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IN THIS ISSUE

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Compliance Perspectives: How to Manage Liability Risks for Pass-Through Billing Arrangements

By Adam M. Walters, Walters Law, P.C.

Pass-through billing arrangements are those in which labs send a test specimen to an outside lab for testing and then bill the patient's insurer for the test performed. Here's a look at the potential liability risks and a strategy for managing them.

What Is Pass-Through Billing?

"Pass-through" billing, sometimes referred to as "client billing," is an arrangement in which the lab that bills for a test is different from the lab that performs it. There are two common forms of pass-through billing arrangements:

Lab to Lab arrangements arise when an independent or hospital lab refers a test to an outside lab, called a reference

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Compliance Alert: Not Following Government Guidance May Be Used Against You in False Claims Prosecutions

Unlike the regulations they purport to clarify, guidance materials issued by federal agencies don't carry the weight of law. Accordingly, the longstanding efforts of the U.S. Department of Justice (DOJ) to prosecute labs and other providers for failing to adhere to guidance has been highly controversial. Now, after a bit of a relapse, the DOJ strategy of infusing guidance with quasi-legal authority seems to be back in play.

The Controversy Over Treating Guidance Like Law

If regulations were simpler, there'd be no need for government agencies to issue guidance explaining what they

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lab, to perform and then bills the payor or patient as if it had performed the test itself. The reference lab then bills the ordering lab for the service.

Provider to Lab arrangements mirror lab to lab arrangements, the difference being that the ordering provider is a physician with an in-office lab. **Example:** A physician draws blood and sends the specimen to an outside lab for testing. The outside lab bills the physician and the physician bills the patient's insurer for that expense, along with claims for the other components of the service.

The 7 Laws Pass-Through Billing Arrangements May Violate

While reference lab relationships are often appropriate, pass-through billing arrangements are seen as a way for labs or physicians to work around their lack of a contractual relationship with a payor, avoid scrutiny or recoup some of the financial benefits of in-office testing without actually operating a lab. Pass-through billing may also run afoul of a number of laws.

1. Medicare Reference Lab Billing Requirements

Medicare rules ban labs from billing under the Clinical Laboratory Fee Schedule for diagnostic tests performed by a reference lab unless one of the following criteria are met:

- The referring lab is located in or is part of a rural hospital;
- The referring lab and reference lab are under some form of common ownership, i.e., one wholly owns the other or both are owned by the same entity (42 U.S.C. § 1395l(h)(5)); or
- The referring lab doesn't refer more than 30 percent of its lab tests out to a reference lab during the year (not counting referrals under the common ownership exception).

Strategic Pointer for Medicare Billing

When the referring lab that sends out and the reference lab that performs the test are in different Medicare Administrative Contractor (MAC) jurisdictions, they must comply with special rules determining which MAC has jurisdiction over the claims. For the referring lab to bill its own MAC, the carrier must have the performing lab's certification and fee schedule allowance in-house. Otherwise, the referring lab must submit claims to the performing lab's MAC.

The rural hospital exception is subject to a caveat: If a patient is an in-patient or outpatient, as opposed to patient not-at-hospital (TOB 141), only the hospital may bill for the service. For a patient not-at-hospital (TOB 141) either the hospital or performing lab may bill for the service. The

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third exception, referred to as the Shell Lab Rule, is designed to prevent hospitals and independent labs from shopping for the most favorable reimbursement rate. If a large number of specimens are referred, the 30 percent limit may be eclipsed.

2. Physician-Office Laboratories

The Medicare Anti-Markup Rule applies when a physician bills for lab tests performed by an outside lab. Specifically, it limits payment to the billing physician for the technical or professional component to whichever of the following amounts is lowest:

- The performing supplier (laboratory) net charge to the billing physician (or other supplier);
- The billing physician's actual charge; or
- The fee schedule amount for the test that would have been allowed if the performing supplier had billed directly (42 C.F.R. 414.50(a)(1)).

The Anti Markup rule, however, only applies to laboratory test paid under the Medicare Physician Fee Schedule, e.g., anatomic pathology services. Medicare does not permit physician office laboratories to bill for referred test that are paid under the Medicare Clinical Fee Schedule. (Medicare Claims Processing Manual, Ch. 16, Sec. 50.1-.2, Rev. 10615, 03-09-21)

3. Anti-Kickback Statute

Hospital and independent lab pass-through billing arrangements may violate the federal Anti-Kickback Statute (AKS) ban on payment, receipt, offering or solicitation of remuneration in exchange for the referral of services or items reimbursed by Medicare or Medicaid (42 U.S.C. § 1320a-7b). For example, offering remuneration to the ordering providers to induce them to refer the testing to the lab in question would be considered a kickback.

