I. LEGISLATIVE MANDATE

A. Medical device reporting (MDR) is intended to help the U.S. Food and Drug Administration (FDA) identify medical device problems that pose a threat to public health and safety.

B. On December 11, 1995, the Food and Drug Administration (FDA) issued its final rule on medical device reporting (FedRegist 1995 Dec. 11; 60[237]:63578-606) under the Safe Medical Devices Act (1990). This rule expanded the existing requirements for medical device reporting, record keeping, confidentiality, mandatory forms, coding manuals, written policies and procedures, and includes new definitions.

C. Under the Safe Medical Devices Act of 1990 (SMDA) and the FDA Modernization Act of 1997 (FDAMA), mandatory reporters are required to report to FDA and/or the device manufacturer certain adverse events and/or product problems involving medical devices. Device-related incidents that must be reported include deaths and serious injuries and illnesses.

D. In addition, the FDA also encourages health care professionals, patients, caregivers and consumers to submit voluntary reports about serious adverse events that may be associated with a medical device, as well as use errors, product quality issues, and therapeutic failures. These reports, along with data from other sources, can provide critical information that helps improve patient safety.

E. Mandatory reports are to be made as soon as practicable but no later than 10 work days after the user facility becomes aware of a reportable event. Reports of death must be submitted directly to FDA, and a copy of the report must be sent to the manufacturer, if known. Reports of serious illness or serious injury must be submitted to the manufacturer or, if the manufacturer is unknown, to FDA. In addition, user facilities must provide an annual summary of their mandatory device-related event reports to FDA.

F. All mandatory reporter agencies must develop and implement a written MDR program. The program should assign responsibility for reporting, identify tasks to be assigned, outline documentation requirements, and detail the flow of information.

G. **Penalties for non-compliance:** Failure to comply with FDA medical device reporting (MDR) requirements can result in hefty penalties (e.g., civil money penalties of $15,000 for each violation, up to a maximum of $1 million for all violations adjudicated in a single proceeding), civil injunctions, or criminal prosecutions.

II. DEFINITIONS

A. **Caused or contributed**: A death or serious injury was or may have been attributed to a medical device, or a medical device was or may have been a factor in a death or serious injury.

B. **Medical device:** any instrument, apparatus, or other article that is used to prevent, diagnose, mitigate or treat a disease or to affect the structure or function of the body. This includes disposable and non-disposable products such as catheters, laryngoscope blades, patient restraints and syringes.

C. **Serious injury**: An injury or illness that is life-threatening; results in permanent impairment of a body function or permanent damage to a body structure; or necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure.

III. POLICY

A. The NWC EMSS embraces a **culture of safety**. This includes a reporting culture in which there is an emphasis on all members reporting incidents that could have or did impact worker/patient safety and/or patient care and a just culture where there is an emphasis on trust where members are encouraged to report without fear of retaliation.

B. EMS personnel must submit a report as soon as practical but no longer than 10 work days after they receive or otherwise become aware of information, from any source, that reasonably suggests that a device, drug, or ambulance did not function/operate as intended (malfunction and/or failure) and:

1. did not affect patient care;
2. affected patient care but caused no harm; or
3. affected patient care and may have caused or contributed to harm including serious injury or death. This includes, but is not limited to, events occurring as a result of user error and ambulance crashes within the line of duty.

C. Deaths must be reported to the FDA and the manufacturer, if known. Serious injuries must be reported to the manufacturer or to the FDA if manufacturer is unknown.

D. In any situation involving a medical device failure or malfunction, immediate steps shall be taken to ensure the health and safety of the patient and the healthcare providers.

E. Immediate action shall be taken to preserve the medical device as it was at the time of the occurrence, to document the condition/status of the device pending an inspection and report by the manufacturer.

IV. PROCEDURE – all malfunctions and/or failures while caring for a patient

A. Actions at the time of malfunction:

1. Attend to the medical and safety needs of the patient or the injured parties, removing them from the area if necessary and treating per SOPs.
2. **Immediately remove the malfunctioning device from active service**. **DO NOT toss any part into the trash.** Preserve the device precisely as it was at the time of the malfunction/failure, including attachments and/or disposable items. Do not change any settings or disconnect any attachments. Save all parts if an item breaks into pieces. Return to Agency's Provider EMS Coordinator for analysis by the manufacturer.
3. Document objective, pertinent information regarding the patient's condition, description of the event, and medical interventions taken on the patient care report.
4. **DO NOT** make any reference to the fact that an incident report was completed on the patient care report.
5. **DO NOT** make any judgments or conclusions regarding the cause of the occurrence on the patient care report.

