DOJ INVESTIGATING LAB PAYMENTS TO DOCTORS

The Department of Justice (DOJ) is conducting an investigation into the processing and handling fees that some labs pay to referring physicians. The P&H fees are meant to cover the costs that physicians incur for labeling and packaging patient samples, but DOJ believes the fees may constitute illegal remuneration designed to induce physician lab test orders.

In particular, DOJ is investigating several labs specializing in advanced lipid testing. These labs market test panels, which can include 20 or more tests, designed for early detection of heart attack, stroke and diabetes. A recent front-page article in the Wall Street Journal highlighted Health Diagnostic Laboratory Inc. (Richmond, VA), which, until late June, paid $20 per blood sample to most doctors ordering its tests. Formed in 2008, HDL has rapidly grown into one of the nation's largest lab companies with revenue of $383 million in 2013, including 41% from Medicare.

In response to the WSJ article, HDL said that it “vehemently disagrees with any insinuation that payments to doctors were an inducement, or that the payments were illegal or known to violate any law.” Cont’d on page 6.

CMS DRIVING BLIND AS IT PUSHES MORE SERVICES INTO OUTPATIENT BUNDLES

This year CMS eliminated separate payment for approximately 1,000 clinical lab tests by packaging them under the outpatient prospective payment system (OPPS) rather than continuing separate payment for them under the CLFS. The agency asserted that this policy would “contain unnecessary growth” in spending in the outpatient setting. CMS’s move towards greater levels of packaging is an effort by the agency to move the OPPS away from a fee-for-service type system and more towards a true prospective payment system where a single payment is made for a larger “bundle” of services. For 2015, CMS has proposed eliminating separate payment for 300+ more codes, including most pathology TC services and some professional services. Cont’d on page 2.

Proposed to be Bundled in 2015

- X-ray exams
- Blood typing tests
- Most Pathology TC services
- Some Pathology PC services

Source: CMS Proposed OPPS Rule 2015

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DOJ INVESTIGATING LAB PAYMENTS TO DOCTORS (cont’d from page 1)

In a Sept. 8 press release, HDL said:

“As we confirmed to The Journal, the Department of Justice (DOJ) is conducting what we understand to be an industry-wide review of certain clinical laboratory practices, many of which have been longstanding within the industry. HDL, Inc. has been cooperating fully with the government investigation and has consistently complied with all applicable legal and regulatory requirements. In the event that the DOJ investigation results in legal action against HDL, Inc., we are prepared to defend our business practices vigorously.”

Other labs under investigation include Quest’s Berkeley HeartLab, Singulex Inc., Boston Heart Diagnostics and Atherotech Diagnostics Lab. Quest says Berkeley ended payments of $7.50 to $11.50 in 2011 when Quest acquired Berkeley. HDL, Singulex, Boston Heart and Atherotech say they stopped payment after the Office of Inspector General issued a Special Fraud Alert on June 25.

According to the OIG alert, the characteristics of a specimen processing arrangement that may violate the anti-kickback statute include: 1) Payment exceeds fair market value for services actually rendered by the party receiving the payment; 2) Payment is made on a per-specimen basis for more than one specimen collected during a single patient encounter or on a per-test, per-patient, or other basis that takes into account the volume or value of referrals; and 3) Payment is offered on the condition that the physician orders either a specified volume or type of test or test panel, especially if the panel includes duplicative tests (e.g., two or more tests performed using different methodologies that are intended to provide the same clinical information), or tests that otherwise are not reasonable and necessary or reimbursable.

While HDL and the other labs have stopped paying doctors packaging and handling fees, they are now offering to place in-office phlebotomists to draw specimens.

Laboratory Economics believes that the OIG may also be looking into the test panels offered by HDL and the other cardiovascular disease testing labs to see if they included medically unnecessary tests.

Earlier this year, on the Science-Based Medicine Blog, Harriet Hall, MD, wrote about a particularly egregious example of ordering unnecessary tests. The name of the ordering physician was not mentioned, but the lab conducting the tests was HDL.

“A friend’s 21-year-old son went to a board-certified family physician for a routine physical. This young man is healthy, has no complaints, has no past history of any significant health
problems and no family history of any disease. The patient just asked for a routine physical, and did not request any tests; the doctor ordered lab work without saying what tests he was ordering, and the patient assumed that it was a routine part of the physical exam. The patient’s insurance paid only $13.09 and informed him that he was responsible for the remaining $3,682.98 (no, that’s not a typo).”

More than 25 tests were performed, including genetic tests for CYP2C19*2*3, CYP2C19*17, Factor V Leiden, Prothrombin Mutation, MTHFR (C677T) and MTHFR (A1298C). The blog went on to report that the young man called his doctor’s office to complain about the lab test charges. They referred him to the billing department. The billing department said there was nothing they could do and he should call the lab that did the tests. He called HDL and they told him to just forward the check for $13.09 that his insurance company had sent to him and he would not be billed for the rest of the charges.

HDL collected total payments of $139.1 million from Medicare in 2012, according to the latest available Medicare utilization and payment data. The company provided 6.8 million lab test services for 147,691 Medicare beneficiaries. That works out to an average of 46 test services and $942 in collected revenue per Medicare patient served in 2012.

In comparison, Quest’s Berkeley HeartLab performed an average of only 21 test services and $469 in collected revenue per Medicare beneficiary in 2012.

Meanwhile, since the start of year, HDL has seen the departure of two of its top executives. CFO Steve Carroll retired on March 1, while Mark Herzog, Senior VP of Corporate and Government Affairs, left HDL in mid-March. New hires at HDL include Kathy Johnson, Chief Compliance Officer.

### Lab Companies Offering Specialized Cardiovascular Disease Testing

<table>
<thead>
<tr>
<th>Laboratory Company</th>
<th>Location</th>
<th>Total Beneficiaries</th>
<th>Total Services</th>
<th>Total Medicare Payment</th>
<th>Avg. Payment Per Beneficiary</th>
<th>Avg. Services Per Beneficiary</th>
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<tbody>
<tr>
<td>Health Diagnostic Laboratory</td>
<td>Richmond, VA</td>
<td>147,691</td>
<td>6,848,884</td>
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<td>Berkeley Heartlab Inc</td>
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<td>Atherotech</td>
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<td>Boston Heart Diagnostics</td>
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<td>Singulex, Inc</td>
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<td>Hunter Laboratories Inc</td>
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<td>Cleveland Heartlab Inc</td>
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<td>Liposcience Inc</td>
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<td>Spectracell Laboratories</td>
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<td>Avil, Inc.</td>
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<td><strong>AVERAGES</strong></td>
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Source: Laboratory Economics from Medicare Provider Utilization and Payment Data CY2012