4. Stark Law

Pass-through billing arrangements between physicians and outside labs bring the federal physician self-referral law, aka, Stark Law, into play (42 U.S.C. §1395nn) to the extent it includes referrals by the physician to a lab that will share a portion of the revenue received for performing the tests. Moreover, arrangements involving discounts would raise red flags under both the AKS, EKRA, and Stark Law.

5. Medicaid Billing Rules

While each state has its own rules on reference lab billing, most state Medicaid programs require the performing lab to bill for lab tests. Many states have statutory restrictions on pass-through billing and markup (although some of the restrictions only cover professional component services and not the technical component.)

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6. Commercial Payor Billing Rules

In recent years, many commercial health insurance plans have developed specific rules limiting billing of referred lab test and there are now almost as many rules as there are health plans. In addition, private payors closely monitor reimbursement trends.

7. Billing and Coding Rules

Lab tests performed under pass-through arrangements must also be properly billed and coded. And that can be tricky. When the referring lab is billing for the referred test, it must use modifier -90 and list the CLIA number and address of the reference lab. If the parties are using a paper claim form for a split test, i.e., a test performed by both the referring and reference lab, they must submit separate claim forms for tests performed in-house and tests performed at the reference lab.

Compliance Strategies

There are a number of things your lab can do to ensure compliance and manage risks of liability for improper pass-through billing arrangements:

- Only bill for referred tests when the provider actually orders the test from the referring lab;
- If you're the referring lab, only bill for tests that you have CLIA certification to perform;
- Referring labs should also have controls in place to ensure that reference labs don't double bill;
- Both the referring and reference lab should have a written agreement in place that ensures compliance with the AKS, EKRA, Stark, False Claims Act and other federal and state laws.

About the Author:

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Labs IN COURT

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

Failure to Reimburse Government for Overpayments Is a Reverse False Claim

Case: A dermapathology lab sent a pair of retraction letters notifying TRICARE about overpayments of nearly $4.2 million in the form of reimbursement on nearly 50,000 "erroneous" claims for toxicology and DNA cancer screening tests. The lab repaid about $900,000 of the money, while it pursued the lab system that actually billed for the tests. The sides reached a settlement agreement to fully repay TRICARE. But when the lab then stopped making payments, whistleblowers filed a *qui tam* lawsuit contending that the lab's failure to repay was a reverse false claim under the False Claims Act. The government took over the case and the lab moved to dismiss without a trial

Significance: The Texas federal court denied the lab's motion. Liability for a reverse false claim arises when an individual or entity violates a duty to pay money due to the government. The lab insisted that failure to repay an overpayment didn't cross the line because it had no duty to pay the government. But the court begged to differ, noting that the lab acknowledged that it had received the overpayments and that the settlement constituted a duty to pay the government, even though the government wasn't a party to the agreement [*United States v. Cockerell Dermatopathology, P.A.*, 2021 U.S. Dist. LEXIS 201997, 2021 WL 4894173].

Federal Court Dismisses Quidel's False Advertising Claims against Siemens

Case: The nasty litigation between Quidel and Siemens continued with both sides accusing the other of false and deceptive advertising. The touchstone of the suit are ads run by Siemens referring for its TSI and TBI detection assay Immulite. The latest installment of the case raises the question of whether even if the statements in the ads were false, they influenced the decision of major lab customers LabCorp and Sonic/CPL to purchase Immulite rather than Quidel's Thyretain qualitative assay.

Significance: The Ninth Circuit Court of Appeal affirmed the lower court's decision to dismiss Quidel's claims. "There is no direct evidence in the record for which a reasonable juror could find that Siemens' allegedly false statements were material to the decision-making processes of the two laboratory customers." Both LabCorp's and Sonic's decision to switch from Thyretain to Immulite were based not on Siemens' scientific presentations, press releases and marketing materials, but a comprehensive and rigorous internal validation process, the Court concluded decisions [*Quidel Corp. v. Siemens Med. Sols. USA, Inc.*, 2021 U.S. App. LEXIS 30144, 2021 WL 4622504].

