MORRIS HOSPITAL & HEALTHCARE CENTERS

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POLICY:	**200.37 MEDICAL DEVICE FAILURE AND OR MALFUNCTION**		
APPROVAL:	**VICE PRESIDENT OF PROFESSIONAL SERVICES; MANAGER OF EMS;**		
EFFECTIVE DATE: 2/16/2024			**ORIGINAL EFFECTIVE DATE: 9/2022**
DEPARTMENT SPECIFIC	**EMERGENCY MEDICAL SERVICES**		

I. Purpose:

In order to comply with a request from IDPH in regards to the Federal Food and Drug Administration's rules and regulations concerning Medical Device Failure/Malfunction, the following system policy will be observed.

II. Policy:

The new rules mandate that ambulance provider agencies report any product/equipment that failures or malfunctions, which may have caused significant injury or death of a patient or EMS Personnel.

III. Reporting Mechanism and Guidelines.

A. System agencies and EMS Personnel are required to make reports.

B. System agencies and EMS Personnel must submit a medical device report (MDR) to the device manufacturer, system and the FDA within ten (10) days after becoming aware of a reportable death or serious injury, including serious injury. Note: If the event involves a device-related death, or if the identity of the device manufacturer is not known, the report must be sent to the FDA.

C. System agencies must submit semi-annual reports to the system and the FDA if they have made any reports during the previous six (6) months.

D. System agencies and EMS Personnel must report only information that is reasonably known to them about the device and its malfunction incident, and are not required to investigate adverse events.

E. A System agency is obligated to file a report with the FDA and EMS system on a device malfunction when any of its personnel become aware of a reportable event.

F. Reportable events include adverse device events caused by user error.

G. Adverse device events are reportable for personnel who are injured and/or receive medical care arising from a device-related event.

H. System agencies must develop specifically written individual department policies and procedures to assure compliance with FDA and system regulations regarding device malfunction events. All EMS personnel must be inserviced on this policy as well as new employee orientation.

I. System agencies must maintain MDR event files and retain such documents for two (2) years after the event.

Note: If the System agency determines that an event is not reportable, then the information that leads to this conclusion must be kept in the agency's MDR events file.

J. MDR event files and other information kept by the System agency pursuant to the rules and regulations must be made available to the FDA and EMS System for inspection and audit.

K. Violations of the FDA rules and regulations regarding device failure and malfunction that have gone unreported can result in civil and criminal penalties, depending on specific case violations.

IV. Communication Information and the Report Form

A. Reporting Agency:

Food and Drug Administration
Center for Devices and Radiological Health
Medical Device Reporting
P.O. Box 3002
Rockville, MD
20847-3002
Report "Hotline": 1-800-FDA-1088

B. Report Form.

The eMDR is available through the FDA's website at:
Medical Device Reporting (MDR): How to Report Medical Device Problems

Approval:

James Kirchner Date
Vice President of Professional Services

Kathleen Geiger MSN, RN Date
Manager of EMS & Emergency Management