



EMS Information Bulletin- #046

DATE: March 19, 2007

SUBJECT: Comprehensive Laboratory Improvement Amendments

TO: Regional EMS Directors and Regional EMS Training Coordinators

FROM: Bureau of Emergency Medical Services
Pa Department of Health
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The new statewide ALS protocols include use of blood glucose monitoring device. This device has been added to the essential ambulance equipment list effective July 1, 2007. Use of this test has implications regarding federal standards that have been in effect for 15 years.

The Clinical Laboratory Improvement Amendments (CLIA) were passed in 1988 establishing standards for all laboratory testing to ensure the accuracy, reliability and timeliness of patient test results regardless of where the test was performed. The CLIA definition of a laboratory is: “a facility that performs testing on materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of or assessment of the health of, human beings”.

The measurement of blood glucose using a glucose monitor approved for home use is a test that can be performed under a CLIA certificate of waiver. To obtain a certificate of waiver an ambulance service should complete a form CMS-116 available at www.cms.hhs.gov/clia and submit it to the local State Agency. For Pennsylvania the address is:

Pennsylvania Department of Health
Bureau of Laboratories
110 Pickering Way
Lionville, Pa 19353
610 280-3464
Contact: Clerical Support Section
Internet: www.health.state.pa.us/labs

At a meeting of regional licensing coordinators held on March 6, 2007 the Bureau provided each coordinator with a copy of a fact sheet describing the process to obtain a CLIA certificate of waiver. This document is one of the brochures available at www.cms.hhs.gov/clia web site. The intent is to allow regions to assist ambulance services through education and customer service. The regional EMS councils are not being asked to determine compliance with this federal requirement, rather they have the opportunity to educate service managers of the existence of this federal requirement and give information on how a certificate of waiver can be obtained. Regional EMS councils are not to include status of an ambulance service's CLIA or Emergency Response Employee status when recommending whether an ambulance service should be licensed, not licensed or have their status changed to a provisional or temporary license.

Licensed ALS ambulance services must have blood glucose monitors implemented by July 1, 2007.

Please forward any questions to rcooney@state.pa.us