6 Takeaways From LabSolutions 'Unnecessary Testing' Verdict

By **Scott Liebman, Joseph Jay and Audrey Crowell** (January 11, 2023)

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Last month, jurors returned a guilty verdict against Minal Patel, CEO of LabSolutions LLC, for an arrangement involving the company's promotion of medically unnecessary genetic testing.

The verdict follows a 2019 indictment filed as part of Operation Double Helix, a concerted enforcement action brought by the U.S. Department of Health and Human Services' Office of Inspector General and the U.S. Department of Justice, against 35 defendants, including telemedicine providers and genetic testing laboratories, for over $2.1 billion in losses related to fraudulent reimbursement for genetic testing.[1]

LabSolutions' Arrangement

Under the arrangement in question, LabSolutions allegedly paid kickbacks to patient recruiters in exchange for arranging cancer genomic testing for Medicare beneficiaries, and, in turn, the patient recruiters passed on a portion of the kickbacks to telemedicine providers in exchange for cancer genomic testing referrals, whether or not the referrals were medically necessary.

The scheme targeted cancer survivors and their family members for preventative, rather than diagnostic or treatment-related, testing.

Lack of Medical Necessity

The primary concern reflected in the 13-count indictment was that LabSolutions submitted reimbursements to Medicare for cancer genomic tests that were not medically necessary, i.e., used in diagnosis or treatment.[2]

The U.S. Department of Justice argued that the cancer genomic tests were not medically necessary because the prescribing providers: (1) were not treating the beneficiaries for symptoms of cancer at the time the tests were ordered; (2) did not use the test result to treat the beneficiaries for cancer; (3) did not conduct proper telemedicine visits; and (4) often never communicated with the beneficiaries at all.

Narrow Coverage for Preventative Screening Tests

In 2021, Patel filed a motion to dismiss the indictment, arguing primarily that, although the cancer genomic tests may not have been used for diagnostic or treatment purposes, they were preventative screening tests, and, as such, were reimbursable by Medicare and should be excepted from Anti-Kickback Statute enforcement.[3]

Specifically, Patel argued that the cancer genomic tests were reimbursable by Medicare because LabSolutions followed guidance from the U.S. Preventative Services Task Force, which recommends genetic testing for asymptomatic patients who have a family history of breast cancer, and that Medicare is required to cover any screening test recommended by USPSTF.[4]

Further, Patel argued that the cancer genomic tests should be excepted from Anti-Kickback Statute enforcement based on a 2013 letter issued by the HHS secretary, which established the intent not to enforce the AKS against "ACA patient navigator programs that promote USPSTF preventive services."

However, in its order denying the motion to dismiss, the U.S. District Court for the Southern District of Florida made several important clarifications regarding the nature of Medicare reimbursement and AKS enforcement for preventative screening tests.

First, the court clarified that LabSolutions' cancer genomic tests were not reimbursable by Medicare, despite the USPSTF guidance, because:

- Medicare does not cover any cancer screening tests aside from those specifically listed in Title 42 of the Code of Federal Regulations, Section 411.15(a)(1), and Title 42 of the U.S. Code, Section 1395y(a)(1)(F)-(H), which do not include cancer genomic testing; and

- USPSTF is, ultimately, an independent body whose recommendations do not dictate the scope of Medicare coverage for preventative screening tests.[5]

Additionally, in response to Patel's reliance on the HHS secretary's 2013 letter, the court clarified that the reference to "patient navigators" in the secretary's letter referred to insurers that assist consumers in purchasing health insurance from state and federal health care exchanges that have been specifically certified by the Centers for Medicare and Medicaid Services, not patient recruiters like those employed by LabSolutions.

Key Takeaways

In the wake of Patel's verdict, and Operation Double Helix generally, there are six key takeaways that testing laboratories, telemedicine firms and health care providers should consider.

First, a laboratory should not make payments to either internal patient recruiters or external health care providers in exchange for arranging or referring genetic testing for Medicare patients.

As an initial matter, such payment is a prima facie violation of the AKS, since it constitutes an exchange of remuneration for the promotion or referral of testing that is eventually submitted to Medicare for reimbursement.

Further, the Office of Inspector General, the DOJ, and the Southern District of Florida have made clear that these payments do not qualify for any AKS safe harbor and are not protected by the enforcement discretion referenced in the HHS secretary's 2013 letter, which is only available for arrangements facilitated by individuals or entities specifically certified as "patient navigators" by CMS.

