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MEDICARE UNMASKED

A Fast-Growing Medical Lab Tests Anti-Kickback Law

BY JOHN CARREYROU AND TOM MCGINTY

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Health Diagnostic Laboratory CEO Tonya Mallory, left, founded the cardiac-biomarker-testing company after leaving a California lab in 2008. PR Newsfoto/Associated Press

A fast-growing Virginia laboratory has collected hundreds of millions of dollars from Medicare while using a strategy that is now under regulatory scrutiny: It paid doctors who sent it patients' blood for testing.

Health Diagnostic Laboratory Inc. transformed itself from a startup incorporated in late 2008 into a major lab with $383 million in 2013 revenues, 41% of that from Medicare.

It built that business selling tests to measure "biomarkers" that help doctors predict heart disease. HDL bundles together up to 28 tests it performs on a vial of blood, receiving Medicare payments of $1,000 or more for some bundles.

Until late June, HDL paid $20 per blood sample to most doctors ordering its tests — more than other such labs paid.

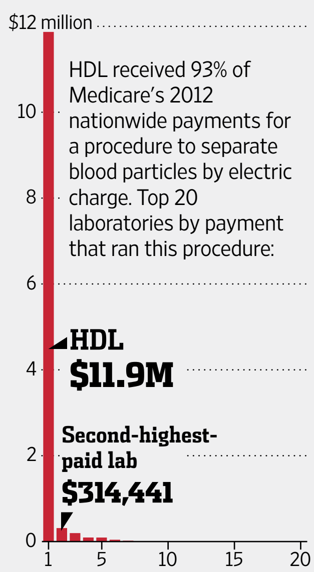
For some physician practices, payments totaled several thousand dollars a week, says a former company employee.

HDL says it stopped those payments after a Special Fraud Alert on June 25 from the Department of Health and Human Services, which warned that such remittances presented "a substantial risk of fraud and abuse under the anti-kickback statute."

The fraud alert is part of an investigation the health agency's Office of Inspector General is conducting with the Justice Department into doctor payments by HDL and several other labs specializing in cardiac-biomarker testing, people familiar with the investigation say. The agencies decline to comment.

HDL is cooperating with the investigation, a spokesman says. Its fee fairly compensated doctors for the labor cost of handling blood that went beyond the $3 that Medicare pays for each blood draw, he says.

Dominant Biller



Source: WSJ analysis of Medicare data
The Wall Street Journal

HDL "rejects any assertion that we have grown and succeeded as a result of anything other than proper business practices," says Chief Executive Tonya Mallory in a statement, and "has consistently complied with all applicable laws."

Payments like HDL's $20 fee could give doctors an incentive to order unnecessary tests, says Kirk Ogrosky, a former federal prosecutor on the Medicare Fraud Strike Force who now works for the law firm Arnold & Porter LLP. "With every allegation of kickbacks," he says, "the real question is whether money was paid to get the referral of Medicare patients."

Large established labs like Quest Diagnostics Inc. don't pay such fees. They operate blood-draw sites and sometimes place blood-drawing technicians in physician practices — doctors get no financial compensation for the blood draw.

At issue is a "safe harbor" exception to the federal anti-kickback statute. A vendor selling something to doctors may compensate them for certain related services. For instance, a lab could reimburse a doctor the partial cost of employing a blood-drawing technician who sends samples to the lab.

Under the exception, payments must not offer a financial incentive for doctors to send more business the vendor's way. They must not exceed a "fair market value" for the service and must be a fixed amount set beforehand. The government is examining whether the labs' payments were excessive and encouraged doctors to send more samples because they were paid for each one.

HDL and several other labs under investigation say that their payments were fair-market-value compensation for handling blood, that they had been a widespread industry practice and that the fraud alert represents new government guidance.

HDL documents and emails reviewed by The Wall Street Journal reveal details about its fee and another practice that raised internal concerns: performing a genetic test on thousands of blood samples it had refrigerated after previous tests. A former HDL lab employee says the lab performed the test on many more samples than she thought medically legitimate. HDL says it ran only tests doctors requested.

Tax dollars helped fuel HDL. It collected $139 million from Medicare in 2012, according to federal data released in April after a legal effort by the Journal. HDL's Medicare receipts rose to $157 million in 2013, a company document shows.

'One word makes it legal,' explained an email about what to call HDL's payment to doctors, 'the other illegal.'

