COMMENTARY

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Court Overreaches in Requiring Medical Necessity Determination by Labs

IN SHORT

The Situation: A district court in Washington, D.C. has held that alleging a laboratory's failure to independently verify the medical necessity of tests ordered by treating physicians is sufficient to survive a Rule 12(b) challenge to a federal False Claims Act claim.

The Result: Although at the pleading stage, the ruling, if left uncorrected, could create a standard that laboratories processing thousands of tests a day cannot possibly meet.

Looking Ahead: If accepted, the court's position could dramatically increase compliance costs and slow important medical services, not only for laboratories, but for other medical providers who rely on treating physicians' orders to determine the medical necessity of the goods and services that they provide.

On June 9, 2017, the U.S. District Court for the District of Columbia denied a motion to dismiss brought by a laboratory in *U.S. ex rel. Groat v. Boston Heart Diagnostics Corp.*, 2017 WL 2533341. Part of the grounds for denying the motion was the court's conclusion that the laboratory was obligated to independently determine whether physician-ordered tests were medically necessary before submitting them for payment by Medicare. The court concluded that the qui tam plaintiff alleged a viable claim under the federal False Claims Act by asserting that the laboratory submitted claims without independent verification of the medical necessity of the physician-ordered tests. The decision, we believe, is legally erroneous, and the standard it espouses is unworkable in the real world.

Background

The case was brought by former United Healthcare medical director Tina Groat, who alleged that a certain suite of tests offered by Boston Heart—and ordered by treating physicians—was in all cases medically unnecessary for patients with certain diagnostic codes. Rather than being medically necessary, Groat argued, the tests were used "solely for screening purposes." Boston Heart's claims for payment were false, Groat said, because the standard claim form Boston Heart was required to submit to federal payors includes a certification that the tests performed were medically necessary.

In response, Boston Heart pointed out that it is a patient's doctor, and not the laboratory tasked with performing the physical test, who rightly determines the medical necessity of a specific test for a particular patient. As such, Boston Heart argued, it was not in a position to make an independent determination of whether the test(s) ordered was medically necessary. But the court disagreed, concluding that, under the circumstances alleged, "Boston Heart ha[d] an obligation to establish that the tests for which it s[ought] … reimbursement [were] medically necessary."

> 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.

A Key Error

While the court's opinion sets out in considerable detail the technical reasoning behind its conclusion, it makes a wrong turn as to at least one crucial point of law. The upshot of this is a holding that is unworkable in practice.

The *Groat* opinion relied on an unpublished California district-court case, *Garcia v. Sibelius*, as the primary support for its holding. But the *Garcia* matter involved laboratory tests billed by a physician, not by an independent laboratory. Nevertheless, *Groat* quoted *Garcia*'s pronouncement that the governing regulations "place[] the burden of establishing the medical necessity of diagnostic tests on the entity submitting the claim" (there, the physician).

Garcia, in turn, relied on two subdivisions of a single regulation, 42 C.F.R. § 410.32(d)(2)(ii) and 410.32 (d)(3), as the sole support for that statement. But § 410.32(d)(2)(ii) simply requires that the laboratory maintain "[t]he documentation that it receives from the ordering physician." And § 410.32(d)(3), far from placing the burden of determining medical necessity on the laboratory, provides that if CMS is unable to determine that the testing was "reasonable and necessary," CMS will "[r]equest[] *from the ordering physician* … those parts of [the patient's] medical record that are relevant" to such a determination (emphasis added). The regulation thus *undermines* the conclusion, crucial to the *Groat* decision, that the *laboratory* bears the burden on medical necessity.

Potential Impact of the Decision

Unfortunately, the court's error is not simply a legal technicality. 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. Laboratory employees, by contrast, in many instances do not even have occasion to interact with the patient in person.

Further, asking laboratory employees to make independent judgments of medical necessity could violate licensing requirements and practice-of-medicine restrictions in many states. Under the court's understanding of the law, laboratories would (arguably) need to obtain each patient's medical records and review those records in order to ensure they concur with the treating physician's medical necessity determination. The court fails to recognize that, if widely adopted, its interpretation of the law will result in delay, or even denial, of needed medical treatment to patients. Such a regime would dramatically increase the cost of testing, and thus the costs incurred by the federal health care programs—precisely what the governing statutes and regulations seek to avoid.

Additionally, the ruling could have significant implications far beyond the realm of laboratory testing. The court's flawed reasoning should raise a concern for any health care provider that relies on a treating physician's determination of medical necessity. Pharmacies filling prescriptions, chemotherapy centers administering treatments, stand-alone imaging centers, and other providers could, by *Groat*'s logic, be required to obtain complete patient medical records and independently verify medical necessity.

On June 23, 2017, Boston Heart filed a motion requesting that the *Groat* court reconsider its ruling, pointing to legal and practical flaws in the opinion.

THREE KEY TAKEAWAYS

1. Under *Groat*, when a qui tam plaintiff asserts that the tests performed conflict with the diagnostic codes provided, it is insufficient for a laboratory to rely on a treating physician's determination of medical necessity.
2. Should *Groat* become more widely accepted, the cost of compliance with the medical-necessity requirement will increase significantly for non-physician health care providers.
3. The case, in our view, was wrongly decided, and should not be followed by other courts.

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