B. NOTIFICATIONS and Communication - Documentation requirements

1. Contact immediate supervisor as soon as patient safety and care is ensured.
2. **NOTIFICATION TO EMS MD**
   a. **These are all reportable incidents. The EMS MD must be notified each time there is a device malfunction/failure/ambulance crash in the line of EMS duty.**
   b. **If malfunction caused or contributed to a death or serious injury to patient or crew**: **Contact EMS MD immediately**
      (1) **Dr. Matt Jordan; mjordan@nch.org cell: (847) 962-6008**
      (2) If EMS MD is not reachable within 30 minutes, page the EMS Administrative Director at 708-999-0141 or call 847-493-9974
   c. All others: Contact EMS MD by e-mail (mjordan@nch.org)

3. **Complete the Medical Device/Ambulance Malfunction/Failure Report** appended to this policy whenever they are aware of information, from any source, that reasonably suggests that a device, drug, or ambulance has or may have malfunctioned or failed whether or not it involved patient care or an injury. **If patient involved:** Complete report as soon as patient care is appropriately transferred to the receiving hospital. Be as specific as possible.

C. **Investigation / evaluation**

1. **EMS Agency**: Complete a thorough investigation of the occurrence, interviewing all crew present at the time of the incident and the patient, if necessary.
   a. Pull all manufacturers' product specifications, preventive maintenance records and repair records for review during the investigation.
   b. Contact the manufacturer's representative or contracted service agreement agency to perform an inspection.
   c. Complete a thorough inspection of the device in accordance with manufacturer's specifications and document in accordance with EMS Agency policy.
   d. Photographs may be taken of the device, drug, or ambulance if they would enhance the written description.
   e. Append the manufacturer's analysis to the Medical Device Failure/ Malfunction Report as soon as it is received.
   f. Forward the preliminary report to the NWC EMS office within 72 hours of the event. Fax: (847) 618-4489 or send an electronic copy to cmattera@nch.org who shall forward to the EMS MD.

2. **EMS System**
   a. The System must track all incidents of malfunction/failure to perform an informed risk/benefit analysis prior to determining if a product should be recalled from System use.
   b. The System will maintain records of MDR events and correspond with manufacturers as EMS MD deems necessary.
   c. The device shall only be returned to service upon approval of the EMS MD.

D. **Records retention**

1. Providers must establish and maintain Medical Device Reporting (MDR) event files that contain information related to the adverse event, documentation of deliberations and decision-making processes, copies of forms, and other information submitted to the manufacturer, FDA and others.
2. These records must be retained in an MDR event file for a period of two years.
3. FDA employees are permitted to access, copy, and verify the records in the MDR event file.

V. **FDA Reporting – See end of policy for details**

A. If it is determined by the EMS MD that the medical device caused or contributed to a patient or healthcare worker's death or resulted in serious illness or injury, a report must be submitted to the FDA Med Watch VOLUNTARY reporting of adverse events form 3500 (12-11) or the FDA Med Watch MANDATORY reporting of adverse events form 3500A.

B. These reports are to be made as soon as practical, but not later than 10 working days after the provider becomes aware of the information. A provider "becomes aware" when medical personnel or employees acquire such information about a reportable event.

C. For assistance in completing FDA form 3500 A, contact the EMS Administrative Director for full instructions and a list of codes.

D. If there is any dispute regarding the cause of the equipment failure or malfunction, a review panel comprised of at least the crew members present at the time of the occurrence, the Chief or his designee, the EMS MD and a Biomedical Engineering manager shall meet to review the details of the occurrence and make a determination if the medical device caused or contributed to a patient's death, serious illness or injury.

E. Semiannual reports or electronic equivalents must be submitted by the EMS Agency to the FDA by January 1 for reports made July through December, and by July 1 for reports made January through June of each year. If no reports are submitted to either the FDA or a manufacturer during these six month time periods, no semiannual report is required.

