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CLIENT ALERT

D.C. District Court Clarifies Standard for Laboratory Determination of Medical Necessity

By Arthur J. Fried; Melissa L. Jampol; Charles C. Dunham, IV; Alison M. Wolf; and Elena M. Quattrone

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Executive Summary

This past June, a federal district court in the District of Columbia made headlines when it declined to dismiss an action brought by a *qui tam* plaintiff ("Relator") against defendant Boston Heart Diagnostics ("Boston Heart"), a clinical laboratory. In the case, *U.S. ex rel. Groat v. Boston Heart Diagnostics Corp*.,[1] the D.C. District Court concluded, in part, that Boston Heart had an independent obligation to establish that the tests for which it sought government reimbursement were medically necessary. In effect, the laboratory would not be allowed to prove medical necessity simply by relying on the ordering physician's determination that the tests were medically necessary. The implications of this outcome for the laboratory industry were so significant that the American Clinical Laboratory Association ("ACLA") weighed in on the case. In December 2017, the D.C. District Court reversed its June conclusion relating to the laboratory's obligation to make medical necessity determinations.

Medical Necessity Cases

The issue of medical necessity for diagnostic services has been front and center in many health care-related cases filed pursuant to the False Claims Act, 31 U.S.C. §§ 3729 *et seq*. ("FCA"). Recently, the clinical laboratory sector has been hit with various *qui tam* suits involving a myriad of fraud and abuse issues. These actions are, in part, fueled by the focus of the Office of Inspector General ("OIG") of the U.S. Department of Health and Human Services ("HHS") on clinical laboratories and governmental concerns regarding the increasing popularity of laboratory developed tests.[2] Even private payors have heightened their scrutiny of laboratory billing practices, including increasing their claim denials and overpayment allegations.

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[1] 255 F. Supp. 3d 13 (D.D.C. June 9, 2017), *available at* https://cases.justia.com/federal/district-courts/district-of-columbia/dcdce/1:2015cv00487/171060/54/0.pdf?ts=1497085543.

[2] Office of the Inspector Gen., Dep't of Health and Human Servs., OIG Work Plan: Fiscal Year 2017.

The *Groat* Decisions

The June 2017 *Groat* decision explored the question of whether a clinical laboratory must make an independent determination of medical necessity for each test it performs, or may rely upon a determination by the ordering provider that the test is medically necessary, when making such a certification to a government payor. After the D.C. District Court refused to grant Boston Heart's motion to dismiss the case and then ruled that the laboratory had the burden of proving that its tests were medically necessary, Boston Heart urged the court to reconsider, noting the negative consequences of imposing such a significant burden on clinical laboratories and emphasizing that, unlike a treating physician, a laboratory has no direct contact with the patient and is not in a position to make clinical judgments regarding a patient's treatment.

The ACLA joined the defendant with an *amicus curiae* brief to the court in which it argued that a determination regarding medical necessity is the practice of medicine, which a clinical laboratory does not and cannot do under state laws. The ACLA further reasoned that such a requirement would impose an impossible burden on laboratories to confirm medical necessity for each and every of the nearly 500 million laboratory tests billed to Medicare each year, which would adversely impact access to necessary testing and wreak havoc on the relationship between clinical laboratories and ordering providers.

In an unusual move, and one that has implications for clinical laboratories nationwide, on December 11, 2017, the D.C. District Court changed course upon reconsideration and reversed its June conclusions regarding a lab's obligation to government payors. Upon reconsideration, the court held that it had "overstated a laboratory's obligation to establish that the tests for which it seeks government reimbursement are medically necessary" and clarified that "a laboratory may rely on the ordering physician's determination of medical necessity in the laboratory's certification to HHS on the CMS-1500 form."[3] The court noted that neither the applicable Medicare regulations (including the negotiated rulemaking history of 42 C.F.R. § 410.32(d)(2)) nor the HHS-OIG's Compliance Program Guidance relies on the premise that clinical laboratories make determinations of medical necessity. In fact, the HHS-OIG guidance expressly states that "laboratories do not and cannot treat patients or make medical necessity determinations."[4]

