash or splatter to the face; and
- Gowns or aprons for larger scale or frequent cleaning (large surface area).

# Billing & Collections: OIG Targets Pandemic's Impact on Billing of Medicare Part B Lab Testing

Looking upon Medicare billing and payment of lab services with suspicion is and has always been part of the OIG's organizational DNA. So, the fact that audits of Medicare Part B lab services during the pandemic are among the new items the OIG added to its Work Plan in February should come as no surprise. But this item comes with a twist to the extent that the OIG's primary concern seems to be not overbilling but whether labs have actually been billing enough for Part B tests since the pandemic began.

## OIG Oversight of COVID-19 Testing

This isn't the first time that the OIG has incorporated review of COVID-19 testing into its Work Plan. Last July, the agency announced plans to look into potential abuses of add-on tests, e.g., to confirm or rule a diagnosis other than COVID-19. In the Work Plan item, the OIG agency said it had "program integrity concerns" related to add-on tests in conjunction with COVID-19, particularly the potential of fraudulent billing for associated respiratory pathogen panel (RPP) tests, allergy tests or genetic tests.

Adding to the concern, the OIG explained, was the decision of CMS to temporarily relax the rules requiring an order from the treating physician or nonphysician practitioner (NPP) for COVID-19 tests during the public health emergency. Relaxation of physician ordering/NPP rules gives "unscrupulous actors more leeway for fraudulent billing of unnecessary add-on testing," the OIG warned. As of February, the agency has yet to release its report on the add-on testing audit.

## The New OIG Initiative

However, the OIG audit item in the February 2021 Work Plan is a bit different from previous initiatives. The agency's normal inclination is to

question whether commonly billed lab tests are really necessary; but this time, the OIG is wondering why more tests *are not* being performed—specifically, tests for conditions other than COVID-19. The "number of non-COVID-19 tests billed for Medicare Part B beneficiaries during the COVID-19 pandemic has decreased compared to the six-month period before the pandemic," the OIG notes. The agency also expresses a seldom seen sympathy for labs by acknowledging that "many independent labs have encountered challenges in providing COVID-19 testing."

As a result, the OIG says it will audit utilization of Medicare Part B lab services during the pandemic focusing initially on non-COVID-19 testing. Of course, the Work Plan item adds, the agency will also look into "aberrant billing of COVID-19 testing during the pandemic."

### Takeaway

*It was only a matter of time before the OIG took a good hard look into lab testing during the pandemic. But this latest audit initiative is different in tone and scope. While rooting out the bad apples is always will be the objective—including with regard to the still pending July Work Plan item targeting add-on tests for COVID-19 test subjects—this time it sounds like the OIG's primary motivation is genuine concern for and eagerness to assist testing labs in their efforts to survive pandemic struggles.*

## False Claims: The Liability Risks of Failing to Report Tests of Dubious Medical Necessity, *From Page 1*

The central players in the scheme were Massachusetts lab and Cordant subsidiary Secon Laboratories and Secon client Crossroads, Inc., a behavioral health treatment center located in New Haven, Conn.

The problems began in 2015, when Crossroads implemented a new policy requiring residents, many of whom were enrolled in the Connecticut Medicaid program, to submit to regular urine drug testing for purposes of monitoring rather than medical treatment. Crossroads ordered Secon to perform presumptive (screening) drug tests and definitive (confirmatory) drug tests for all residents every week. In many cases, Crossroads ordered residents to undergo duplicative tests three, four and even five times per week.

The Justice Department press release doesn't suggest that Cordant and Secon actively plotted the scheme with Crossroads. But the DOJ claimed that they "knew or should have known" that the tests were medically unnecessary. Instead of smelling a rat, they went ahead and performed the tests and then sent the bill to Medicaid, starting in October 2015 and ending in February 2017. In so doing, they violated the *False Claims Act*. While denying the charges, Cordant and Secon decided that discretion is the better part of valor and settled the case for $845,108 rather than risk a trial.

*Continued on page 12*

False Claims: The Liability Risks of Failing to Report Tests of Dubious Medical Necessity, *From Page 11*

Medically unnecessary urine drug testing has been a millstone around Cordant's neck in recent months. On July 20, 2020, the firm agreed to pay $11.9 million to settle a case that began as a whistleblower suit claiming that its Denver and Tacoma labs paid kickbacks to physicians and marketing companies to generate referrals of urine-drug tests that were subsequently billed to Medicare and TRICARE.

## Inactions Speak Louder than Words

For lab compliance managers, the takeaway from the Cordant case is how your lab can get into trouble not just for action but inaction. Specifically, while labs are neither qualified nor expected to second guess referral source determinations, they are expected to raise a red flag when ordered tests raise clear issues of medical necessity. In other words, if you know or should know that tests don't meet medically necessary criteria and bill for them anyway, you're partaking in a false billing that may result in liability under the FCA.

And that's not all. The litany of violations for labs that bury their head in the sand when confronted with suspicious ordering behavior may include failing to report and return overpayments. In fact, this is what happened to Cordant and Secon.

## Takeaway

*The best way to sum it all up is by paraphrasing the words of John Durham, the U.S. Attorney in the Cordant case. Labs have a responsibility to ensure that the claims they submit to government health care programs are for medically necessary testing services. If a lab discovers that it's performed and billed for tests that weren't medically necessary, it must report and return any overpayments, and modify its practices.*