HDL received 64% of Medicare's nationwide reimbursements for the nine lab procedures from which the company earned the most in 2012. It received 93% of Medicare's reimbursements for a procedure to separate blood particles based on their electric charge. HDL billed Medicare for it 262,308 times, collecting $11.9 million. The 35 other labs using the procedure together billed Medicare for it 19,621 times, collecting $850,000.

The HDL spokesman says its billing reflects proprietary lab methods and that detecting disease early with its tests "is far less expensive, in both human and financial terms" than treating heart attacks or strokes.

HDL traces its roots to efforts to improve heart-disease detection. Researchers have found that when the body produces certain molecules in abnormal quantities, its ability to process fats and cholesterol diminishes, increasing cardiovascular risk. Those molecules have become known as biomarkers of potential heart disease.

In the late 1990s, a California company, Berkeley HeartLab Inc., began developing tests to measure those biomarkers. It was acquired by Celera Corp. and is now a Quest unit.

Ms. Mallory was Berkeley's senior lab-operations manager in 2008 when she left to found HDL in Richmond, Va. Two Berkeley sales representatives, Cal Dent and Brad Johnson, later left to form BlueWave Healthcare Consultants Inc., which became HDL's independent sales-and-marketing contractor.

Berkeley sued HDL, accusing it of stealing Berkeley's business after some doctors switched to ordering tests from HDL. In court filings, HDL denied the allegations. It settled the case for about $7 million, Celera said in 2010. Berkeley and HDL sued each other in 2011 and settled those suits under undisclosed terms. The companies declined to comment on the litigation.

HDL began offering tests in 2009, promising doctors a fee for each sample. In a May 1, 2010 memo, Ms. Mallory distinguished between a venipuncture — drawing blood — and other aspects of processing and handling a sample, such as vial labeling, cooling and shipment coordination. HDL called those aspects "P&H."

Medicare doesn't pay additional P&H fees beyond the $3 it reimburses for a venipuncture. Citing a time-motion study HDL conducted, Ms. Mallory's memo valued the P&H tasks at $17. Adding the two, her memo concluded, doctors were entitled to an overall $20-per-sample fee from HDL.

The fee, she wrote, met anti-kickback-law exceptions allowing compensation for services at fair market value. The memo demonstrates good faith, the HDL spokesman says. "That P&H fees could have been misinterpreted or misread by others was the very reason that HDL" put it in writing.

HDL paid some practices more than $4,000 a week in blood-sample fees, says a former HDL marketing manager whose duties included sending doctors checks. In an October 2010 email copied to Ms. Mallory, he asked how to handle a doctor who said HDL had promised a $25 "draw fee," $5 more than HDL paid.

After Ms. Mallory forwarded his query to BlueWave's Messrs. Johnson and Dent, Mr. Johnson emailed: "Fyi To all I want to refocus that this is an ph fee not a draw fee. One word makes it legal the other illegal."

The manager emailed Ms. Mallory: "Can you explain the difference between a draw fee and a P&H fee?" She explained that $17 was for packaging, he says. He says he expressed concerns to her about the fee's ethics.

Ms. Mallory declined interview requests. Mr. Johnson declined to comment. Mr. Dent didn't respond to inquiries.

That month, Becky Morrissey, a representative for the Tennessee Medical Association, which represents doctors in the state, emailed HDL about the payments: "My question, how is this not a kickback and a violation of federal law?" Ms. Morrissey says HDL referred her to outside lawyers who said the payments were legal.

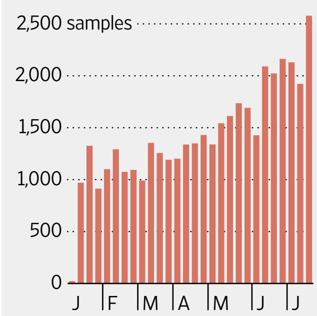
Blood-sample fees were “a long-standing, industrywide practice” before the fraud alert, which was “new guidance,” Ms. Mallory said in her statement.

Other labs under investigation — Quest’s Berkeley HeartLab, Singulex Inc., Boston Heart Diagnostics Corp. and Atherotech Diagnostics Lab — say they are cooperating. Quest says Berkeley ended payments of $7.50 to $11.50 in 2011 when Quest bought Berkeley. HDL, Singulex, Boston and Atherotech say they stopped payments after the June 25 alert.

