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# COMPLIANCE & POLICY REPORT

*Compliance and Regulatory Analysis for Lab Directors and Managers*

## Settlement Highlight Benefits of Self-Disclosure

A recent settlement by a company providing billing services for clinical laboratories highlights the benefits of self-disclosure when noncompliance is discovered.

VitalAxis Inc., a Maryland-based billing company for diagnostic laboratories, has agreed to pay more than \$300,480 to resolve False Claims Act allegations that it caused the submission of false claims to Medicare for medically unnecessary respiratory pathogen panels run on seniors who received Covid-19 tests, the Department of Justice (DOJ) announced June 15, 2023.

Throughout 2020, VitalAxis performed billing services for a diagnostic laboratory in Atlanta that provided Covid-19 testing to residents of senior living communities. For one chain of communities, the laboratory directed VitalAxis to bill Medicare for respiratory pathogen panels purportedly ordered by a physician who had not actually ordered the tests and who was ineligible to treat Medicare beneficiaries. VitalAxis found the credentials of a different physician and, without authorization, billed Medicare using that physician's name. Medicare subsequently paid the laboratory for these medically unnecessary tests.

VitalAxis received a credit in connection with the settlement in recognition of its cooperation, including by performing and disclosing the results of an internal investigation, disclosing relevant facts and material not known to the government but relevant to the investigation, providing information relevant to potential misconduct by other individuals and entities and admitting liability, according to DOJ.

### DOJ Touts Self-Disclosure



Karen Lovitch

Karen Lovitch, Chair of the Health Law Practice and co-Chair of the Health Care Enforcement Defense Practice at Mintz (Washington, DC), tells *LECPR* that VitalAxis might have received a civil investigative demand or subpoena in the context of the government's investigation of the laboratory performing the testing and discovered the noncompliance in the context of responding to it. It is also possible that VitalAxis discovered the noncompliance on its own and made a self-disclosure to the government, she says. That self-disclosure, in turn, could lead to the laboratory being investigated.

"Labs should be aware that the Department of Justice has been touting the benefits of self-disclosure and has made known that a party who self-discloses may receive a more favorable settlement than a party that does not," says Lovitch.

"If a lab is working with a vendor, such as a billing company, that discovers noncompliance involving the lab, the vendor might make a self-disclosure without the laboratory knowing about it. Labs should take steps to be sure that their respective compliance programs are effective, that potential noncompliance is investigated and (if appropriate) reported to the government, and that auditing and monitoring activities are robust and focused on high-risk areas."

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