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Insights

D.C. District Court Clarifies Lab Requirement for Establishing Medical Necessity

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A June 2017 decision by a federal district court in the District of Columbia determined that a reference laboratory cannot rely on the ordering physician's determination to establish medical necessity for testing paid for under Medicare, Medicaid, or other federal health care programs.[1] In effect, the court created an obligation for labs to independently establish medical necessity for federally-reimbursed testing. As most reference laboratory providers can attest, this ruling created operational and compliance challenges.

However, on December 11, 2017, the same D.C. District Court found that it had overstated a laboratory's "obligation to establish that the tests for which it seeks government reimbursement are medically necessary." [2] The Court further clarified that "neither the Medicare statute nor the regulation regarding laboratories require laboratories to independently determine the medical necessity of the tests billed."[3] Ultimately, the Court recognized the special circumstances of laboratories, when they frequently do not have direct contact with the patient and, like durable medical equipment suppliers, are dependent upon physician documentation of medical need in order to receive payment.

In reconsidering its prior decision, the court looked to the Office of Inspector General (OIG) Compliance Program Guidance for Clinical Laboratories ("OIG Guidance").[4] The Court concluded that, while the OIG Guidance does describe a laboratory's duties to ensure that it does not submit claims for medically unnecessary tests, it does not include among those duties a laboratory's obligation to make an independent determination of the medical necessity of each test performed and billed. From the Court's perspective, the OIG Guidance would have explicitly

included the obligation to determine medical necessity among its recommended compliance processes if it intended laboratories to do so, and to suggest otherwise would entirely contradict

the explicit language of the OIG Guidance.

While the Court's reversal of its earlier decision benefits laboratory providers, labs should seize the opportunity to interact and educate with their referring physicians to ensure that the physician's order supports medical necessity for the laboratory service. In addition to receiving or collecting needed physician documentation, laboratories must be able to demonstrate that a physician's documentation supports medical necessity. If medical necessity cannot be established, then the lab's claim may be denied or at risk for audited recoupment.

If you have any questions related to the reference laboratory operations and compliance issues, please contact Stephanie T. Eckerle or your regular Krieg DeVault attorney.

[1] https://cases.justia.com/federal/district-courts/district-of-columbia/dcdce/1:2015cv00487/171060/54/0.pdf?ts=1497085543

[2] https://cases.justia.com/federal/district-courts/district-of-columbia/dcdce/1:2015cv00487/171060/70/0.pdf?ts=1513069778

[3] *Id.*

[4] 63 Fed. Reg. 45,076-79 (Aug. 24, 1998).