

Department of Public Health
Laboratory Field Services
October 6, 2008

Notice to CLTAC and Participants of CLTAC meeting on 9/5/08 regarding proficiency testing referral.

It has come to our attention that there may have been a misunderstanding of a discussion during our CLTAC meeting on September 5, 2008. Under new business, Bea O'Keefe was asked to respond to a question submitted by a member of CLTAC. The question had to do with referral of proficiency testing (PT) within a medical complex.

The situation is this: When the laboratory in question is asked to perform a protein electrophoresis, it routinely splits the patient sample and has the total protein component done at another laboratory in the same medical complex. The other lab has the same laboratory director and owner, but a different CLIA certificate. The laboratory that initially received the specimen then performs the electrophoresis and uses the total protein result obtained from the other laboratory to calculate electrophoretic fractions. The question was, if proficiency testing is handled in the same way as patient testing, would this violate the proficiency testing sharing prohibition?

Bea O'Keefe responded that ordinarily proficiency testing is performed in an identical manner as patient testing. However, this mode of testing may violate the PT sharing prohibition. She said any laboratory with this type of situation should contact Region IX CMS in San Francisco for a ruling before splitting a PT sample in this manner. She stressed that the sanctions for PT sharing are severe and include prohibition of the owner and director from owning or directing a lab for two years and termination of the CLIA certificate.

In conferring with CMS on this issue, LFS was told that CMS wants to make this issue very clear. *Under no circumstance should a laboratory send its proficiency testing samples to another laboratory for testing or engage in any inter-laboratory communications pertaining to the results of proficiency testing samples.*

If you have any questions about this matter, contact
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