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LABS IN COURT: A roundup of recent cases and enforcement actions involving the diagnostics industry, *from page 5*

Ex-CEO of NWPL Settles Urine Drug Test Kickback Claims for $1.1 Million

Case: The former CEO of now-defunct Northwest Physicians Laboratories (NWPL) has agreed to shell out $1.1 million to settle charges of accepting millions in illegal payments for referring Medicare and TRICARE patients to a pair of labs owned by Cordant Health Solution for urine drug testing. Because NWPL was physician-owned, it couldn't test urine samples for patients covered by government health programs. The kickbacks were allegedly disguised as fees for marketing services, even though no marketing services were performed.

Significance: This is the third settlement in connection with the NWPL kickback scheme. In July 2020, Cordant Health settled with the DOJ for $11,942,913, 20 percent of which went to the relator who filed the whistleblower suit that brought the scam to the government's attention. And in December 2018, Vancouver/Washington testing lab MTL agreed to pay $1,777,738 to settle charges stemming from its role in the scheme.

Billing Medically Unnecessary Nuclear Stress Tests Costs Urgent Care Practice $1.25 Million

Case: A physician-owned primary and urgent care practice with clinics across South Carolina has agreed to pay $1.25 million to settle claims of billing Medicare, Medicaid and TRICARE for medically unnecessary nuclear stress tests (NSTs) over a seven-year period. The feds also claim that the practice systematically billed for unnecessary Crystatin-C lab tests for detecting kidney dysfunction by allegedly adding the test to its Basic Metabolic Panel that it ran on most patients, even though the test is covered only for a limited set of patients.

Significance: Before the pandemic, federal enforcers were turning up the heat for false billing of SSTs ordered by cardiologists. There are three things about NSTs, which use radioactive dyes to measure blood flow to the heart both when the patient is resting and stressed either via exercise or chemical inducement, that put them high on the list of FCA enforcement priorities:

- They're very expensive;
- They expose patients to significant doses of radiation; and
- They can generate false positives resulting in the ordering of medically unnecessary invasive procedures.

Quiz: Can Employees Who Wrongly Flunk Drug/Alcohol Test Sue the Testing Lab for Medical Malpractice?

In addition to potentially fatal misdiagnoses and erroneous treatment decisions, mistakes during the specimen collection and testing process can expose your lab to risk of liability under state medical malpractice laws. But what if the victim isn't a patient but an employee of a company that hires your lab to perform drug and alcohol testing rather than deliver medical treatment? What, if any, legal recourse do employees have against you if your carelessness in administering the drug/alcohol test leads to a false result that costs them their job? Consider the following scenario.

SITUATION

A commercial pilot loses his flying license after flunking a random blood-spot alcohol test required by his employer. The pilot claims the positive result was false and blames it on the lab technician's use of an ethanol-based alcohol pad in violation of United States Drug Testing Laboratories' (USDTL) rules. He sues the testing lab for negligence in failing to properly train the technician. But he doesn't provide the lab 60-days' defendant notice required by the state medical malpractice statute, aka, the Tennessee Health Care Liability Act (THCLA). So, the lab asks the court to dismiss the case.

QUESTION

Does the pilot have a valid negligence case against the lab, assuming he can prove his claims?

A. No, because his failure to provide the required THCLA notice doomed his malpractice claim

B. No, because the lab's duty of care was owed to the client, i.e., the employer, and not the pilot

C. Yes, because use of the alcohol pad in violation of USDTL rules is medical malpractice

D. Yes, because use of the alcohol pad in violation of USDTL rules is negligence

ANSWER

D. The pilot has a legally valid claim against the lab for negligently administering the blood-spot alcohol test

EXPLANATION

This scenario, which is based on a recent Tennessee case called *Cahoon v. Premise Health Holding Corp.*, 2021 U.S. Dist. LEXIS 113169, 2021 WL 2474460, illustrates the negligence/malpractice liability of labs

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Quiz: Can Employees Who Wrongly Flunk Drug/Alcohol Test Sue the Testing Lab for Medical Malpractice?, *from page 7*

to employees they test as part of an employer's drug/alcohol testing arrangement. **Bottom Line:** Although rules may differ from state to state, testing labs are generally liable to employees for regular negligence, but not medical malpractice. While that may sound like little more than a technical distinction, it can have significant practical consequences to the extent that medical malpractice laws typically include special defenses, legal procedures and other liability limitations that don't come into play in a lawsuit for ordinary negligence. So, D is the right answer.

