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G2 Compliance Advisor

For Clinical and AP Laboratories and Pathology Practices

September 2017

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Lab Institute 2017
October 25-27
Hyatt Regency Washington on Capitol Hill, Washington, DC
www.labinstitute.com

That CAN'T Be Right: Court Says Labs Must Independently Verify Medical Necessity of M.D. Ordered Tests

Based on the enforcement track record, if your lab ever gets charged with falsely billing Medicare for lab tests, failure to document the medical necessity of the ordered tests will be the reason. Medical necessity is a shared burden between labs and ordering physicians:

- The physician determines whether the test is medically necessary for the patient; and
- The lab certifies that the tests it bills actually are medically necessary.

Thus, while labs are on the hook if the tests turn out not to meet medically necessary criteria, they're allowed to rely on the fact that the physician ordered the tests as proof of necessity.

At least that is how it works under current rules. However, a new federal court case challenges that common understanding

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Medicare Reimbursement: CMS Issues New Medical Review Instructions to Contractors

On Aug. 14, CMS issued new marching orders to Medicare Administrative Contractors (Contractors). The message: Tighten up the way you target suppliers and providers for medical review.

The Targeted Medical Review Process

The orders involve execution of the so called Targeted Probe and Education, a pilot started in 2014 in which Contractors carry out a detailed medical review process to crack down on improper Medicare billing and claims.

The review process lasts up to three rounds but providers can get out after any of the three rounds by demonstrating low error rates or sufficient improvement. Providers who still have high error rates after three rounds may be subject to additional actions, including 100 percent prepay review, extrapolation or referral to a recovery auditor.

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Court Says Labs Must Independently Verify Medical Necessity of M.D. Ordered Tests, *from page 1*

by requiring labs to independently verify the medical necessity of ordered tests. Here's a look at the case and why it's so scary.

What Happened

The case began as a whistleblower suit filed by a former United Healthcare medical director claiming that Boston Heart Diagnostics routinely billed Medicare for tests that were medically unnecessary for certain diagnostic codes. Boston Heart noted that all of the tests were properly ordered by the treating physicians and that it's up to physicians to determine whether those tests were necessary. So it asked the court to dismiss the complaint.

What the Court Decided

The D.C. District Court ruled that the medical director had a valid whistleblower claim and deserved the chance to prove it in court. Having billed Medicare for the tests, Boston Heart had an obligation to provide independent verification of their medical necessity, according to the court. The fact that the ordering physicians' medical necessity determination conflicted with the diagnostic codes provided should have raised a red flag and led Boston Heart to make its own inquiry, the court reasoned [*U.S. ex rel. Groat v. Boston Heart Diagnostics Corp.*].

The ruling cites a California case (called *Garcia v. Sibelius*) stating that Medicare regulations "place the burden of establishing the medical necessity of diagnostic tests on the entity submitting the claim." But, as attorneys have noted, the comparison is apples and oranges because unlike in *Groat* where the lab billed for the tests, the ordering physician was the billing entity in *Garcia*.

What It May Mean

Attorneys have criticized the Groat ruling. "The court fails to recognize that treating physicians—who have the most complete picture of an individual patient's needs and medical conditions—are in the best position to make determinations of medical necessity," according to an attorney with the leading law firm Jones Day. "Lab employees, by contrast, often do not even have occasion to interact with the patient in person," the attorney adds. Requiring lab employees to independently evaluate medical necessity would be not only unrealistic but potentially illegal under state licensing rules and practice-of-medicine restrictions.

Takeaway: Getting physicians to document medical necessity is hard enough. The Groat case is scary because it's saying that labs could no longer simply rely on physicians to verify that ordered tests are medically necessary. They'd also have to do their own independent assessment to ensure those tests are medically necessary for the patient.

The good news is that Boston Heart has already appealed the ruling. And if the attorneys are right, Boston Heart will win the appeal. Of course, if the attorneys are wrong, labs (at least the ones in the D.C. Circuit where the Groat appeal will be decided) will have a significant new billing burden to contend with.

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OIG Work Plan Monthly Review: September 2017

Many of the 12 new items that the OIG added to its 2017 Work Plan in September target state and federal government agencies, including the Department of Health and Human Services itself—specifically, whether HHS's incident response measures are adequate to safeguard the agency's IT systems and data from cyber threats and attack. While none of the new items specifically or address lab tests, three *might* affect labs indirectly.

