

**LEHIGH VALLEY HOSPITAL
AND HEALTH NETWORK**

**PATIENT SAFETY PLAN
(MCARE -ACT 13)**



January 2008

Approved by the Board of Trustees – June 2002
Approved by the Board of Trustees – November 2003
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LEHIGH VALLEY HOSPITAL & HEALTH NETWORK'S

PATIENT SAFETY PLAN

INTRODUCTION

In accordance with **Act 13 (MCARE)**, the Patient Safety Plan and guidelines are designed to insure that licensed health care providers comply with existing professional and legal responsibilities with respect to the notification of patients when a serious event has occurred that is unanticipated and requires added health care services. This act requires written notification to the patient and family within a designated time period by the Patient Safety Officer.

Lehigh Valley Hospital & Health Network (LVHHN) hereby establishes a Patient Safety Plan as required by Act 13, The Medical Care Availability and Reduction of Error Act (MCARE), for continuing the purpose of improving the health and safety of its patients. The goal of the Act is to provide fair compensation and a prompt determination to a person who has sustained injury or death as a result of medical negligence by a health care provider while exerting every effort to reduce and eliminate medical errors through the identification of problems and implementing solutions that promote patient safety. The MCare Act was amended by Act 52 to include disclosure of hospital acquired infections.

LVHHN strives to promote a culture of patient safety. Reporting of patient safety events is the basis of this culture and allows LVHHN to identify areas for improvement. Providers, allied health professionals and clinical staff are encouraged to report patient safety events. The network is committed to patient safety, teamwork, collaboration and honest, open communication. The contribution of physicians, nurses and staff is valued in the pursuit of clinical excellence and safe patient care. Early identification of system and process issues is key to sustaining a culture of patient safety.

A. DEFINITIONS

Serious Event: an event, occurrence, or situation involving the clinical care of a patient in a medical facility that results in death OR compromises patient safety AND results in UNANTICIPATED injury REQUIRING the delivery of ADDITIONAL health care services to the patient. The term DOES NOT include an incident. The occurrence of a health care – associated infection as defined by the Centers for Disease Control and Prevention and its National Health Care Safety Network (NHSN) is considered a serious event.

Incident: an event, occurrence, or situation involving the clinical care of a patient which could have injured the patient but did NOT cause an unanticipated injury or require the delivery of additional health services.

B. PATIENT SAFETY OFFICER

LVHHN hereby appoints Kristie Lowery, Patient Safety Officer.

The responsibilities of the Patient Safety Officer are:

1. Serve on the Patient Safety Council.
2. Ensure the investigation of all reports of serious events and incidents.
3. Take such action as is immediately necessary to ensure patient safety as a result of any investigation.
4. Report to the Patient Safety Council regarding any action taken to promote patient safety as a result of investigations.
5. Comply with the organization's reporting responsibilities to the State under this Act by assuring that all serious events and infrastructure failures are reported within twenty-four (24) hours of confirmation that such failure has occurred.
6. Provide facilitation to the health care team to provide patient/family with disclosure and written notification of the event within the designated time period.

C. PATIENT SAFETY COUNCIL

1. LVHHN's Patient Safety Council will be composed of the Patient Safety Officer, and at least three health care workers who shall be a physician, a nurse, infection control practitioner and one ancillary staff member. At least two residents of the community will be appointed as members. Additional members will be added as deemed appropriate by the CEO or his designee. The Council will meet on a monthly basis.
2. The responsibilities of the Council are to:
 - (a) Receive reports from the Patient Safety Officer;
 - (b) Evaluate investigations and actions of the Patient Safety Officer on all reports;

- (c) Review and evaluate the quality of patient safety measures utilized by the hospital. A review shall include the consideration of reports made under the Anonymous reporting section, the 24-hour hot line, and the serious event reporting requirements as defined below.
 - (d) Make recommendations to eliminate future serious events and incidents; and
 - (e) Report to the administrative officer and governing body of the hospital on a quarterly basis regarding the number of serious events and incidents and its recommendations to eliminate future serious events and incidents.
3. Because LVHHN encompasses two licensed hospitals, representatives of each licensed hospital will be appointed to the Council.
 4. Each Council member, that is not an employee, will be required to sign a confidentiality attestation.

* Council membership is available upon request.

D. CONFIDENTIALITY ACCORDING TO ACT 13

1. **Materials.** Any documents, materials or information solely prepared or created for the purpose of compliance with Act 13 (as amended by Act 52) which arise out of matters reviewed by the Patient Safety Council or the governing board of a hospital are confidential and will not be discoverable or admissible as evidence in any civil or administrative action or proceeding. Any documents, materials, records or information that would otherwise be available from original sources will not be construed as immune from discovery or use in any civil or administrative action or proceeding merely because they were presented to the Patient Safety Council or governing board of a hospital. These materials include the reports referred to previously as well as the serious event reports, incident reports, and infrastructure failure reports noted below.
2. **Meetings.** No person who performs responsibilities for or participates in meetings of the Patient Safety Council or governing board of a hospital will be allowed to testify as to any matters within the knowledge gained by the person's

responsibilities or participation on the Patient Safety Council or governing board of a hospital. However, the individual shall be allowed to testify as to any matters within the person's knowledge which was gained outside of the person's responsibilities or participation on the Patient Safety Council or governing board of a hospital pursuant to Act 13.