WHY WRONG ANSWERS ARE WRONG

A is wrong because the court found that the pilot's case was an ordinary negligence rather than a medical malpractice lawsuit. **Explanation:** As in other states, the Tennessee THCLA statute covers negligence in providing "health care services." The alcohol test performed in this case didn't count as "health care services" because it was provided for the purposes of employment rather than medical treatment. The court also cited a previous case using the same reasoning to dismiss a medical malpractice lawsuit against a DNA testing lab for allegedly botching a paternity test. Thus, the 60-day notice rule didn't apply and the court said the pilot could take his case to trial.

B is wrong because courts across the country have found that drug/alcohol testing labs do have a duty of care to the employees they test, even though their client is the employer that hires them. The reason for this is common sense: Employees have a lot to lose, including their jobs and professional reputations, if careless practices by the lab result in their falsely testing positive for drugs or alcohol.

C is wrong because to the extent it actually does violate professional standards, use of the alcohol pad in violation of USDTL rules would constitute negligence, not malpractice, at least in this context in which no medical treatment was provided. However, it would amount to malpractice if it occurred in an actual diagnosis and treatment setting.

Takeaway

Labs that perform drug/alcohol testing on employees of an outside client for employment rather than medical treatment purpose may be liable to employees for negligence, but not medical malpractice. Accordingly, if employees sue for negligence, specific rules, procedures and limitations contained in state malpractice laws wouldn't apply. That may help or hurt the lab's case, depending on the circumstances involved.

Compliance Alert: OSHA Orders Inspectors to Use the Hammer to Enforce New COVID-19 Protocols

On June 21, OSHA issued a new Emergency Temporary Standard (ETS) requiring labs, hospitals and other providers to take extensive measures to protect frontline workers against risk of COVID-19 infection (for a detailed analysis of the ETS, see *Lab Compliance Advisor*, June 28, 2021). Exactly one week later, the agency issued internal Compliance Directive 2021-02 (the Directive) telling OSHA inspectors how to enforce the new ETS. The 67 pages of instructions shed light on how the agency intends to hand out penalties for violations, which, in turn, offers insights for labs on how to avoid them.

What the ETS Covers

Responding to criticism about health care workers being left unprotected during the pandemic, the ETS lays down a laundry list of things providers must do to guard against workplace COVID-19 infections. Although most of the measures were already required under previous public health guidelines, the ETS also imposes a number of onerous new obligations, including the controversial rule that employers must provide paid leave to workers who are medically removed.

As with other OSHA standards, field inspectors will be visiting workplaces to check on compliance and issuing citations to those found in violation of the ETS. The directive makes it clear that OSHA is determined to enforce the ETS aggressively. The Directive tells inspectors to issue "Serious" citations to employers who don't pay workers at their regular rate of pay when they work remotely or in isolation as part of a medical removal. That's a big deal because if your lab gets cited, inspectors could hit you with a "Repeat" citation carrying a fine of up to $136,532 if they find similar violations during subsequent inspections.

But the Directive doesn't stop there. The Directive also gives inspectors the greenlight to bring in the really heavy artillery, namely, liability for punitive damages under the OSHA Whistleblower Protection Program. Essentially, OSHA is treating medical removal violations as potential acts of retaliation rather than run of the mill health and safety infractions.

Look at the payroll records, interview workers and consider other aspects of the situation, including the employer's size and resources, and verify that the employer is "appropriately compensating" workers that it medically removes due to COVID-19, the Directive instructs. It also tells inspectors to accrue back wages, insurance premiums and other costs in determining how much the employer owes the worker and how big a proposed fine a citation should carry.

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Compliance Alert: OSHA Orders Inspectors to Use the Hammer to Enforce New COVID-19 Protocols, *from page 9*

Takeaway

OSHA's mandate is to ensure workplace health and safety. However, the ETS extends the agency's authority to matters of pay, benefits and medical leave. Ultimately, this may prove an unlawful incursion into matters beyond OSHA's jurisdiction. But the agency isn't backing down and is relying on its authority over whistleblowers as justification. Meanwhile, it's doubling down, ordering inspectors to be aggressive in enforcement, including via resort to punitive damages. Consequently, labs have no choice but to comply to avoid serious penalties.

