

This policy applicable to:

All Subsidiaries     All Hospitals  
 All Acute Care Hospitals

BMRH  
 Mirmont Treatment Center

## ADMINISTRATIVE POLICY AND PROCEDURE MANUAL

**Subject: Patient Safety Plan**

### **VISION**

Main Line Hospitals, including Lankenau, Bryn Mawr and Paoli Hospitals, is committed to a culture of safety in an environment that promotes reporting of sentinel events, serious events, incidents, and infrastructure failures (patient safety occurrences) in order to identify and fix unsafe systems while holding everyone accountable for safe behaviors. Our organization enhances patient safety by educating employees and professional staff about system-based causes of error and reliable risk prevention practices. Our organization recognizes and rewards staff for quality patient safety innovations. When patient safety occurrences arise, we seek to identify the cause(s), review for trends, improve the process and educate the individuals involved as appropriate. We support timely disclosure of unanticipated outcomes to patients in order to improve the quality and safety of patient care.

### **POLICY**

The Patient Safety Plan provides a systematic, coordinated and continuous approach to the maintenance and improvement of safety through the establishment of mechanisms that support effective responses to actual occurrences; ongoing proactive reduction of risk that could lead to patient safety occurrences; and integration of patient safety priorities into the new design and redesign of all relevant organizational processes, functions and services.

As patient care, and therefore the maintenance and improvement of safety, is a coordinated and collaborative effort, the approach to optimal patient safety involves multiple departments and disciplines in establishing plans, processes and mechanisms that comprise the patient care activities at Main Line Hospitals. The Patient Safety Plan outlines the components of the organization-wide Patient Safety Program.

### **PURPOSE**

The purpose of the Patient Safety Plan at Main Line Hospitals is to improve patient safety and reduce risk to patients through an environment that encourages:

- Recognition and acknowledgement of risks to patients' safety and that medical/human errors will occur in a complex environment.
- The initiation of actions to reduce these risks.
- The internal reporting of the facts related to patient safety occurrences, the root and contributing causes, and the actions taken to prevent recurrence.
- Investigations and analyses that focus on processes and systems, as well as human behaviors and human factors that impact ability to perform safely.
- Minimization of individual blame or retribution for involvement in a medical/human error
- Organizational learning about patient safety occurrences.

- Sharing knowledge to effect behavioral changes in individuals and the broader organizations.
- Open, honest and timely disclosure to patients/families about serious patient safety occurrences by professionals trained/supported in having these conversations.

## DEFINITIONS

- Action Plan: The product of a Root Cause Analysis that identifies the strategies that an organization plans to implement to reduce the risk of similar events occurring in the future. The plan should address responsibility for implementation, oversight, pilot testing if appropriate, time lines and methods for measuring the effectiveness of the recommended actions. Action plans will include the adequacy of staffing, including nursing staffing, in its analysis of possible causes.
- Incident: An event, occurrence or situation involving the clinical care of a patient in a medical facility which could have injured the patient but did not either cause an unanticipated injury or require the delivery of additional health care services to the patient. The term does not include a serious event. Incidents include near misses.
- Infrastructure failure: An undesirable or unintended event, occurrence or situation involving the infrastructure of a medical facility or the discontinuation or significant disruption of a service which could seriously compromise patient safety.
- Root Cause Analysis: A process for identifying the basic or causal factors that underlie the event. In particular, a root cause analysis: (1) focuses on systems and processes, not individual performance; (2) analyzes particular events then extrapolates potential process improvement opportunities for the entire organization, if any, that would tend to decrease the likelihood of such events occurring in the future; (3) continues asking “Why?” to ensure meaningful in depth analysis. Root cause analysis will include the evaluation of staffing effectiveness.
- Sentinel Event:

An unexpected occurrence involving death or serious physical or psychological injury, or risk thereof. Such events are called sentinel because they signal the need for immediate investigation and response.