Second, a laboratory should not submit reimbursement to Medicare for genetic testing unless the test is (1) medically necessary, i.e., used in the diagnosis or treatment of a

specific condition, or (2) a preventative screening test specifically listed in statute or regulation.

As illustrated by Patel's case, submitting medically unnecessary testing to Medicare for reimbursement is a plain violation of the False Claims Act, and testing is only considered medically necessary if it is used in the diagnosis or treatment of a specific condition.

There is, however, a narrow circumstance in which Medicare will permit the submission of genetic testing that is not used in the diagnosis or treatment of a specific condition — preventative testing. That said, the order denying Patel's motion to dismiss the indictment made clear that Medicare does not accept reimbursement submissions for just any preventative testing.

Rather, to fall within this narrow exception to False Claims Act liability for submitting medically unnecessary testing, preventative testing must be preapproved under the handful of categories specifically enumerated under Title 42 of the Code of Federal Regulations, Section 411.15(a)(1), and Title 42 of the U.S. Code, Section 1395y(a)(1)(F)-(H).

Third, for a genetic test used in the diagnosis or treatment of a specific condition, a physician-patient relationship, as well as the relevant condition, must be established before the health care provider orders the test.

If a health care provider has not met with a patient or has met with a patient but has no reason to believe that the patient presents any symptoms that would warrant genetic testing for a certain condition, then any genetic test ordered for the patient by the health care provider would be considered medically unnecessary, as it could not have been ordered for the purposes of diagnosing or treating a specific condition.

Fourth, although laboratories do not have an independent duty to determine medical necessity, they may be held liable for fraud if they encourage the ordering of medically unnecessary testing.

In his motion to dismiss the indictment, Patel cited a 2017 False Claims Act, U.S. v. Boston Heart Diagnostic Corp. in the U.S. District Court for the District of Columbia, to argue that he should not be liable for the submission of medically unnecessary testing because laboratories are not required to independently determine the medical necessity of tests ordered by health care providers.

The district court acknowledged that laboratories have no legal duty to determine medical necessity, but pointed to an equally important holding from the case — that laboratories do have an affirmative duty to avoid submitting claims for medically unnecessary tests. Thus, laboratories seeking reimbursement for genetic testing have an indirect duty to determine medical necessity and should ensure that partnering telemedicine firms and health care providers are doing the same.

Ffith, for preventative screening tests, it is best practice to follow USPSTF guidance, but such guidance does not dictate the scope of Medicare coverage.

In his attempt to argue that the tests submitted by LabSolutions were medically necessary, and that, in turn, their submission to Medicare for reimbursement did not represent a False Claims Act violation, Patel argued that, because the tests qualified as preventative testing recommended by USPSTF, they had to be medically necessary.

However, the district court made clear that the meaning of "medically necessary testing" for purposes of Medicare reimbursement is narrower than the meaning of "medically necessary testing" in general, and only covers those tests used in the diagnosis or treatment of a specific condition, as required by statute.

Finally, telemedicine firms should be cautious in their activities as they become a focus of the DOJ's investigations.

In addition to Operation Double Helix, which signified the DOJ's commitment to dismantling the fraudulent exploitation of telemedicine platforms, the OIG has recently issued a special fraud alert, warning industry participants to exercise caution in telemedicine arrangements, as they present a heightened risk of fraud and abuse.[6]

It is clear that both the OIG and the DOJ intend to meet the swift rise of telemedicine technology, necessitated by the COVID-19 pandemic, with an equally swift enforcement initiative.

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[1] See Press Release No. 19-1039, DOJ (Sept. 27, 2019).

[2] The indictment cited 42 U.S.C. § 1395y(a)(1)(A), which provides that Medicare generally does not cover items or services that are "not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member," and 42 C.F.R. § 411.15(a)(1), which provides that Medicare does not cover "examinations performed for a purpose other than treatment or diagnosis of a specific illness, symptoms, complaint, or injury." (See Indictment at p. 6).

[3] See Motion to Dismiss Indictment and Request for Oral Argument, Case No. 19-CR-80181-RAR, ECF No. 187 (Jan. 7, 2021).

[4] See Motion to Dismiss, at 7.

[5] See Order Denying Defendant's Motion to Dismiss Indictment, Case No. 19-CR-80181-RAR, ECF No. 197, pp. 5-10 (June 22, 2021).

[6] See Special Fraud Alert: OIG Alerts Practitioners To Exercise Caution When Entering Into Arrangements With Purported Telemedicine Companies, OIG (July 20, 2022).