While the December 2017 *Groat* decision indicates that a clinical laboratory can rely on the ordering physician's determination of medical necessity in certifying to this material factor when submitting a claim to a government payor for reimbursement, upon review, Medicare will still require documentation that demonstrates medical necessity to support payment for the tests. If adequate documentation is not provided, even when the

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[3] *U.S. ex rel. Groat v. Boston Heart Diagnostics Corp*., 2017 U.S. Dist. LEXIS 202982 (D.D.C. Dec. 11, 2017) *available at* https://cases.justia.com/federal/district-courts/district-of-columbia/dcdce/1:2015cv00487/171060/70/0.pdf?ts=1513069778 (quotations omitted).

[4] Publication of OIG Compliance Program Guidance for Clinical Laboratories, 63 Fed. Reg. 45076, 45079 (Aug. 24, 1998).

ordering provider failed to maintain the appropriate diagnostic or other medical information for his or her patient, it is the laboratory that will suffer the consequences of the denial or recovery of reimbursement for the claim.

Outstanding Issues in the *Groat* Case

Still at issue in the *Groat* case are the Relator's surviving allegations that Boston Heart violated the FCA and various state laws by knowingly presenting false claims for reimbursement to federal health care programs based on how Boston Heart promoted the tests to the ordering providers. Specifically, the D.C. District Court has yet to determine whether Boston Heart encouraged non-cardiology physicians to order medically unnecessary tests by marketing panels of genetic and non-genetic tests as "innovative methodologies for cardiovascular risk assessment" when they allegedly do not and cannot (i) screen patients for current heart disease, (ii) assess patients for cardiac risk, (iii) provide any additional information regarding the cardiovascular-related diagnoses used to justify the tests, or (iv) have any bearing on potential treatments for those diagnoses.[5]

According to the Relator, Boston Heart specifically targets its marketing of these tests to primary care physicians and general practitioners who are "less sophisticated in the field of cardiovascular testing" and thus could be "more easily swayed by Boston Heart's false marketing statements."[6] The Relator further argues that Boston Heart violated the FCA and various state laws by promoting test panels that purposefully include a mix of both necessary and unnecessary tests, and by providing easy-to-use pre-printed test requisition forms with the panels featured in a prominent position, practices which the Relator argues are intended to increase the number of tests that are ordered, including medically unnecessary tests.[7]

In response, Boston Heart argues that (i) its tests are covered by Medicare; (ii) there is extensive medical literature that supports the clinical value of Boston Heart's tests for the diagnosis or treatment of cardiac disease and related conditions; and (iii) other laboratories, such as LabCorp, perform a number of Boston Heart's tests referenced by the Relator.[8]

Up to this point, the court's analysis of these issues has been limited to the context of Boston Heart's motion to dismiss, requiring the court to adhere to the appropriate standard of review and accept the facts of the Relator's complaint as true under the Federal Rules of Civil Procedure. The court's ultimate determination in this case, particularly as to the remaining issues, will likely continue to impact the clinical laboratory industry.

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[5] Relator's Second Amended Complaint ¶ 5.
[6] *Id.* at ¶¶ 4, 127.
[7] *Id.* at ¶¶ 4, 50-52.
[8] Memorandum of Law in Support of Boston Heart Diagnostics Corporation's Motion to Dismiss Relator's Second Amended Complaint, pp. 5, 29-31.

Epstein Becker Green will continue to monitor the *Groat* case and other enforcement actions against clinical laboratories as these cases develop.

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This Client Alert was authored by **Arthur J. Fried; Melissa L. Jampol; Charles C. Dunham, IV; Alison M. Wolf;** *and* **Elena M. Quattrone.** *For additional information about the issues discussed in this Client Alert, please contact one of the authors or the Epstein Becker Green attorney who regularly handles your legal matters.*

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