Singulex says it paid $10, saying such fees were “a long-standing industrywide practice,” before the “government clarified their view.” Boston says it paid $15 and thought the practice lawful before the alert. Boston and Singulex didn’t include a $3 draw fee. Berkeley did include the $3, as did Atherotech, which says it paid $10, declining further comment.

Sample Growth

Health Diagnostic Laboratory’s testing grew rapidly in 2010. Weekly blood samples received for analysis:



Source: HDL internal documents
The Wall Street Journal

Of those labs, HDL collected the most from Medicare in 2012. Its $139 million receipts compared with Berkeley’s $17 million, Atherotech’s $16 million, Boston Heart’s $13 million and Singulex’s $8 million.

Some doctors stood out for heavy use of HDL’s services in 2010 Medicare data. The data, which the Journal obtained for a fee, include reimbursement claims for a random 5% sample of Medicare patients and are the most recent the Journal could obtain showing individual patient billings.

In that sampling, Charles “Sam” Fillingane was the most prolific test prescriber among 296 doctors who referred patients to HDL. HDL submitted 140 Medicare claims in 2010 for the 12 patients in the sample referred by the Flowood, Miss., family practitioner — 11.7 claims per patient. HDL collected $14,780 from Medicare for those 140 claims. Doctors in the HDL sampling averaged 3.8 claims per patient.

Dr. Fillingane is on HDL’s medical advisory board, a position that HDL paid doctors up to $3,000 a month for in 2010. He also earned speaking fees from HDL, says the former marketing manager. In a YouTube video, jazz musician Steamboat Willie says the doctor changed his life with HDL’s tests.

Dr. Fillingane and the musician, whose real name is Larry Stoops, didn’t respond to inquiries. A company document shows Dr. Fillingane sent HDL 1,179 blood samples in 2010’s first half, which would have earned him $23,580 in fees.

The other HDL practice raising internal concerns involved Plavix, a blood thinner ineffective in an estimated 2% to 14% of people. In July 2010, HDL introduced a test measuring sensitivity to the drug. For a doctor considering prescribing Plavix, the test helped determine if the drug wouldn't work.

HDL had refrigerated samples it tested earlier and told doctors it could run the Plavix test on those. By December 2010, orders for retroactive Plavix tests totaled nearly 5,600 patients from about 30 doctors, internal documents show. Many ordered the test on all their stored samples. HDL says it ran only tests doctors requested.

HDL says it didn't pay doctors additional sample fees for those retroactive tests. It did bill insurers or Medicare. About 35% of the patients tested were 65 or older and would have been predominantly on Medicare.

Allison Cicero, then-manager of HDL's lab, says she told Ms. Mallory that performing the test on so many was inappropriate because only a fraction were likely to be candidates for Plavix. She says Ms. Mallory ignored her concerns.

The former HDL marketing manager, taken aback that the lab was retesting so many samples, emailed Ms. Mallory on July 8, 2010: "It was my understanding that this test was going to be run on approximately 10% of our patients." She responded that doctors would add it to "baseline" bundles of tests they prescribed to patients.

Prescribing the Plavix test routinely to patients "is not something we would endorse," says Allan Jaffe, a Mayo Clinic cardiologist. It is appropriate only for patients with blood-clot risk whom doctors want to treat with the drug, he says.

Later on July 8, Ms. Mallory emailed Ms. Cicero and others with instructions to perform the test for a South Carolina doctor, J. Frank Martin Jr., who had ordered it on all his stored samples. Dr. Martin had sent 1,237 samples up to that point, which would have earned him $24,740 in fees.

The task was urgent, Ms. Mallory wrote, to generate revenues to pay what HDL owed Berkeley HeartLab under their settlement. "I'd like to have all of the backlog of back testing cleared by the end of July so that the reimbursement will hit us in September when we will need it to pay our next settlement fees to BHL," she wrote.

Dr. Martin didn't respond to inquiries. The HDL spokesman says Ms. Mallory wrote the email "to make clear that the company has bills to pay and there is no reason to wait to run testing once already ordered."

Ms. Cicero says HDL fired her for insubordination in 2011 after she expressed her misgivings. HDL says it dismissed her for performance issues and irregular behavior.

HDL continued to grow, inaugurating a new $100 million headquarters in June.

In a July 2 letter to doctors, Ms. Mallory disagreed with the government's suggestion that HDL's payments "might inappropriately affect some physicians' decisions."

But stopping them, she wrote, "is the right decision for us and for you."