VI. **Ambulance malfunction/failure/crash in the line of duty**

A. If at any time an ambulance is unexpectedly taken out of service and unable to complete a run, either enroute to or during a call due to malfunction/failure or crash, notify the EMS MD per this policy and complete the Equipment Malfunction/Failure form as soon after the event as possible and forward to the NWC EMS Office on the same shift as the incident occurrence. Review of these incidences is considered continuous quality improvement, and, as such is protected under the Medical Studies Act.

B. In all cases of ambulance malfunction/failure enroute to a call, a second ambulance or licensed EMS non-transport vehicle shall be called that can arrive within normal response times under Illinois law to begin care. If an ambulance or licensed EMS non-transport vehicle cannot respond within 6 minutes in their primary service area for a 9-1-1 call, the provider agency must attempt to notify the person requesting aid and inform them of the anticipated delay.

FDA information

Mandatory Medical Device Reporting Requirements:

The Medical Device Reporting (MDR) regulation (21 CFR 803) contains mandatory requirements for manufacturers, importers, and device user facilities to report certain device-related adverse events and product problems to the FDA.

Voluntary Medical Device Reporting:

The FDA encourages healthcare professionals, patients, caregivers and consumers to submit voluntary reports of significant adverse events or product problems with medical products to MedWatch, the FDA's Safety Information and Adverse Event Reporting Program or through the MedWatcher mobile app.

How to Report a Medical Device Problem:

Medical device reports are submitted to the FDA by mandatory reporters (manufacturers, importers and device user facilities) and voluntary reporters (health care professionals, patients, caregivers and consumers).

Mandatory Reporting for Manufacturers, Importers and Device User Facilities (Form FDA 3500A):

Find information and instructions for mandatory device reporting at:

- Reporting Medical Device Adverse Events for Manufacturers, Importers and Device User Facilities
- Instructions for Completing Form FDA 3500A
- eMDR- Electronic Medical Device Reporting
- Draft Guidance for Industry and Food and Drug Administration Staff: Medical Device Reporting for Manufacturers
- FDA Guidance: Medical Device Reporting for User Facilities (PDF Only) (PDF - 313KB)
- For Questions about Medical Device Reporting, including interpretation of MDR policy: Call: (301) 796-6670
- Email: MDRPolicy@fda.hhs.gov
- Or write to:

Food and Drug Administration
Center for Devices and Radiological Health
MDR Policy Branch
10903 New Hampshire Avenue
WO Bldg. 66, Room 3217
Silver Spring, MD 20993-0002

Voluntary MedWatch Reporting for Patients, Health Professionals and Consumers (Form FDA 3500):

Patients, healthcare professionals and consumers who find a problem related to a medical device are encouraged to report medical device adverse events or product problems to FDA through MedWatch, the FDA Safety Information and Adverse Event Reporting Program. Submit reports to FDA through the MedWatch program in one of the following ways:

- Using the MedWatcher mobile app that allows individuals to submit voluntary reports of serious medical device problems to the FDA using a smart phone or tablet.
  Download the MedWatcher Mobile App
  - iTunes Store: MedWatcher App Download
  - Google Play Store: MedWatcher App Download
- Complete the MedWatch Online Reporting Form
- Download form or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178.

To Report an Emergency

If you have identified a public health emergency, use the following contact information to alert the FDA:
FDA Office of Crisis Management, Emergency Operations Center

- Voice (24hr/day) phone: 866-300-4374 or 301-796-8240
- FAX: 301-847-8543

Searching Medical Device Reports

The Manufacturer and User Facility Device Experience (MAUDE) database contains mandatory reports filed by manufacturers and importers from August 1996 to present, all mandatory user facility reports from 1991 to present, and voluntary reports filed after June 1993. The MAUDE database houses MDRs submitted to the FDA by mandatory reporters (manufacturers, importers and device user facilities) and voluntary reporters such as health care professionals, patients and consumers.
Although MDRs are a valuable source of information, this passive surveillance system has limitations, including the potential submission of incomplete, inaccurate, untimely, unverified, or biased data. In addition, the incidence or prevalence of an event cannot be determined from this reporting system alone due to potential under-reporting of events and lack of information about frequency of device use. Because of this, MDRs comprise only one of the FDA's several important postmarket surveillance data sources. Individuals are also able to request information related to Medical Device Reports by submitting a Freedom of Information Act (FOIA) request either in writing or online.