A Sentinel Event includes any event that meets the following criteria:

- a. The event has resulted in unanticipated death or major permanent loss of function not related to the natural course of the patient’s illness or underlying condition<sup>§</sup>
- or,**
1. The event is one of the following (even if the outcome was not death or major permanent loss of function unrelated to the natural course of the patient’s illness or underlying condition):
    - Suicide of any patient receiving care, treatment and services in a staffed around-the-clock care setting or within 72 hours of discharge
    - Unanticipated death of a full-term infant
    - Abduction of any patient receiving care, treatment, and services
    - Discharge of an infant to the wrong family
    - Sexual abuse/assault (including rape) \*

- Hemolytic transfusion reaction involving administration of blood or blood products having major blood group incompatibilities (ABO, Rh, other blood groups)
- Invasive procedure, including surgery, on the wrong patient, wrong site, or wrong procedure
  - All events of invasive procedure, including surgery, on the wrong patient, wrong site, or wrong procedure are reviewable under the policy, regardless of the magnitude of the procedure or the outcome.
- Unintended retention of a foreign object in a patient after surgery or other invasive procedures
- Severe neonatal hyperbilirubinemia (bilirubin >30 milligrams/deciliter)
- Prolonged fluoroscopy with cumulative dose >1,500 rads to a single field or any delivery of radiotherapy to the wrong body region or >25% above the planned radiotherapy dose

(See Administrative policy 1.43 Sentinel Event for more specific detail.)

- 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 an unanticipated injury requiring the delivery of additional health care services to the patient. The term does not include an incident.

## **I. SCOPE OF ACTIVITIES**

### **A. RISK IDENTIFICATION AND ANALYSIS**

The scope of the Patient Safety Program includes an ongoing assessment, using internal and external knowledge and experience, to prevent patient safety occurrence and maintain and improve patient safety. The Patient Safety Program encompasses the patient population, visitors, volunteers, hospital staff and medical staff.

The Patient Safety Program also addresses maintenance and improvement in patient safety issues in every department throughout the facility.

In addition, the Patient Safety Program also includes risk identification and analysis through trending of confidential patient safety occurrence information from individual event reports and aggregate data reports.

### **B. PRO-ACTIVE RISK ASSESSMENT – FAILURE MODE AND EFFECT ANALYSIS**

At least one high-risk patient safety process will be selected at a minimum of 18 months, for proactive risk assessment, selected through review of internal data reports and reports from external sources, including, but not limited to The Joint Commission sentinel event alerts, Core Measure performance data, occurrence reporting information from state and federal sources and current literature, and through the Performance Improvement Priority Matrix. The following criteria will be considered when selecting pro-active risk reduction process:

Variability  
Complexity

Standardization  
Coupling steps

Human dependency  
Hierarchical approach and time constraints

Proactive Risk Assessment includes:

- An assessment of the intended and actual implementation of a particular process to identify: the steps in the process where there is, or may be, undesirable variation; the possible effects of the

undesirable variation on patients (Failure Mode and Effects Analysis); and how serious the possible effect on the patient could be;

- For the most critical effects, a Root Cause Analysis may be conducted to determine why the undesirable variation leading to that effect may occur;
- Pilot testing and implementing the redesigned process;
- Identifying and implementing Measures of the Effectiveness of the redesigned process;
- Implementing a strategy for Maintaining and Monitoring the Effectiveness of the redesigned process over time.

### C. SURVEYS

Finally, the Patient Safety Program includes a periodic survey of patients' opinions, needs and perceptions of risks to patients and requests suggestions for improving patient safety. This is accomplished through the patient satisfaction-monitoring tool as well as other means of communication. Additionally, Main Line Health Hospitals periodically address staff perception of patient safety.

## II. AUTHORITY & RESPONSIBILITIES

### A. GOVERNING BOARD

The overall authority for the direction of the Patient Safety Program rests with the Governing Board who delegates its authority to implement and maintain the various components of the Patient Safety Program to the President and CEO. The Governing Board has delegated responsibility for the quality improvement activities to its subcommittee, the Quality and Patient Safety Committee of the Main Line Hospitals Board.

### B. PRESIDENT AND CHIEF EXECUTIVE OFFICER

The President and CEO, in collaboration with administrative, managerial and clinical staff, ensures that the Patient Safety Program is implemented throughout the organization and integrated appropriately with other activities within the organization which contribute to the maintenance and improvement of patient safety, such as performance improvement, environmental safety, and risk management. The President and CEO will designate a qualified individual in the organization to manage the Patient Safety Program.