3. Records and Documents. Records and documents received by the State Authority or department will not be discoverable.

E. REPORTS

1. Serious Event Reports. The hospital will report the occurrence of a serious event to the department and the Authority within twenty-four (24) hours of the hospital's confirmation of the occurrence of the serious event. The report to the department and the Authority will be in the form and manner prescribed by the Authority in consultation with the department and shall not include the name of any patient or any other identifiable individual information. Hospital acquired infections as defined by the Centers for Disease Control and Prevention and National Health Care Safety Network, will be submitted to NHSN in accordance with Act 52.
2. Incident Reports. The hospital will report the occurrence of an incident to the Authority in a form and manner prescribed by the Authority and will not include the name of any patient or any other identifiable individual information.
3. Infrastructure Failure Reports. The hospital will report the occurrence of an infrastructure failure to the department within twenty-four (24) hours of the hospital's confirmation of the occurrence or discovery of the infrastructure failure. The report to the department will be in the form and manner prescribed by the department.
4. Notification to Licensure Boards. If a hospital discovers that a licensee providing health care services in the hospital during a serious event failed to report the event, the medical facility will notify the licensee's board of the failure to report.

F. EMPLOYEE REQUIREMENTS

1. A health care worker who reasonably believes that a serious event or incident has occurred will report the serious event or incident according to the Patient Safety Plan, unless the health care worker knows that a report has already been made. The report will be made immediately or as soon thereafter as reasonably practicable, but in no event later than 24 hours after the occurrence or discovery of a serious event or incident to the Risk Management Office during normal business hours or to the Risk Manager on-call evenings, nights, weekends, and holidays.
2. Incidents should be reported in accordance with Hospital policy regarding event reports.
3. Once the health care worker has reported internally, he or she may file an anonymous report regarding a serious event with the State Authority. Upon receipt of the report, the Authority will give notice to the affected hospital that a report has been filed. The Authority will conduct its own review of the report, unless the hospital has already commenced an investigation of the serious event. The hospital will provide the Authority with the results of its investigation no later than thirty (30) days after receiving notice. If the Authority is dissatisfied with the adequacy of the investigation conducted by the hospital, the Authority will perform its own review of the serious event and may refer a hospital and any involved licensee to the Department for failure to report.
4. No retaliatory action will be taken against a health care worker for reporting a serious event or incident as set forth in the act of December 12, 1986 (P.L. 1559, No.169), known as the Whistleblower Law.
5. Upon approval of the Patient Safety Plan by the State, (Plan approved by DOH September 17, 2002) LVHHN will notify all health care workers of the Plan. Compliance with the Plan will be required as a condition of employment or credentialing.
6. No individual providing information to the Patient Safety Council, governing board or State will be considered to have violated any criminal law or to be civilly liable under any law, unless the information is false and the individual knew, or had reason to believe the information was false and was motivated by malice.

G. FACILITY REQUIREMENTS

If a medical facility discovers that a licensee providing health care services in the medical facility during a serious event failed to report the event (in accordance with Section 308(a) of the Act), the medical facility shall notify the licensee's licensing board of the failure to report.

Failure to report a serious event or an infrastructure failure as required by this section or to develop and comply with the patient safety plan (in accordance with Section 307 of the Act) or to notify the patient (in accordance with Section 308(b) of the Act) shall be a violation of the Health Care Facilities Act. In addition to any penalty which may be imposed under the Health Care Facilities Act, a medical facility which fails to report a serious event or an infrastructure failure or to notify a licensure board in accordance with the Act may be subject to an administrative penalty of \$1,000 per day imposed by the department.

H. DISCLOSURE TO PATIENT

The Patient Safety Plan requires that disclosure AND written notification be provided to a patient who has been affected by a serious event. This notification must be provided within seven days of the occurrence or discovery of a serious event. ***Please refer to Disclosure Guidelines for further information**

1. The Patient Safety Officer (or his/her designee) will provide written notification to a patient affected by a serious event or, with the consent of the patient, to an available family member or designee, within seven (7) days of the occurrence or discovery of a serious event. If the patient is unable to give consent, the notification will be given to an adult member of the immediate family or authorized representative. If an adult member of the immediate family cannot be identified or located, notification will be given to the closest adult family member. For unemancipated patients who are under 18 years of age, the parent or guardian will be notified.
2. Disclosure of hospital acquired infections will be conducted in accordance with Act 13.
3. Notification will not constitute an acknowledgement or admission of liability. The written notification is provided to document the discussion with the patient or family. The designee will include but not be limited to the physician or nurse caring for the patient.