1. Medicaid Nursing Home Life Safety Reviews

Concern: CMS recently changed its life safety and emergency preparedness rules health care facilities by requiring long term care facilities to install expanded sprinkler and smoke detector systems and implement an emergency preparedness plan that includes sheltering in place for residents who cannot evacuate during emergencies.

What OIG Will Investigate: The OIG will review whether long term care facilities are complying with these requirements.

2. Part D Sponsors Reporting of Direct and Indirect Remuneration

Concern: Medicare calculates certain payments to sponsors based on amounts sponsors actually paid, net of direct and indirect remuneration (DIR). DIR includes all rebates, subsidies and other price concessions from manufacturers, pharmacies and other sources. Part D sponsors must submit their DIR reports to CMS for use in the payment reconciliation process.

What OIG Will Investigate: The OIG will determine whether Part D sponsors are complying with DIR reporting requirements.

3. Controls Over Opioid Treatment Programs

Concern: The OIG has recommended that SAMHSA (the Substance Abuse and Mental Health Services Administration) require hospitals and pharmacies that receive funds opioid treatment program funds from State agencies via the Substance Abuse Prevention and Treatment Block Grant program to implement stronger security protocols to reduce thefts of opioids.

What OIG Will Investigate: The OIG will determine whether a State agency is effectively monitoring its opioid treatment programs' services and medications in accordance with the federal guidelines for opioid treatment programs.

Takeaway: Although none of the new OIG initiatives directly involve lab services, you need to be aware of them if you're involved in providing any of the affected goods and services to Medicare, Medicaid or other government health program beneficiaries.

Be a part of the conversation this year!

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Case of the Month: FMC Settlement Is Poster Child for False Billing of Lab Tests

In the grand scheme of things, $2 million is fairly small potatoes for false billing of lab tests—especially considering that it allegedly went on for 10 years. Even so, if you're running your lab's compliance program, the recently settled case involving Family Medicine Centers of South Carolina LLC (FMC) is worth your attention. Here are three reasons why:

1. How It Came About

Like so many health care fraud cases, this one began as a *qui tam* lawsuit. The whistleblower in was an FMC physician who ended up pocketing $340,510 of the settlement amount. FMC will pay $1.56 million of the settlement and its CEO and medical director the remaining $443,000.

The other significant aspect of the FMC case was the medical necessity allegations stemming from use of customized panels and standing orders.

2. The Stark Claim

Claims under the Stark law, which bans paying or receiving remuneration to physicians in exchange for Medicare, Medicaid and other government health care program referrals, often involve pretty byzantine and complex schemes. But this one was pretty vanilla. The government contended that over a nearly 10-year period, FMC implemented a physician compensation arrangement that improperly:

- Encouraged physicians to refer Medicare and TRICARE patients to FMC's labs for lab tests;
- Passed along a percentage of the reimbursement it received from the government to the referring physician; and
- Threatened to cut the compensation of physicians who didn't order lab tests from FMC.

Since the tests were borne of improper physician relationships, billing the government for them represented a false claims violation.

3. The Medical Necessity Claims

The other significant aspect of the FMC case was the medical necessity allegations stemming from use of customized panels and standing orders.

Custom Panels: The government claimed that the disease panels FMC created and pressured physicians to order were bloated with medically unnecessary tests not typically used for screening or routine testing. As a result, FMC allegedly ran up bills of:

- $4 million for unnecessary lipid tests;
- Over $1.6 million for unnecessary chemistry panel tests;
- Over $500,00 for unnecessary hepatic function tests; and
- Over $1 million for unnecessary thyroid panel tests.

Standing Orders: The other medical necessity charge in the FMC case that is typically associated with lab testing involved standing orders. Specifically, the government claimed that FMC devised improper lab standing

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orders that required staff to automatically perform certain diagnostic tests in response to indications regardless of whether those tests were actually ordered by a physician.

Takeaway: Because the procedural dynamics and allegations are so typical of false claims prosecutions against labs, compliance managers would do well to go to school on the FMC case, which for those of you who want to look it up is captioned United States ex rel. Schaefer v. Family Medicine Centers of South Carolina, LLC, Stephen F. Serbin, M.D. and Victoria Serbin, No. 3:14-cv-342-MBS (D.S.C.).

