Alternate CLIA inspecting authority closer to approval

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Physicians with in-office labs are a major step closer to being allowed to have their colleagues, rather than government officials, inspect their facilities for CLIA compliance.

Members of the U.S. Health Care Financing Administration (HCFA) and U.S. Centers for Disease Control and Prevention (CDC) have recommended that HCFA’s administrator approve the Commission on Office Laboratory Accreditation (COLA) as a deeming authority to enforce CLIA regulations, government and COLA sources say.

The recommendation, made in mid-June, according to Judy Yost, Medical Technologist Adviser for the Health Standards and Quality Bureau of HCFA, will still have to navigate the maze of government department-head approvals before it can be presented to U.S. Health and Human Services Secretary Donna Shalala for the final signature and publication in the Federal Register.

“We’re now in an administrative process, awaiting the signature from the administrator and (Shalala),” COLA Chief Executive Officer J. Stephen Kroger, M.D., said, “but all of the comparisons between the federal program are complete and satisfactory. It’s just a matter of formalities, but we don’t know how long it’s going to take.”

Government officials could not predict a time-line either, although Yost and Anthony Tirone, director of HCFA’s Office of Survey and Certification, indicated they expected it to be OK’d without a hitch.

“We expect to approve it soon and we don’t expect any problem,” Tirone said. “COLA appears to be in compliance with CLIA requirements. Terms are equal to, or greater than, the government’s and approval should occur in the near future.”

Changes

Dr. Kroger said the government modified the COLA proposal, making its quality control standards stricter than originally submitted. However, COLA provisions barring unannounced first-contact lab inspections were left unaltered.

“(Government officials) wanted us to go into a laboratory unannounced,” Dr. Kroger said. “If there are complaints against a COLA laboratory, we will investigate, but the lab director will know and (we’ll) give them opportunity to respond.”

Dr. Kroger said that if COLA officials received complaints that a lab was doing “sink tests” (dumping samples down the drain and fabricating results) or using faulty equipment, they would investigate such facilities in an “expeditious manner.”

However, for most complaints, Dr. Kroger predicts officials would communicate solely via mail. However, unannounced follow-up visits would be possible, provided written correspondence occurred first. For example, if COLA received a complaint that a lab didn’t have quality control measures, officials would request paperwork verifying that the facility has such measures. If documentation was submitted and verified, an inspection would not occur.

“In most cases, a lab will not need a survey,” Dr. Kroger said. “Which is a whole lot better than just showing up, which is what HCFA wanted. If I was a lab director, I’d want to know there was a complaint against my lab before someone came to my door with a badge.”

Enrollment

Yost said, as of late June, government officials had inspected approximately 2,000 laboratories under the CLIA provisions. Dr. Kroger said physicians seeking non-government inspection of their labs should sign up with COLA as soon as possible if they want to avoid government-conducted surveys.

“People can sign up now,” he said. “We’ve enrolled about 3,000 laboratories in the past eight months. Anyone who wants to sign up for private accreditation should do so now.”

According to COLA, its fees are competitive with the government’s and, in some cases, may be lower.

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