For general questions, please contact the Division of Industry and Consumer Education (DICE) by telephone at (301) 796-7100, or by email at DICE@fda.hhs.gov.

Additional Resources

- MedWatch: FDA's system for voluntary reporting
- MDR Database Search: This database captures MDRs that were received prior to July 31, 1996.
- Device Advice: Regulatory Assistance for Industry on Mandatory Reporting and Regulation History
- Electronic Medical Device Reporting
- CDRH Learn with Medical Device Reporting

Matthew T. Jordan, M.D., FACEP, FAEMS
EMS Medical Director

Connie J. Mattera, M.S., R.N., EMT-P
EMS Administrative Director

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Northwest Community EMS System

Medical Device/Ambulance MALFUNCTION/FAILURE Report

CONTACT EMS MD: Serous pt/crew harm or death ASAP by phone**: (847) 962-6008** **All others**: e-mail mjordan@nch.org

Submission of this report does not constitute an admission that medical personnel, a user facility, distributor, manufacturer or product caused or contributed to the event. This report constitutes CQI and is protected by the Medical Studies Act.

PATIENT INFORMATION

Initials (in confidence)	Age at time of event or date of birth:	Gender ☐ Female ☐ Male	Weight lbs. or kgs

EMS Agency: | EMS Incident #:

Adverse event or product problem: ☐ Adverse event ☐ Product problem

Status of patient pre-event: ☐ Stable ☐ Unstable ☐ Cardiac/respiratory arrest
Status of patient post-event: ☐ Stable ☐ Unstable ☐ Cardiac/respiratory arrest

Paramedic impression of patient's diagnosis at time of event:

Medical Device malfunction/failure: The equipment did not function/operate as intended and (check one):
- ☐ Did not affect patient care
- ☐ Affected patient care but caused no harm
- ☐ Affected patient care and may have caused or contributed to harm including injury, hospitalization, disability, or death (see below).

Outcomes attributed to adverse event (check all that apply)

☐ Death _____ (month/day/year) ☐ Life-threatening ☐ Hospitalization ☐ Disability

Date of event: | Date of this report:

MEDICAL DEVICE

Device name: | Brand name:

Manufacturer name, address, & phone # | Operator of device at time of malfunction:
- ☐ Health professional
- ☐ Lay user/patient
- ☐ Other:

Model #:
Catalog #:
Serial #:
Lot #:

Expiration/Use before date (if known):
How long in use:
Condition prior to malfunction:
Date last inspected or serviced:
If implanted, give date (if known):

Were other devices or accessories involved?
☐ Yes ☐ No
If yes, please describe:

Are other units of the same model similarly affected?
☐ Yes ☐ No
If a single-use device was involved, had it been reprocessed at any time before the incident?
☐ Yes ☐ No

Location in which device was being used: | Settings and modes operative at the time of event:

Describe problem/malfunction and how the device contributed to the event or problem:

Describe the medical interventions taken as a result of the event:

List any EMS workers who were injured:

Initials	Age	Gender	Status pre-event	Status post-event

Device available for evaluation? ☐ Yes ☐ No ☐ Returned to manufacturer on:

AMBULANCE MALFUNCTION/FAILURE

Time of failure: Time mutual aid arrived: Time arrived at hospital:

Describe the malfunction/hazard or problem in detail. Include how it was discovered, any action taken at the time

Potential or actual adverse impact to patient:

MEDICATION(s)

Name (give labeled strength & mfr/labeler, if known)
#1.
#2.

Dose, frequency & route used
#1.
#2.

Indications for use
#1.
#2.

Lot number, if known	Expiration date, if known:
#1. #2.	#1. #2.

INITIAL REPORTER

Name:		Agency:	
Phone: e-mail:	Health professional? ☐ Yes ☐ No	Occupation:	**Initial reporter also sent report to FDA?** ☐ Yes ☐ No