Put It on the Board, 6/15

Keep close eye on payments to physicians

Recent legal developments should give laboratories new cause to tightly monitor efforts to win physician referrals, attorney Jane Pine Wood said at last month’s Executive War College meeting.

In April, the federal government reached a settlement with cardiovascular-disease testing labs Health Diagnostic Laboratory and Singulex to resolve allegations that they violated the False Claims Act by paying doctors in exchange for patient referrals. The U.S. Justice Department also alleged the companies billed Medicare and Medicaid for medically unnecessary testing. HDL agreed to pay $47 million to settle the matter, while Singulex will pay $1.5 million.

According to the Justice Department, HDL, Singulex, and another company paid doctors between $10 and $17 in processing and handling fees for each blood test. They also routinely waived patient copays and deductibles.

“These lawsuits didn’t go to court, so we don’t know if these actions would have been held to be a violation of the antikickback law,” Wood said. Nonetheless, she added, earlier advisories from the Office of the Inspector General specify that payments to physician offices for blood collection are subject to scrutiny if they exceed what Medicare pays for phlebotomy services.

Wood

“Even if you only pay the $3.50 that Medicare pays for phlebotomy to a physician office, it should be pursuant to a written agreement that meets all the Stark requirements,” Wood said. “There should be a term of one year describing the services and providing fixed, fair-market compensation.”

Earlier cases that were resolved in court shed light on the white lines of the law in this area. Wood, an attorney at the McDonald Hopkins law firm, said laboratory owners, sales representatives, and even physicians are serving criminal prison sentences for actions related to illegal inducements disguised as handling fees.

“The real difference from the past is physicians being prosecuted for accepting these payments and handling fees. If you have a physician doing a blood draw for you, I can get a comfort level with paying the physician the Medicare fee to do the draw for you, assuming that there are not other viable options for the draw. However, the Medicare draw is not much. It might not be enough to get the physician to want to do it,” she said.

“But remember the physician also is at risk, so if you start to go above the Medicare fee, you start to go higher on

the risk scale. If you're paying more than that and paying the physician some type of handling fee, at that point you should start asking, 'Is this something we really need?'... You might be able to justify the payment, but you should recognize those payments will come under extraordinary scrutiny."

If laboratories are going to pay referring physician offices for specimen collection and handling, it should be justified with great detail in writing.

"Do something like a time-and-motion study, where you go through a mockup and say here's how much time it would typically take to do this, and note the salary level of the person doing the work," Wood said. "I can understand reimbursing a physician for the time spent, but giving the physician a profit motive [to order tests] could get you into trouble."

Another area where laboratories must tread carefully is in paying physicians to participate in studies or patient registries, Wood said.

"This is a question I get, not infrequently. A laboratory explains that the sales team would like to put together a study to offer to physicians. Well, a study needs to have a legitimate business purpose for your laboratory services other than gaining referrals," she said. "I'm not sure, for most sales departments, how they would be tied to your R&D, for example. If R&D comes and says they want a study to help refine an existing test, that's one thing. But if it's something that comes in from sales, look at it with a skeptical eye."

Three elements should be in place before approving payment to physicians for study participation, Wood advised. First, identify a legitimate need for the study, such as to correlate patient outcomes with a surgical intervention. Second, offer fair-market value payment based on time-and-motion studies orother objective measures of the expenses for which the physician practice is being reimbursed. Third, the results of the study must be used.

"This is a problematic area," she said. "I am aware of studies that have been ongoing for quite some time, and no one is talking about how to use the results. They don't even have interim use of the data.... If a study goes on indefinitely, it has the flavor of being a way to generate referrals over time."

The study, Wood advised, should have a specified end date and goal to collect a certain number of samples or data points over a given period. Referring doctors can be the source of legally questionable compensation arrangements.

"Be very, very wary of physicians who will offer to send you work if you can have them participate in a study," she said, noting that they may be willing to order tests without properly documenting the reason for those orders.

More generally, Wood said, laboratories must keep a close watch on the sales and marketing efforts undertaken on their behalf, whether by in-house staff, independent contractors, or marketing agencies. One element of the federal government's settlement with HDL and Singulex is that there be unannounced ride-alongs with sales staff. Laboratories should implement a similar approach in-house.

"Go visit some accounts with sales reps," Wood said. "Just saying you want to do a ride-along and visit clients can highlight problems. If the sales rep says, 'Great! Come along. I'm sure the doctor wants to meet the owner of the lab,' then you're probably in good shape. If the salesperson balks and tries to put you off, they may be trying to hide something." *—Kevin B. O'Reilly*

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NIST releases first 'genome in a bottle'

The National Institute of Standards and Technology has released the first reference material from its Genome in a Bottle project (see "Groups closing the gap in reference materials for sequencing assays," CAP TODAY, March 2015, page 1).