4. The Patient Safety Officer will assist the clinical staff with the analysis and evaluation to determine whether the occurrence is a serious event requiring disclosure and notification.
5. Prior to initiating discussion, the attending physician and the Patient Safety Officer will determine whether the patient is competent. If the patient is not competent, disclosure and written notification must be provided to the patient's family or authorized representative.
6. The Patient Safety Officer, will assume responsibility for complying with the written notification requirements on behalf of the Institution. The Patient Safety Officer will either prepare or review the written notice that will be provided to the patient to assure that the requirements of Act 13 are met.
7. The Patient Safety Officer will assist the clinical staff with fulfilling their disclosure responsibilities under the law.
8. All health care workers are responsible for reporting the serious event immediately upon discovery to the Patient Safety Department during daily business hours or to the on-call Risk Manager.
9. Failure to immediately report a serious event to the Patient Safety Officer may result in disciplinary action according to Human Resource policies or medical staff bylaws. Licensed health care providers may also be subject to sanctions by their respective licensing bodies for failure to comply with the reporting and disclosure responsibilities.
 - (a) Unless the cause has been clearly determined, there should be no discussion or assumptions of cause and effect that may be misleading to the patient.
 - (b) Discussion of actions taken against any of the caregivers involved is not appropriate nor are assignments of blame.
 - (c) Assurances that the hospital and its clinical providers are taking appropriate steps to reduce a likelihood of recurrence should be part of the discussion.

- (d) Following disclosure of the event, the physician should then discuss how this would affect the care of the patient.

June 2002, November 2003, January 2005, May 2005
October 2007, January 2008

DISCLOSURE GUIDELINES

ACT 13: THE MEDICAL CARE AVAILABILITY AND REDUCTION OF ERROR ACT (MCARE)

In accordance with ACT 13 the following guidelines are to be used as stated in The Patient Safety Plan which requires that disclosure AND written notification be provided to a patient who has been affected by a serious event. This notification must be provided within seven days of the occurrence or discovery of a serious event.

GUIDELINES:

1. The Patient Safety Officer, will assume responsibility for complying with the written notification requirements on behalf of the Institution. The Patient Safety Officer will either prepare or review the written notice that will be provided to the patient to assure that the requirements of Act 13 are met. A copy of the written notification will be kept in the medical record.
2. The Patient Safety Officer will assist the clinical staff with the analysis and evaluation to determine whether the occurrence is a serious event requiring disclosure and notification or authorized representative.
3. Prior to initiating discussion, the attending physician and the Patient Safety Officer will determine whether the patient is competent. If the patient is not competent, disclosure and written notification must be provided to the patient's family.
4. The Patient Safety Officer will assist the clinical staff with fulfilling their disclosure responsibilities under the law.
 - (a) Unless the cause has been clearly determined, there should be no discussion or assumptions of cause and effect that may be misleading to the patient.
 - (b) Discussion of actions taken against any of the caregivers involved is not appropriate nor are assignments of blame.
 - (c) Assurances that the hospital and its clinical providers are taking appropriate steps to reduce a likelihood of recurrence should be part of the discussion.
 - (d) Following disclosure of the event, the physician should then discuss how this will affect the care of the patient.

- (e) The physician or nurse involved in the event and the disclosure should document a complete chart note indicating that the discussion has occurred and that the patient or family verbalized their understanding of the occurrence.
- 5. **All health care workers are responsible for reporting any serious event immediately upon discovery to the Patient Safety Hotline during daily business hours and/or to the on-call Risk Manager.**
- 6. Failure to immediately report a serious event to the Patient Safety Officer may result in disciplinary action according to Human Resource policies or medical staff bylaws. Licensed health care providers may also be subject to sanctions by their respective licensing bodies for failure to comply with the reporting and disclosure responsibilities.
- 7. Under Act 13, healthcare workers may submit Anonymous Reports of serious events directly to the Patient Safety Authority, if they have previously complied with item #5 above. The Anonymous Reporting form is available via the Patient Safety Authority's Website at <https://www.papsrs.state.pa.us/>
- 8. No retaliatory action will be taken against a healthcare worker for reporting a serious event or incident as set forth in the Act of December 12, 1986 known as the Whistleblower Law.



PATIENT SAFETY HOTLINE

610-402-2830

Patient Safety Officer – Kristie Lowery

Leave a brief message providing the following information:

1. **Patient's Name and Medical Record Number**
2. **Location of Patient**
3. **Nature of the Serious Event or Incident**
4. **Person Involved in Serious Event or Incident**
5. **Your Name (*not required*)**