### C. PATIENT SAFETY OFFICER (PSO)

The Patient Safety Officer is an individual designated by the President and CEO and is responsible for the Patient Safety Program. The PSO will have a working knowledge of quality improvement, patient safety and risk management for an acute care setting. The PSO at each MLH Hospital will have the title of Patient Safety Specialist (PSS).

The PSO/PSS will:

- Oversee the creation, review and refinements to the Patient Safety Plan/Program.
- Ensure compliance with Sentinel Event, Serious Event, Incident, and Infrastructure Failure reporting requirements as mandated by law/regulations or to meet accreditation standards.
- Oversee and ensure the investigation, root cause analyses, and development and implementation of action plans of reports of Sentinel Events, Serious Events, Incidents and Infrastructure Failures, as appropriate.
- Take such action as is immediately necessary to ensure patient safety as a result of any investigation.
- Serve on the Main Line Hospital Patient Committee and the specific Hospital Patient Safety Subcommittees.

- Inform key members of the Patient Safety Committee and/or Patient Safety Subcommittee of the facts and recommendations as a result of the investigation of Sentinel Events, Serious Events, Incidents and Infrastructure Failures as soon possible as appropriate, via SBAR, and provide updates as necessary.
- Report to the Patient Safety Committee regarding any action taken to promote patient safety as a result of the investigations of Sentinel Events, Serious Events, Incidents and Infrastructure Failures.
- Ensure that disclosure of unanticipated outcomes to patients and/or families is carried out in accordance with the Patient Safety Plan and law/regulations.
- Devise strategies to enlist medical staff, employee, and patient/family input into the organization's Patient Safety Program. Serve as the link to the Board Quality and Patient Safety Committee and the President and CEO on all matters related to patient safety.
- Serve on the Main Line Hospitals Quality/Patient Safety Council

#### D. PATIENT SAFETY COMMITTEE (PSC)

The Patient Safety Committee shall, at a minimum, be composed of the PSO/PSS for each hospital, the Chief Medical Officer, the System VP for Quality & Patient Safety, the Medical Staff Department Chairs, the President for each hospital, the Nursing Vice President for each hospital, the System Director of Regulatory Affairs & Nursing Quality and **a minimum of two** residents of the community who are not agents, employees or contractors of a Main Line Hospital. **No more than one member of the committee shall be a member of the Hospital Board of Trustees.** Main Line Health legal counsel will serve as counsel to the committee. The committee shall meet at least monthly.

The Patient Safety Committee shall do all of the following:

- Receive reports from the PSO/PSS regarding any action taken to promote patient safety as a result of investigations of Sentinel Events, Serious Events, Incidents and Infrastructure Failures.
- Evaluate investigations, root cause analyses, action plans and actions of the PSO/PSS on all reports.
- Review and evaluate the effectiveness and efficiency of patient safety measures of Main Line Hospitals. The review will consider reports of Serious Events and Incidents made by healthcare workers of Main Line Hospitals to the organization and/or the Patient Safety Authority as well as reports from the Patient Safety Authority and/or its designee.
- Make recommendations to eliminate future Sentinel Events, Serious Events, Incidents, and Infrastructure Failures.
- Report to hospital leadership and the Board Quality and Patient Safety Committee (QPSC) on a quarterly basis. The number of Sentinel Events (disclosures), Serious Events (disclosures), Incidents, and Infrastructure Failures and all actions taken to improve safety, both proactively and in response to actual occurrences.

