

Long-Term Care Survey Alert

CLIA Compliance CMS TO SURVEY WAIVED LAB TESTING IN SNFS

Nursing facilities that wave off those "waived" lab testing requirements may have a new survey headache on the horizon.

State agencies recently began surveying a sample of skilled nursing facilities that have a certificate of waiver (COW) under the Clinical Laboratory Improvement Amendments. Your SNF must have such a certificate to perform any lab testing on human specimens, to diagnose, treat or monitor disease. Common testing that occurs in SNFs includes blood glucose monitoring and fecal occult blood testing.

The Centers for Medicare & Medicaid Services insists the focus of the surveys is to assist providers to improve their waived lab testing.

"The purpose of these surveys is to educate, not sanction, so when surveyors discover problems, their first effort would be to work with the lab to comply with CLIA regulations," a CMS official tells Eli. CMS decided to launch the voluntary surveys of 2 percent of waived labs annually following studies showing widespread and serious problems with such testing. For example, a CMS pilot study found staff in some labs using expired test strips or the wrong strips for an instrument. Many labs performing waived tests didn't have the manufacturer instructions for performing the tests on hand or weren't following them. Some were even cutting test strips to save money, CMS reports.

Some survey experts fear the CLIA surveys could serve as a springboard for other compliance actions. "One would hope that education comes first, but CMS has little if any control over state survey agencies, which go in their own direction, as we know," says attorney Joseph Bianculli, with The Law Offices of Bianculli & Impink in Arlington, VA. "And the regional offices aren't exactly shy violets regarding enforcement."

According to the list of surveyor questions for COW labs obtained by Eli, surveyors are instructed to contact the regional office if the lab "performs testing in a manner that constitutes an imminent and serious risk to public health."

"The various government agencies are supposed to communicate with each other," agrees Andrew Cutler, a consultant with FR&R Healthcare Consulting in Deerfield, IL. "So if CLIA surveyors found a facility wasn't doing blood glucose monitoring or another waived test correctly, I wouldn't be surprised if it didn't trigger a full state survey, or at least flag the facility in some way."

"There could also be a potential false claims issue if the facility were found to be billing for lab tests that it wasn't performing appropriately."

The CMS official agrees that CLIA regulators might handle some situations "differently" for example, "if a surveyor confronted SNF staff with serious clinical issues arising from their lab testing and it became clear through the process that they had no interest in compliance. Or if surveyors found a facility purposefully doing something wrong, such as using one blood specimen to bill four patients that's different, as well. That's not a mistake resulting from lack of knowledge."

Target Common Problems

Meanwhile, SNFs should give themselves a CLIA checkup to ensure surveyors will give them a clean bill of health on their lab testing. "The primary problem SNFs make with waived testing is where staff doesn't sign off on each test and document the results in the resident's medical record," observes Marilyn Mines, also a consultant with FR&R. "The facility must document the results for each test. If the test results are abnormal, staff must report the results to the physician and document they did that and the outcome."

Staff should also make sure to follow the manufacturer's instructions for performing tests, including quality control, calibration and instrument maintenance. "COW labs, including SNFs, must perform and document quality control [as recommended by the manufacturer] before reporting test results, even on urine dipsticks," according to Karla Scholl, a CLIA compliance consultant in Palatine, IL. "As part of QC, SNFs have to make sure the blood glucose machine is calibrated every day," adds Mines.

The SNF's standard operations and procedures manual should include the test instructions as well as operating instructions for any instrument and any package inserts from the controls and strips being used.

The facility's nursing staff should also question any waived lab results that seem way off the mark or don't match residents' symptoms — for example, very high blood sugars in the absence of other signs of hyperglycemia. In such a case, staff should quickly check the QC results and rerun the test. When in doubt, always contact the physician or medical director immediately before administering insulin based on questionable blood glucose readings.