BACKGROUND

At the January, 2005 meeting of the New York State Emergency Medical Advisory Committee (SEMAC), the use of glucometers by Emergency Medical Technicians (EMT) in Basic Life Support (BLS) EMS agencies was approved. The SEMAC approval was granted with the specific condition that the EMS service wishing to use a glucometer at the BLS level, be granted approval by the local Regional Emergency Medical Advisory Committee (REMAC), each EMT complete an approved training program and the service apply and be granted a Limited Laboratory Registration.

The purpose of this policy is to explain the approval process for agencies wishing to implement a glucometry program. The addition of prehospital blood sugar evaluation is intended to assist in the recognition of hypoglycemia and improve the speed with which proper treatment is received.

AUTHORIZATION

Each REMAC, interested in allowing their BLS EMS agencies to participate, will adopt protocols which will allow a basic EMT to obtain a blood sample, using a lancet device, or equivalent and test the blood sample in a commercially manufactured electronic glucometer. The REMAC will also determine the type and level of record keeping and quality assurance required for this procedure.

To be authorized to use an electronic glucometer, the EMS agency must make written request to the local Regional Emergency Medical Advisory Committee (REMAC). The request must include, but not be limited to the following items and possess the necessary Clinical Laboratory authorizations required by Public Health Law.

- Include a letter from the service medical director supporting the request and indicating an understanding of their role in the quality assurance process.
• Complete the NYS Department of Health Clinical Laboratory Limited Laboratory Registration application (DOH-4081) for blood testing licensure.

• Develop written policies and procedures for the operation of the glucometer that are consistent with local protocol. This shall include at least the following:
  • written policies and procedures for the training and documentation of authorized users;
  • a defined quality assurance program, including appropriateness review by the medical director;
  • documentation of control testing process; and
  • written policies and procedures for storage of electronic glucometer, and proper disposal of sharps 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)

The information and appropriate application paperwork is available at:

http://www.wadsworth.org/labcert/clep/Administrative/ChangeForms.htm

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

NOTIFICATION

Once the EMS service has received written approval from the REMAC, the EMS Service must provide the Bureau of EMS with a new Medical Director Verification Form (DOH-4362), indicating the Limited Laboratory Registration permit number and authorization by the service medical director.