#### 1. HOSPITAL PATIENT SAFETY SUBCOMMITTEES

- Established by the Patient Safety Committee
- Purpose:
  - Review hospital-specific Patient Safety Action Plans (PSAP) and issues;
  - Oversee, implement and monitor effectiveness of PSAPs; and
  - Develop hospital based response to issues identified as system-wide and implement
- Review hospital-specific safety data and trends
- Report to the Patient Safety Committee

#### 2. MAIN LINE HEALTH LABORATORY (MLHL) SAFETY SUBCOMMITTEE:

- Established by the Patient Safety Committee

- b. Purpose:
  - i. Review Laboratory-specific Patient Safety Action Plans (PSAP) and issues;
  - ii. Oversee, implement and monitor effectiveness of PSAPs; and
  - iii. Develop Laboratory based response to issues identified as system-wide and implement
- c. Review Laboratory specific safety data and trends
- d. Report to the Patient Safety Committee

### **3. PATIENT SAFETY TASK FORCES**

The Patient Safety Committee will establish Task Forces and request Performance Improvement teams based on the analysis of patient safety serious and sentinel events, incidents, and aggregated system data. The Committee may also identify high risk areas or programs where temporary or permanent task forces or PI teams are chartered. Additionally State or National safety data trends, results of RCA, FMEA, literature review, and evidence-based practices may serve as sources for areas of focus. Reports and recommendations will be made by these groups to the Patient Safety Committee.

### **2. ROOT CAUSE ANALYSIS OVERSIGHT COMMITTEE**

Each MLH hospital will have an oversight committee whose purpose is to monitor trends and the effectiveness of and compliance with action plans, especially where they relate to system issues that have a broad organizational impact. The oversight committee will consist of decision-makers and process owners and be led by the PSO/PSS or their delegate. Reports and recommendations are made to the hospital Patient Safety Subcommittee, and in turn to the PSC.

## **E. MANAGEMENT STAFF**

Ensuring that the Patient Safety Program will be given high priority and support, managers will:

- Assure allocation of adequate resources for organizational and departmental patient safety initiatives.
- Assign staff to participate in risk reduction activities.
- Reinforce reporting expectations and management of serious events and incidents.
- Establish a culture of safety that encourages reporting, identifies broken processes and systems, and holds every one accountable for safe behaviors.
- Supplement mandatory education programs with patient safety education and training that relates directly to the jobs performed by employees in that area of the organization; and
- Ensure safe practice by all staff through observation and use of other appropriate evaluative processes.

## **F. MEDICAL STAFF AND EMPLOYEES**

Members of the medical staff, employees, and volunteers are responsible for actively participating in the Patient Safety Program. Participants should:

- Assume responsibility for identifying processes or systems that could potentially lead to patient safety occurrences
- Know and follow organizational and departmental policies and procedures applicable to assigned duties.

- Inform patients and families about care, medications, treatments, and procedures; encourage them to ask questions and participate with caregivers in the development of their treatment plan.
- Use sound judgement and awareness of potential hazards before taking action.
- Participate in required organizational and departmental patient safety education programs and other activities designed to improve departmental and organizational patient safety.
- Receive education and training during their initial orientation and on an ongoing basis regarding job-related aspects of patient safety, including the need and method to report patient safety occurrences
- Respond to queries regarding their willingness to report patient safety occurrences and barriers to effective communication among caregivers.
- Promptly report patient safety occurrences in accordance with established hospital policy and procedure.

## **G. PATIENTS AND FAMILIES**

The safety of health care is enhanced by the involvement of the patient, as a partner in the health care process, as appropriate to his/her condition. It is recognized that patients and families play an important role in ensuring patient safety. Our organization will educate patients and families about their role in helping to facilitate the safe delivery of care. We will educate patients and families to:

- Disclose relevant medical and health information to caregivers to facilitate appropriate care delivery.
- Report unexpected changes in a patient's condition or perceived risks to the patient's health and well being to responsible caregivers.
- Question any variation in medications, treatment, or plan of care from what the patient or family was informed to expect.
- Follow the care, service, or treatment plan developed. They should express any concerns they have about their ability to follow and comply with the proposed care plan or course of treatment
- The patient and family are expected to accept outcomes resulting from them not following the care, service, or treatment plan.
- Follow the hospital's rules and regulations concerning patient care and conduct.
- Encourage completion of any specific questionnaire related to satisfaction, quality or patient safety.

## **III. REPORTING STRUCTURE**

When the Hospital's PSO/PSS is notified of a potential reportable Serious Event, Incident, or Infrastructure Failure, an initial investigation is conducted to obtain relevant information. The information is reviewed by the PSO/PSS, in conjunction with legal counsel when necessary, for the purpose of determining reportability to the Pennsylvania Patient Safety Reporting System (PA-PSRS) and the event classification. When an event is determined to be reportable as defined by Act 13, submission is made utilizing the PA-PSRS.