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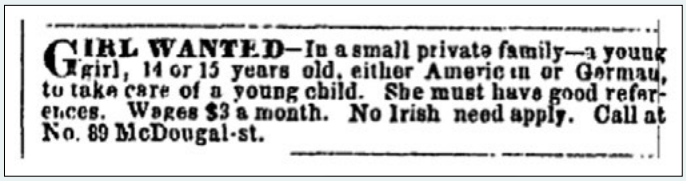
Beware of Accidental Discrimination in Lab Job Ads



GIRL WANTED—In a small private family—a young girl, 14 or 15 years old, either American or German, to take care of a young child. She must have good references. Wages $3 a month. No Irish need apply. Call at No. 89 McDougal-st.

New York Times job ad, Nov. 10, 1854
https://www.nytimes.com/2015/09/08/insider/1854-no-irish-need-apply.html?mcubz=0

Before civil rights laws, job ads like these were seen as perfectly normal. Today, employers aren't allowed to post job ads with phrases that exclude or express preferences based on race, gender, nationality, religion or other grounds protected by discrimination laws.

The Risk of Accidental Discrimination

Of course, the folks who do the hiring and recruiting for your lab know better than to use a phrase like "No Irish need apply" in a written or internet job ad. But what they may overlook is how statements that appear neutral on their face can still discriminate if they have the *effect* of excluding or preferring a particular group. And there are all kinds of everyday phrases and code words that seem harmless but can get you into trouble.

Example: The argument could be made that requiring job applicants to have a valid driver's license is a form of discrimination against individuals with visual impairments and other disabilities that make them incapable of driving.

If You Require It, You Must Justify It

The moral is **not** that requiring job applicants to have a driver's license is illegal. Preferences and qualifications that may be otherwise discriminatory are not only acceptable but essential for some positions. The fancy legal name for this concept is "bona fide occupational requirement" (BFOR). Thus, requiring a valid driver's license would be deemed a BFOR for a lab courier who needs to drive to collect samples from remote locations.

A couple of more legal technicalities you need to know to understand how the BFOR rule works. In a legal proceeding, job applicants or employees generally have to make out what's called a *prima facie* (Latin for "first face") case showing that the job ad was discriminatory. And that's not always a slam dunk.

But when and if the *prima facie* case is made, the burden shifts to you to show that the ad is justifiable as a BFOR. To meet the burden, you must prove three things about the problematic preference, qualification or restriction expressed in the job ad:

- It is essential to performing the job;

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- You adopted it in the good faith belief of its necessity to fulfill a legitimate and non-discriminatory work-related purpose; and
- It really is reasonably necessary to accomplish that work-related purpose.

Thus, for example, requiring physicians to have a medical degree is a BFOR even if it has the effect of excluding minorities who do not have access to medical school.

Requiring job applicants to speak a language without an accent is even more problematic than a fluency requirement.

What To Do

Moving from law to day-to-day operation, the takeaway is to ensure that your lab can justify every qualification, preference and restriction you list in your job ad as a BFOR in case you get sued. Better yet, because prevailing in litigation is less desirable than preventing disputes altogether, be sensitive to the language you use in your job ads and the hidden (and inadvertent) discriminatory messages they may send.

8 Code Words to Avoid

There are eight phrases and buzzwords that raise red flags of discrimination that you want to avoid using if possible.

1. "Recent Graduate"

Because recent graduates are predominately younger, the phrase may be deemed a veiled method of excluding older job applicants in violation of age discrimination laws.

2. "Experienced" or "At Least X Years of Experience"

"Experience" is also a red flag for age discrimination but in the opposite direction—it indicates a preference for an older job applicant.

3. "American Citizenship" or "American Experience"

Requiring American work experience or citizenship may be seen as a covert way of excluding immigrants and discriminating on the basis of nationality, ethnic origin and even race and religion.

4. "Proficiency" in English or Other Language

Fluency or proficiency in a language may also be a form of ethnic or nationality discrimination that you would have to justify as a BFOR.

5. "Accent-Free"

Requiring job applicants to speak a language without an accent is even more problematic than a fluency requirement. For example, while it might be a BFOR to require a receptionist to speak English, requiring that he/she speak unaccented English would much harder to justify.

6. "Post-Secondary Degree"

Higher education requirements may pose barriers for the disabled and even races underrepresented in universities and trade schools. The simplest way to avoid opening this can of worms is by not requiring a higher degree unless it is essential. Don't insist on a college degree where a high school diploma will do.

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7. Personality Traits

Personality and professional traits may be associated with some groups to the exclusion of others. Common examples your lab should try to avoid:

- "Dynamic" = young;
- "Career-minded" = male;
- "Dedicated" = male;
- "Good fit" = individuals with the same characteristics as current employees;
- "Traditional" ≠ women, minorities, LGBT individuals;
- "Long-term career potential" ≠ older.

