

## DOJ Crackdown on Genetic Testing Telefraud

In a continuing effort targeting fraudulent telemedicine arrangements, the U.S. Department of Justice has charged two lab owners with schemes to defraud Medicare by billing unnecessary tests, including cardiovascular and cancer genetic tests. The charges are part of a nationwide enforcement action in which dozens are being charged with \$1.2 billion in Medicare fraud.

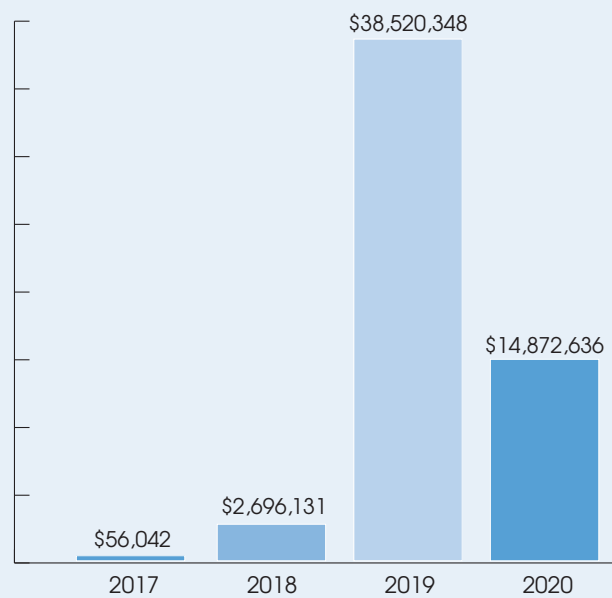
The federal investigations, announced July 20, 2022, targeted schemes involving the payment of illegal kickbacks and bribes by lab owners in exchange for the referral of patients by fraudulent telemedicine companies. Basically, the labs would contract with telemarketing call centers that would call Medicare beneficiaries, sometime multiple times per day, with the promise of “no-cost” genetic screening tests to determine risk of cancer or heart disease. The telemarketers would obtain beneficiary medical information and then pay telemedicine doctors to electronically sign off on lab test orders.

These charges include some of the first prosecutions in the nation related to fraudulent cardiovascular genetic testing, a burgeoning scheme, according to DOJ. The DOJ says that cardiovascular genetic testing is not approved by Medicare for use as a general screening test for determining increased risk of developing cardiovascular conditions.

### McNamara’s Labs

In one case, defendant Jamie McNamara, 47, acquired a group of small independent labs in Texas and Louisiana, including LPS Toxicology Labs (dba Clarity Diagnostic Labs), S&A Sleep Solutions (dba Mercury Laboratory Services), Opteo Laboratory and Signify Laboratory. As alleged in court documents, orders for cardiovascular and cancer genetic tests were used by the defendant and others to submit more than \$174 million in false and fraudulent claims to Medicare between November 2018 and July 2020. Of these submitted claims, Medicare reimbursed the McNamara’s

McNamara’s Labs: Medicare Allowed Payments\*



\*Includes total Medicare Part B allowed amounts for LPS Toxicology, S&A Sleep Solutions, Opteo Laboratory and Signify Laboratory  
Source: *Laboratory Economics* from CMS

labs over \$55 million. The indictment seeks forfeiture of more than \$7 million in cash, three homes in Missouri, a yacht, a Tesla and other vehicles.

### Akrivis Labs and Dynamic Diagnostics

Also involved in the crackdown was Christopher Thigpen, 48, of Hammond, LA, who was charged with a 12-count indictment for his role in a \$54 million scheme to defraud Medicare between March 2014 and January 2021. Thigpen, through his lab companies, Akrivis Labs and Dynamic Diagnostics, is alleged to have submitted thousands of claims for definitive urine drug testing and genetic testing to Medicare that were not medically necessary and tainted by kickbacks, according to the DOJ. Of the \$54 million of submitted claims, Medicare reimbursed Akrivis and Dynamic over \$9.5 million.

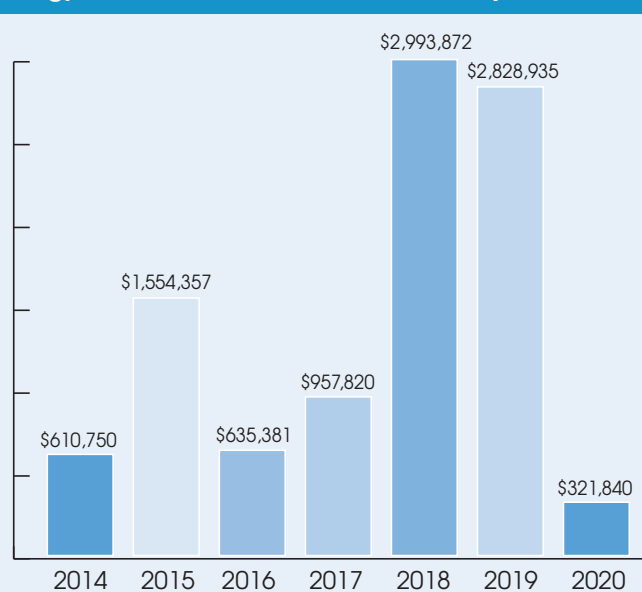
## National Telefraud Crackdown

The crackdown is a continuation of a nationwide coordinated effort to target telefraud, says Karen Lovitch, Chair of the Health Law Practice at Mintz (Washington, DC). This area continues to be a high priority for enforcement authorities, as evidenced by the publication of a Special Fraud Alert by the Health and Human Services Office of Inspector General on the same day that DOJ announced charges involving \$1.2 billion in health-care fraud.

“Cancer genetic testing has been at issue in many of the telefraud schemes uncovered over the past few years, so it was inevitable that new schemes would emerge,” says Lovitch. “The type of testing might differ, but the allegations remain the same – the testing is allegedly being ordered for patients who do not need it, and Medicare does not permit the testing to be used as a general screening test, so it was not medically necessary.”

Lovitch advises that clinical labs consider periodically auditing test orders to look for aberrant patterns, such as whether a particular provider is ordering a large volume of tests per day on a regular basis. Labs should also consider conducting formal or informal background checks of other labs with which they are doing business, she adds.

### Thigpen's Labs: Medicare Allowed Payments\*



\*Includes total Medicare Part B allowed amounts for Akivis Laboratories and Dynamic Diagnostics  
Source: *Laboratory Economics* from CMS

## SALSA Bill To Fix PAMA Slowly Gaining Support

The Saving Access to Laboratory Services Act (S. 4449 and HR ), which would provide a permanent fix to the lab reporting of private-payer data for determining CLFS rates, has been referred to the Senate Finance Committee, House Committee on Energy and Commerce, and House Committee on Ways and Means. The SALSA bills were initially introduced by Sens. Sherrod Brown (D-OH) and Richard Burr (R-NC) in the Senate and by five reps in the House in late June. The House bill has since gained support from two more members, Reps. G.K. Butterfield (D-NC) and Brian Fitzpatrick (R-PA). Without congressional intervention, more than 800 tests on the Medicare CLFS will receive up to 15% rate cuts effective January 1, 2023 (see *LE*, July 2023). Under the current schedule, labs are also required to report their private-payer data from the first half of 2019 to CMS in the first quarter of 2023

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