The PSC, through the Vice President for Quality and Patient Safety or the Chief Medical Officer, will present trend and/or summary reports directly to the Board QPSC, as well as to the President and CEO, at least quarterly. Reports will review data and trends for Sentinel and Serious Events, types of event and root causes identified, and recommendations to eliminate future Serious Events and Incidents. An annual patient safety report will be forwarded to the Governing Board on actions taken to improve patient safety, both in response to actual occurrences and proactively.

At least once per year a written report of the results of any analysis related to the adequacy of staffing and any actions taken to resolve identified problems will be completed and reviewed at the MLH Patient Safety Committee.

## IV. REPORTING REQUIREMENTS

### A. Internal Reporting

1. All departments within the organization, patient care and non-patient care, are responsible to report patient safety occurrences and potential occurrences to the Hospital PSO/PSS through the event reporting process (Event Reporting Policy I.45). Data regarding patient safety occurrences will be aggregated and reported to the PSO/PSS who will in turn report to the PSC. The information will be analyzed and further patient safety activities will be determined as appropriate.
2. An effective Patient Safety Program cannot exist without optimal reporting of patient safety occurrences.. Therefore, it is the intent of Main Line Hospitals to adopt a culture of safety in its management of patient safety occurrences.
  - a. All personnel and medical staff are required to report suspected and identified patient safety occurrences and should do so without the fear of reprisal in relationship to their employment. A health care worker who reasonably believes that a Serious Event, Incident or Infrastructure Failure has occurred shall report the occurrence by completing an Event Report, unless the health care worker knows that a report has already been made. The report shall be made immediately or as soon thereafter as reasonably practicable, but in no event later than 24 hours after the occurrence or discovery of the Serious Event, Incident or Infrastructure Failure. A health care worker who reports the occurrence of a Serious Event, Incident or Infrastructure Failure shall not be subject to any retaliatory action for reporting. The Hospital PSS, should be promptly contacted, by telephone, voice mail or pager, and informed about any potential serious/sentinel events or infrastructure failures.
  - b. This organization supports the concept that errors may occur due to a breakdown in systems and processes, and will focus on improving systems and process, rather than disciplining those responsible for errors and occurrences. However, in the event that an employee or member of the Medical Staff participates in willful or malicious misconduct, sabotage, substance abuse, criminal activity, fails to report an event truthfully or in a timely fashion, makes an egregious error demonstrating a lack of fundamental knowledge necessary to carry out his/her job responsibilities, or fails to respond to educational efforts or other corrective plans, Main Line Hospitals may institute disciplinary action and information may be subject to reporting to any relevant licensure board. An employee will be subject to corrective intervention in accordance with Human Resources Policy: Performance Improvement Progressive Corrective Intervention, 2.10. Medical staff issues shall be addressed in accordance with the Main Line Hospitals Medical Staff Bylaws and Rules and Regulations.

Health care workers involved in a patient safety occurrence may be offered support regarding the health care worker's professional and emotional reconciliation of the event and may request/receive supportive personal counseling from the Human Resources Department First Call Program, Hospital Chaplain and/or his or her department supervisor. The Patient Safety Plan encourages the health care worker's involvement in the root cause analysis and action plan processes, to allow the health care worker an active role in process resolution.

- c. The hospital disseminates lessons learned from root cause analyses, system or process failures, and the results of proactive risk assessments to all staff who provide services for the specific situation