8. Gender-Specific Terms like "Waitress"

Even though they're used in everyday language, gender-specific terms like "waitress" and "handyman" carry the taint of discrimination and should be avoided. While this may sound like a lecture about being politically correct, in the context of discriminatory job advertising the words you use to describe the position can have a significant and direct bearing on your liability.

Example: A janitor claims she was fired because she was a woman and the co-op community wanted to replace her with a man. The administrative tribunal agrees and awards her $5,000. It also orders the co-op to hire an outside consultant to create a non-discrimination policy. The crucial piece of evidence is the job advertisement calling for "CLEANER/MAINTENANCE MAN." We get that "'maintenance man' may be a casual idiomatic label for the job." But, the tribunal continues, use of a "male-oriented phrase" to designate a job title "has an exclusionary impact for women because it evinces a distinction based on gender. . . and reinforces negative stereotypes about the ability of women to do maintenance work."

Moral: Use gender-neutral rather than gender-specific terms to describe the advertised position.

Don't Use	Do Use Instead
Cleaning lady	Cleaner, cleaning staffer
Chairman	Chairperson
Salesman	Salesperson
Handyman	Maintenance person
Foreman	Supervisor
Waitress/Waiter	Wait staff

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Labs IN COURT

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

Urinalysis Lab Caught Up in Tennessee Opiate 'Pill Mill' Scam

Case: A urinalysis lab with a shady past figures prominently in an equally shady scheme involving TennCare, Tennessee's Medicaid program. According to federal prosecutors, Confirmatrix Labs paid kickbacks to pill mill operators that dispensed medically unnecessary opiates for referring patients to the lab for urine testing patients had to undergo to take the meds. And TennCare was billed for the whole shebang via a series of Confirmatrix shell companies.

Significance: Neither Confirmatrix nor its officials have been charged in the scheme. However, that may be just a matter of time. Confirmatrix's founder has a track record having served three years in federal prison for running a massive music counterfeiting operation. Another red flag is Confirmatrix's abnormally high per-patient costs. One private study named the lab "the biggest outlier" among reviewed firms for Part B payments, noting its $2,406 per-patient billing rate as opposed to the national per-patient average of $751.

Lab Charged with Kickbacks Fights to Keep CLIA License & Business Alive

Case: At stake is more than a fine and negative PR. The legal case against Dallas lab Next Health has become a fight for business survival. The feds indicted two company officials for taking $190,000 in bribes for hospital referrals to provide $200 million in overpriced and medically unnecessary drug and genetic tests earlier this year. Then in May, CMS inspectors cited Next Health for CLIA testing violations. Claiming that it's the victim of a "premeditated" scheme, Next Health is asking a federal court for a restraining order preventing CMS and state agencies from revoking or suspending its CLIA accreditation. Loss of the CLIA license would put Next Health out of business, the suit contends.

Significance: Next Health's legal adversaries aren't limited to the public sector. In February, UnitedHealthcare brought a private lawsuit against the firm in connection with the kickback scheme that it contends generated around $100 million in referrals for testing. (For more on private lawsuits against labs, see "Private Sector Joins the Battle against Lab Fraud," GCA, August 2017.)

Gift Cards-for-Urine Samples Pitch Leads to Kickback Charges

Case: Speaking of Next Health, one of the lab's former marketers is dealing with kickback troubles of its own. In an unrelated case, an Austin marketer has been charged with giving soldiers $50 Walmart gift cards for urine and saliva samples. Next Health and other client labs allegedly performed tests on the samples under the guise of a "wellness study" and billed Tricare for reimbursement. The marketer has pleaded not guilty to the charges.

Significance: The case is a reminder that kickbacks and bribes may implicate not only the referral source and testing lab but the sales and marketing personnel involved in making the allegedly illegal business arrangements.

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Compliance Quiz: Disciplining Employees for Smoking Pot at Work

SITUATION

Your lab is located in Colorado, Washington or another state where recreational and medical marijuana use is legal. But you're still shocked to find three of your employees smoking pot at work. The employees recognize that they've been caught red-handed but each offers up a different explanation.

- Bud reveals that he's addicted to marijuana;
- Herb explains that he uses medical marijuana to treat his cancer-related pain; and
- Mary Jane admits to being a recreational (rather than medical) user but can prove that she got the pot legally.

QUESTION

Which employee(s) can you fire for violating your lab's zero tolerance workplace drug policy?

ANSWER

All three

RULE

Use of marijuana *in the workplace* is grounds for discipline up to and including termination.