Compliance Alert: Not Following Government Guidance May Be Used Against You in False Claims Prosecutions, *from page 1*

mean. But in the real world where regulations are far from clear and easy to understand, guidance provides crucial clarification. This is especially true in the health care realm.

While helping regulated entities, prosecutors, judges and other stakeholders interpret the law, guidance materials don't carry the weight of law. However, the DOJ has prosecuted regulatory entities for not complying with guidance materials. In the health care context, that typically involves using guidance as evidence of guilt for False Claims Act (FCA) violations. The argument: A lab or other provider that submitted a false claim did so "knowingly" to the extent it failed to follow the recommendations set out in guidance pertaining to the issue.

There's a constitutional problem with this practice, namely, the principal that agencies may regulate only within the authority that Congress delegates to them. The instrument of Congressional delegation, the Administrative Procedure Act, requires federal agencies to go through the notice-and-comment rulemaking process to promulgate new regulations. The guidance that agencies issues doesn't require notice-and-comment rulemaking. So, treating it like a law would circumvent the constitutional process.

The Trump Administration: The Sessions & Brand Memoranda

The above reasoning was the basis of a November 2017 memorandum written by then U.S. Attorney General Jeffrey Sessions memorandum banning publication of guidance documents "that purport to create rights or obligations binding on persons or entities outside the Executive Branch (including state, local and tribal governments)." The Sessions

Memorandum directed the DOJ to adhere to certain principles in constructing and publishing guidance documents, including refraining from the use of mandatory language and including specific language in the guidance to point out that the guidance represents a voluntary standard, non-compliance with which would not result in enforcement action. Sessions also called for including unambiguous statements that published guidance documents are not legally binding final agency actions.

In January 2018, the DOJ issued another memorandum to limit the use of agency guidance documents in litigation. What came to be known as the "Brand Memo" (named for then-Associate Attorney General Rachel Brand) stated that "effective immediately for [affirmative civil enforcement] cases, the Department may not use its enforcement authority to effectively convert agency guidance documents into binding rules." Specifically, "this memorandum applies when the Department is enforcing the [FCA], alleging that a party knowingly submitted a false claim for payment by falsely certifying compliance with material statutory or regulatory requirements."

The DOJ codified the policy statements from the Brand Memorandum into the Justice Manual at Section 1-20.000, which states that "criminal and civil enforcement actions brought by the Department must be based on violations of applicable legal requirements, not mere noncompliance with guidance documents issued by federal agencies, because guidance documents cannot by themselves create binding requirements that do not already exist by statute or regulation." Therefore, the "Department may not bring actions based solely on allegations of noncompliance with guidance documents."

The Biden Administration: The Garland Memo

Perhaps not surprisingly, when the administration changed, so did the DOJ policy. On July 1, 2021, Attorney General Merrick Garland issued a memorandum "clarif[ying] the principles that should govern the issuance and use of guidance documents by the Department of Justice" and rescinding the Sessions and Brand memoranda. The Garland Memo contends that the previous administration's directives against using guidance materials as evidence of proving "knowingly" in FCA cases are "overly restrictive" and might discourage agencies from developing guidance in the first place.

Just over two weeks later, the DOJ issued an interim final rule to implement the Garland Memo directive to "revoke the amendments to its regulations," characterizing them as "unnecessary and unduly burdensome, lack[ing in] flexibility and nuance and limit[ing] the ability of the Department to do its work effectively." The interim rule also states that the Justice Manual sections regarding agency guidance revised by the Trump administration "will be revised as appropriate at a later date."

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Impact on Labs

The Garland Memo and new interim rule reaffirm the DOJ's position that guidance documents don't equate to regulations. But actions speak louder than words. The recent DOJ actions mean that US attorneys can once more cite failure to follow guidance as evidence that a lab "knowingly" submitted a false claim in violation of the FCA. Essentially, we are right back to where we were in 2017.

Going forward, expect DOJ attorneys to continue and perhaps even step up their reliance on the Medicare Manuals, agency memoranda, advisory opinions, and other guidance documents to go after labs that don't follow guidance advice. Also likely to benefit from the new/old DOJ policy are whistleblowers to the extent it opens the door to using guidance violations as evidence in *qui tam* lawsuits against labs and other providers.

Bottom Line: While being aware of and seeking to follow HHS, OIG, CMS and other guidance is always sound advice, it's especially important now that the DOJ can use guidance to establish your guilt for an FCA violation.