## B. External Reporting

1. External reporting will be performed in accordance with Act 13; the Pennsylvania Medical Care Availability and Reduction of Error Act (“M-CARE”), 40 P. S. § 130.101 et seq and all other applicable state, and federal laws and regulations.
2. Serious Event reports – The organization shall report the occurrence of a Serious Event to the Patient Safety Authority and the Department of Health (DOH) within 24 hours of the organization’s confirmation of the occurrence. This report shall be submitted using the PA-PSRS and shall not include the name of any patient or any other identifiable individual information.
3. Incident reports – The organization shall report the occurrence of an Incident to the Patient Safety Authority using the PA-PSRS and shall not include the name of any patient or any other identifiable information.
4. Infrastructure Failure reports – The organization shall report the occurrence of an Infrastructure Failure to DOH within 24 hours of the organization’s confirmation of the occurrence or discovery of the Infrastructure failure. The report shall be submitted using the PA-PSRS and shall not include the name of any patient or any other identifiable individual information.
5. Notification to Licensure Boards – If the organization discovers that a licensed health care provider providing health care services within the facility during a Serious Event failed to report the event as required in Section IV.A.2.a, the organization shall notify the licensee’s licensing board of the failure to report.
6. Employee notification –The organization shall notify all health care workers of the organization of the Patient Safety Plan. Compliance with the Patient Safety Plan shall be required as a condition of employment or credentialing with the organization.
7. Health Care Worker (HCW) – may report a Serious Event to the Commonwealth of Pennsylvania’s Patient Safety Authority (PSA). Before reporting a Serious Event to the PSA, HCW will ensure the event has been internally reported according to Main Line Hospitals Patient Safety Plan. (See **Attachment A.**)

A health care worker (HCW) who has a concern about the safety or quality of care provided in our organization can anonymously report the occurrence by contacting the Patient Safety Hotline 484-337-8888 (337-8888). The HCW may also contact TJC (1-630-792-5636). (See **Attachment B.**)

## **V. CONFIDENTIALITY**

All documents, materials and/or information prepared or created for the purpose of compliance with the Medical Availability and Reduction of Error Act, 40 P.S. Section 1303.101 et seq (“M-CARE”) and/or peer review are confidential and deemed protected by the confidentiality provisions of M-CARE and/or the Pennsylvania Peer Review Protection Act, 63 P.S. Section 425.1 et seq. or the corresponding provisions of any subsequent federal or state statute providing protection for related activities. Patient Safety files and their entire contents will be clearly marked “CONFIDENTIAL” and should not be copied or distributed without the advice of Main Line Health Legal Counsel.

## **VII. DISCLOSURE**

At Main Line Hospitals, it is our desire to inform patients of unanticipated outcomes. An unanticipated outcome is a result that differs significantly from what was anticipated to be the result of a treatment or procedure. At a minimum, disclosure will be made for Serious Events and Sentinel Events resulting in an unanticipated outcome. Other unanticipated outcomes will be reviewed and disclosure made on a case-by-case basis depending on the circumstances of the event.

Patients, and when appropriate, their families are informed about the outcomes of care, including unanticipated outcomes by the attending physician/practitioner involved in the care or designee. At least one hospital representative should be present at the time of initial disclosure. If the physician is unable to complete the disclosure, Hospital Administration will appoint an appropriate representative.

Steps to be taken include:

- Gathering all pertinent, relevant facts and information
- Coordinating efforts so there is as little discrepancy as possible in information to be provided
- Truthful and compassionate disclosure, without excuses or blame
- Offering support and recovery where appropriate

Information to be disclosed should include:

- Describe the event that happened
- Who was involved (by job function, not by name)
- What are the reasonable, potential short term and long term consequences
- What have we done to reduce or manage the consequence to the patient
- Signs and symptoms that may indicate complication
- Appropriate actions the patient or decision-maker should take if complications occur

Documentation:

Documentation of the discussion of the unanticipated outcome should be documented in the medical record by the attending physician/practitioner or designee making the disclosure.

Written Notification to Patient:

The organization, through an appropriate designee, shall 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 shall be given to an adult member of the immediate family. If an adult member of the immediate family cannot be identified or located, notification shall be given to the closest adult family member. For unemancipated patients who are under 18 years of age, notification shall be given to the parent or guardian. The written Notification shall not constitute an acknowledgement or admission of liability.

