



GMVEMSC CLIA Certificate of Waiver Participation Requirements

EMS agencies must be covered by a CLIA (Clinical Laboratory Improvement Amendments) Certificate of Waiver to perform blood glucose testing. Failure to meet this requirement could result in the forfeiture of EMS billing reimbursements and other penalties assessed by CMS (Centers for Medicare and Medicaid Services). The Greater Miami Valley EMS Council has obtained and will maintain a CLIA Certificate of Waiver for glucose testing, as a no cost benefit, which provides EMS member agencies with a group coverage opportunity. EMS member agencies may also opt to carry their own CLIA Certificate of Waiver, in lieu of participating in the GMVEMSC's coverage.

CLIA regulations establish quality standards for all laboratory testing on materials derived from the human body. CLIA certification is based on the level of complexity of the testing being performed and are defined into three categories; low, moderate, and high. The utilization of a glucometer by EMS personnel to test a patient's blood glucose level is defined as a low category level, requiring only a Certificate of Waiver. Other laboratory testing that an EMS agency may engage, such as CBC or troponin, could be defined as a higher category level. Each EMS member agency will be responsible for obtaining their own CLIA certificate for any laboratory testing beyond blood glucose.

EMS member agency participation, in the GMVEMSC's CLIA Certificate of Waiver program, requires all of the following:

1. Provide and maintain, with the GMVEMSC, a completed copy of the *GMVEMSC CLIA Waiver Participation Form*
 - Submit a new form, within 30 days, each time any information requires update
 - Submit a written letter to GMVEMSC to withdraw from participation
2. Maintain compliance:
 - Ensure that your agencies glucometer is approved by the FDA and has a complexity status of "WAIVED" (see link on GMVEMSC website)
 - Follow the manufacturers' instructions for performing glucose testing
 - These instructions will be found in the booklet that came with the glucometer
 - Follow instructions for applicable control testing and calibration
 - Follow all expiration dates of testing equipment and supplies, such as strips and control testing fluids
 - Ensure EMS personnel are properly trained and qualified to perform glucose testing
 - Conduct routine quality assurance audits, to ensure EMS personnel are utilizing proper glucose testing procedure
 - Permit site inspection by a CMS designated agent; however, waived agencies are not subject to routine surveys or inspections

It is the responsibility of each EMS member agency to be in compliance at all times with the manufacturer's recommendations regarding the machine(s) and related equipment.