Bud, the Marijuana Addict: EEOC laws require employers to make accommodations for employees with disabilities. Addiction to drugs and alcohol is considered a disability under the law. But accommodations aren't required if they'd impose undue hardship. And while the line between required accommodation and undue hardship is determined case-by-case, the clear consensus from court cases and EEOC guidelines is that permitting employees to use or be impaired while at work would create an unacceptable health and safety risk.

Herb, the Medical Marijuana User: The same disability analysis applies to Herb because cancer and most other illnesses, injuries and conditions for which marijuana is used as a medical treatment would constitute "disabilities" under the law. While tolerating medical marijuana use away from work may be a required accommodation (as long as the employee isn't impaired while actually working), tolerating it *at work* would clearly be undue hardship.

Mary Jane, the Casual User of Legal Marijuana: Disability protections don't apply to Mary Jane because she isn't an addict and doesn't smoke pot to treat a disability. She's only a casual user. The fact that she obtained the marijuana legally won't shield her from discipline for violating a zero tolerance policy banning drug use in the workplace.

PRACTICAL IMPACT

Using marijuana at work in violation of a clear HR policy is justifiable under neither disability discrimination nor marijuana legalization laws and thus subject to discipline up to termination.

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CMS Issues New Medical Review Instructions to Contractors, From Page 1

The New Targeting Criteria

CMS has instructed Contractors to use two criteria to select which claims to review:

- Claims for items and services that pose the greatest financial risk to Medicare; and
- Those that have a high national error rate.

The tactical changes affect which providers are included in the first round. Rather than looking at *all* providers and suppliers billing a particular item or service the way they did before, CMS wants Contractors to focus on the ones with high error rates. "This will eliminate providers who, based on data analysis, are already submitting compliant claims," according to CMS.

You Make the Call: Is Replacing Spoiled Products for Free an Anti-Kickback Violation?

The following scenario comes right out of an August 25, 2017 OIG Advisory Opinion. See if you can guess how the OIG ruled.

SITUATION

A pharmaceutical company manufactures biologics prone to spoilage when exposed to sunlight, temperature changes, and other environmental conditions. The products are labelled and supplied with detailed storage and handling instructions. But the manufacturer also wants to replace products free of charge if they spoil or become unusable after physicians, clinics, and hospitals purchase them.

QUESTION

Does the proposed arrangement violate the anti-kickback laws?

OIG's RESPONSE

No.

THE OIG'S REASONING

Offering free replacements to referral sources is the kind of remuneration that *could* trigger kickback liability, noted the OIG. There is a safe harbor for written warranties that allows for replacing defective or substandard products. But the proposed arrangement wouldn't qualify for the safe harbor because the biologics would be replaced due to spoilage not because they were defective or substandard.

However, the OIG continued, the proposed arrangement would still be okay even *without* a safe harbor. The Advisory Opinion then cited four things about the arrangement that made it so low-risk from a kickback perspective:

1. Free Replacements Not Tied to Referrals

First, free replacement of the spoiled products would be restricted to specific unintentional and unplanned circumstances unconnected to money and

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which would serve the purpose of patient safety and quality of care. The availability of a free replacement would reduce the risk of a customer's administering a potentially spoiled product to avoid financial loss, the OIG explained.

2. Low Risk of Overutilization

The proposed arrangement would pose little risk of increased costs or overutilization since it covers only the products that customers already bought and intended to use.

3. Low Volume

The proposed arrangement would cover only individual claims of spoiled products, not large losses. And the only remedy would be replacement of the same product that the customer had intended to use but for spoilage.

4. The Insurance Analogy

Finally, the OIG noted that the proposed arrangement would be something like an insurance policy, the cost of which the manufacturer would bundle into the price of the products.

The Advisory Opinion is a bit surprising given the OIG's long standing aversion to offering freebies of any kind to referral sources. And while the arrangement involves a pharmaceutical company rather than a lab, the reasoning of the Advisory Opinion may apply equally to lab free replacement arrangements that serve the purpose of patient safety and meet the same transactional criteria listed in the opinion.

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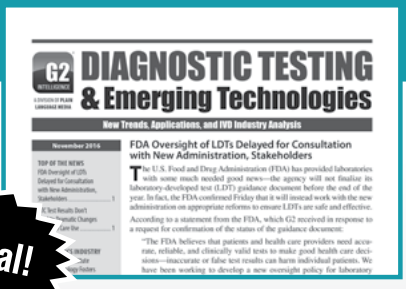
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