LABORATORY ECONOMICS

Competitive Market Analysis For Laboratory Management Decision Makers

UPTICK IN LAB ENFORCEMENT; CUSTOM PANELS UNDER INCREASED SCRUTINY

The recent uptick in enforcement actions against clinical laboratories could be an indication that there are more settlements to come in 2016, says an attorney speaking at the annual meeting of the American Clinical Laboratory Association on March 3.

The increase in cases in 2015 is reminiscent of the Project LabScam settlements of the late 1990s, which involved a number of multi-million-dollar civil and criminal settlements and criminal convictions, said Karen Lovitch, an attorney with Mintz Levin (Washington, DC).

"Some of the issues we're seeing now—such as medical necessity—are the same that we saw almost 20 years ago," said Lovitch. "For example, we are seeing a laser-like focus on custom panels right now."

Recent federal enforcement actions highlight this focus. In the last year, the feds have gone after both Millennium Health and Health Diagnostic Laboratories (HDL) for violations of the False Claims Act (FCA). Both agreed to large multi-million dollar settlements. There were other lower-profile settlements in 2015 as well involving Family Dermatology, Pharmasan Labs and Piedmont Pathology Associates.

Karen Lovitch

Lovitch advises that laboratories offering custom panels should consider requiring each physician who orders one or more custom panels to sign a custom panel authorization form. She says the form should include an acknowledgement that the physician will order the custom panel only when all tests are medically necessary for the patient and a warning that failure to do so could result in liability for the physician and the laboratory.

"Laboratories should educate physicians on Medicare's medical necessity requirements (and similar requirements imposed by commercial insurers) and the clinical utility of each test offering, and offer physicians the opportunity to consult with the laboratory's clinical personnel," Lovitch tells *Laboratory Economics*. "Laboratories should provide this type of education regardless of whether custom panels are offered."

In addition, the laboratory compliance department should participate in the process by establishing a policy governing custom panels and reviewing and approving custom panel

authorization forms, if appropriate, she says. Labs should also consider whether it is appropriate to set a limit on the number of tests that can be included in a custom panel, and recertification should be required at least annually and prior to implementation in any changes to a custom panel.

Individuals at Risk

The federal government is also increasing its focus on the pursuit of individuals in corporate cases as the result of a memo released in September 2015 by Deputy Attorney General Sally Quillian Yates, according to Bill Jordan, a partner with Alston & Bird.

Bill Jordan

The memo mandates a new emphasis on prosecuting individual defendants who are legally responsible for wrongdoing and represents a major shift in federal enforcement policy.

"The Yates Memo set everyone's hair on fire," said Jordan at the ACLA meeting."It's a huge deal."

The Yates memo also calls for expanded information-sharing between criminal and civil investigators during investigations, which can complicate cases. "There's not a week that goes by that I don't get a civil investigative demand or subpoena related to the lab industry," Jordan added.

Jordan advises that lab executives take compliance seriously. "The ideas that underlie the Yates memo are not new, but the government views individuals as the reason for fraud and its goal is to punish and deter by looking at those it perceives as bad actors," he tells *LE*. "Leaders of companies can start by setting a tone at the top that emphasizes and promotes a strong culture of ethical actions."

In addition, it is important to make sure that the lab has a real, functioning compliance program and not merely the "paper" program that sits on a shelf, Jordan adds. The government now routinely asks executives about what they've done to stress compliance, what resources have been provided to the program, and how the company has acted in the face of the regulatory regime in which it operates.

"The government (and whistleblowers) have been focusing most closely on kickbacks and relationships with referral sources," he notes. "A CEO can stress that these relationships must be for legitimate purposes – not for the purpose of generating referrals. This is a very complex area where consultation with counsel is very helpful in demonstrating that a company is trying to comply with the ever-changing regulatory landscape."