References:

1. Medical Consultants Network Inc. (web site)
2. The Joint Commission Standards for Patient Safety
3. HAP Monograph on Patient Safety
4. ASHRM Patient Safety Manual
5. Related policies from: New York Medical College and Dana Farber Cancer Institute.
6. PA MCARE Act 13
7. TJC Sentinel Event Policy

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**Review Date:** 6/06

**Revision Date:** 9/11

**Key Contact:** Director, Patient Safety and Risk Management and System Director, Regulatory Affairs & Nursing Quality

**Approved/Reviewed by MLH Medical Executive Committee –11/11**



**Pennsylvania Patient Safety Reporting System  
Serious Event Anonymous Report Form**

SEE IMPORTANT INSTRUCTIONS ON BACK

\*Have you (or someone you know) reported this serious event as required by your healthcare facility's Patient Safety Plan?  Yes  No

**Who was harmed?**

\*Patient's Gender:  Male  Female \*Inpatient or Outpatient:  Inpatient  Outpatient

Patient's Age: [ ][ ] years [ ][ ] months (for infants only)

**Where?**

\*Facility Name (please print): \_\_\_\_\_

\*City (please print): \_\_\_\_\_

\*Location in Facility (please print): \_\_\_\_\_ For example: NICU, patient room

**When?**

\*Date of event (MM/DD/YYYY): [ ][ ] / [ ][ ] / [ ][ ][ ][ ] For example: 01/01/2003

Time (HH:MM): [ ][ ] : [ ][ ] [ ][ ] AM [ ][ ] PM

**What was the outcome?**

This serious event contributed to or resulted in... (check one):

- Low  Temporary harm that required treatment or intervention
- Temporary harm that required initial or prolonged hospitalization
- Permanent harm
- A near-death event
- High  Death of the patient

**What happened?**

\*Describe the event. Continue on back if necessary. Please print.

**ALL INFORMATION BELOW THE DOTTED LINE IS OPTIONAL**

May we contact you if we need to clarify any aspect of your report?  Yes  No

Name \_\_\_\_\_  
 Street Address \_\_\_\_\_  
 City, State, Zip \_\_\_\_\_  
 Telephone \_\_\_\_\_  
 E-mail \_\_\_\_\_

It is not necessary to identify yourself in your report, but it will enable us to get more information if we have any follow-up questions. We will not release your name to anyone and we will return a copy of the Report Form to you when our analysis is completed. Under Act 112, Section 308(c), healthcare workers who report serious events to the Patient Safety Reporting System are protected by the Whistleblower Law.

## **Instructions for Completing Other Side**

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### **Purpose**

- This form is used by healthcare workers to report a serious event to the Commonwealth of Pennsylvania's Patient Safety Authority.
- A **serious event** is an event, occurrence, or situation involving the clinical care of a patient in a medical facility that **EITHER**:
  - A) Resulted in the patient's **death**, or
  - B) Resulted in an **unanticipated injury** to the patient that required **additional healthcare services AND compromised patient safety**.
- Before reporting a serious event to the Patient Safety Authority, make sure you or someone else has filed a report according to your healthcare facility's Patient Safety Plan.

### **Important Instructions**

- Complete all sections of this form to the best of your ability.
- Please PRINT in BLACK INK
- Required information is designated with an asterisk (\*).
- Please write only in the spaces provided.
- When your report is complete, send it to PA-PSRS via regular mail or facsimile:

**MAIL**  
**PA-PSRS**  
PO Box 706  
5200 Butler Pike  
Plymouth Meeting, PA 19462-0706

**FAX**  
**PA-PSRS**  
(610) 567-1114

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### **Thank you!**

Thank you for submitting this report to PA-PSRS. Our program staff will follow-up on your report with the appropriate healthcare facility.

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*CONTINUE TEXT FROM FRONT IN SPACE BELOW, IF NEEDED*

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*DO NOT WRITE BELOW THE DOTTED LINE*

## Patient Safety or Quality Concern

- Staff may anonymously report without fear of disciplinary action any urgent pt. safety or quality concern as well as an improvement idea to the

**MLH Pt. Safety Hotline: 337- 8888**

- Staff may also report their concerns to the Department of Health or the Joint Commission.

PA Department of Health  
Division of Acute and Ambulatory Care  
P.O. Box 90  
Harrisburg, PA 17108  
1-800-254-5164

or

Joint Commission on Accreditation of Healthcare Organizations  
Division of Accreditation Operations  
Office of Quality Monitoring  
One Renaissance Boulevard