Reference material 8398, human DNA for whole-genome variant assessment, "is intended to provide a whole human genome sample and accompanying reference values to assess performance of variant calling from genome sequencing," NIST said in a technical document released April 15.

Laboratories can use the material to test the performance of their whole-genome and whole-exome sequencing, as well as more targeted sequencing such as gene panels. The material can be used to obtain estimates of true positives, false positives, true negatives, and false negatives for variant calls. Because the material is extracted DNA, it cannot be used to assess preanalytical steps such as a lab's DNA extraction. While the reference material can assess sequencing library preparation, sequencing machines, and the bioinformatic steps of mapping, alignment, and variant calling, it cannot be used to gauge the performance of functional or clinical interpretation.

The material will be valid until 2024. Additional reference materials for sequencing are reportedly under development.
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For blood supply safety, time for technology mandate

Improvement in proper use of blood is having the unintended effect of making it more difficult for blood centers to implement new blood-safety interventions, says a *New England Journal of Medicine* perspective article co-written by physicians from Yale University
and American Red Cross Blood Services.

"Blood management and utilization programs ensuring that blood is used only when needed and in the smallest quantity possible have become widespread, but their adoption is a double-edged sword," said the article (Snyder EL, et al. 372[20]: 1882–1885). "Blood centers are facing a 20 percent decline in blood use, which translates into decreased cost recovery."

"Consequently, centers are downsizing infrastructure, reducing staff, closing facilities, and merging to remain fiscally sound. Individual centers are unable to absorb the additional costs of implementing new blood-safety interventions unless they are reimbursed by hospitals. Hospitals are not directly reimbursed for blood products and will purchase blood from the lowest-cost provider. All these factors inhibit the pursuit of safety innovations."

The authors said "The historical process of reactive, pathogen-specific test development is not sufficient to protect patients" and that proactive pathogen-reducing technologies—such as the Cerus Intercept Blood System—for blood components should be mandated. "This mandate should be supported by a reimbursement process that recognizes the benefits of proactive strategies and offsets the costs," the article said.
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CE for NSCLC liquid biopsy

Qiagen earlier this year announced the CE-IVD marking and launch of its novel liquid biopsy-based companion diagnostic that analyzes circulating nucleic acids obtained from blood samples to assess an important genomic mutation in patients with non-small cell lung cancer.

Qiagen said the registration, which applies to more than 30 European countries, makes the new Therascreen EGFR RGQ Plasma PCR kit the first-ever regulated companion diagnostic assay that has demonstrated clinical utility for guiding treatment decisions in patients with solid tumors based on the analysis of molecular biomarkers obtained from a body fluid.

The Therascreen EGFR RGQ Plasma PCR kit helps physicians identify advanced NSCLC patients who could benefit from treatment with Iressa (gefitinib) when a suitable tumor sample is not available. The test is performed on Qiagen's Rotor-Gene Q PCR detection platform.

Qiagen also recently filed a U.S. regulatory submission for a tissue-based EGFR test using an FFPE sample as a proposed companion diagnostic to guide treatment with Iressa.
FDA clears two Roche tests

The Food and Drug Administration has provided 510(k) clearance for Roche's Cobas Cdiff Test to detect *Clostridium difficile* in stool specimens. The test targets the toxin B gene found in toxigenic C. difficile strains directly in specimens from symptomatic patients.

The agency also approved Roche's Cobas KRAS Mutation Test for diagnostic use. The real-time PCR test is designed to identify KRAS mutations in tumor samples from metastatic colorectal cancer patients and help clinicians determine a therapeutic path for them. The test is intended to help identify patients for whom treatment with cetuximab or panitumumab may be effective if no KRAS mutation is present. It is a TaqMelt assay, a PCR-based diagnostic test intended for the detection of mutations in codons 12 and 13 of the KRAS gene. The test can be performed in less than eight hours on the Cobas 4800 System.

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Siemens launches handheld coagulation analyzer

Siemens Healthcare Diagnostics has introduced a handheld coagulation analyzer for point-of-care monitoring and management of oral anticoagulation therapy with warfarin.

The Xprecia Stride Coagulation Analyzer was designed to meet the growing demand for fast and reliable PT/INR results in physician offices and walk-in clinics. It is about as big as a large-screen smartphone, weighs 300 g, and can be held at any angle and brought directly to the patient's finger for blood-sample application. An integrated barcode scanner simplifies data capture for accurate calibration of new lot numbers prior to testing.

The analyzer uses fresh capillary whole blood, and results are expressed in PT seconds or as a PT/INR. It uses the same reagent as that used by Siemens central laboratory analyzers to minimize the potential for variability. Siemens cited studies showing the performance to be equivalent to that of a reference laboratory hemostasis system, with results available in minutes.