

NEW YORK STATE – DEPARTMENT OF HEALTH

INTEROFFICE MEMORANDUM

To: State EMS Council
State Emergency Medical Advisory Committee
Regional EMS Councils
Regional Medical Advisory Committees
EMS Program Agencies

From: Edward G. Wronski, Director
Bureau of Emergency Medical Services

Subject: FDA Approval of AED Over the Counter Purchase

Date: September 23, 2004

Recently the Food and Drug Administration (FDA) approved a 510K application submitted by Philips Heartstart for over the counter purchase of a home defibrillator. This approval allows the purchase of this specific AED without a prescription for home use for adults only. A prescription is necessary for home use for children.

We have formally requested a legal opinion on whether this ruling affects any aspect of New York State Public Access Defibrillation Programs. However, it is the opinion of the Bureau of Emergency Medical Services, after review of the ruling and discussions with the FDA that this has no effect on PAD programs. A PAD program is established to utilize an AED in a public or business setting. The PAD programs were not developed for implementation in the home, as there was already the ability of cardiac patients to purchase an AED with a prescription for home use.

PAD programs provide early access to defibrillation to “unknown” patients and New York State law requires an organized program under the oversight of an Emergency Health Care Provider (physician or hospital), participation in regional QI and submission of data to the regional EMS QI program. It was not the FDA intent to supercede these public programs. Any suggestion of this is incorrect and misleading.

When we receive a formal legal opinion we will advise you. In the interim we request that this memorandum or a similar note be placed on your regional WEB sites for review by providers who may have questions.

Thank you.

cc: Mark Henry MD, Chair
State Emergency Medical Advisory Committee
Warren Darby, Chair
State EMS Council