



Westchester Regional EMS Council

M e m o r a n d u m

To: All Westchester Regional ALS Services

Fr: Katherine O'Connor, BS, EMT-P
Regional EMS Office

Re: Glucometer Testing and CLEP Registration

Date: May 30, 2006

Last week at the State EMS Council meetings, it was reported by the NYS DOH Bureau of EMS that the Operations Division had been contacted by the Clinical Laboratory Evaluation Program (CLEP) regarding concerns related to EMS adherence to state and federal law for utilization of blood testing devices:

LIMITED LABORATORY REGISTRATION

*The law requires that any EMS service testing blood glucose, whether by electronic glucometer or chemstrip, be required to possess a **Limited Laboratory Registration**. In order to obtain the Registration, EMS agencies must complete and submit the following documents:*

- **Limited Service Laboratory Registration (DOH-4081)**
- **Disclosure of Ownership and Controlling Interest Statement (DOH-3486)**

No EMS service may engage in the testing of blood glucose without a registration permit.

If your service has not obtained this permit, you are urged to do so **IMMEDIATELY**.

If your agency has a permit, you are also reminded that specific Quality Assurance procedures related to the routine testing and calibration of glucometer units **MUST** be followed. CLEP has advised the DOH that they are in the process of conducting inspections to determine the adherence to QA practices.

AGENCIES FOUND IN NON-COMPLIANCE OF STATE REGULATIONS MAY BE TAKEN TO ENFORCEMENT.

Information regarding the requirements, as well as all appropriate application paperwork for filing, is available at: <http://www.wadsworth.org/labcert/clep/Administrative/ChangeForms.htm>

Copies of the CLEP Guide and a Limited Service Lab application have been posted on the Regional EMS website, www.wremsco.org.

Please contact the Regional EMS Office at 914-231-1616 with any questions regarding this memorandum.