

Apple Hill Surgical Center

Patient Safety Program Description

Purpose of the Program

Abundant evidence indicates that most human errors are symptoms of underlying systems failure, not personal failures. The Patient Safety Program will ensure that a culture of patient safety, blameless reporting of patient safety concerns, coupled with a systematic, coordinated and continuous approach to patient safety are the standards of every Surgical Center employee.

Program Philosophy

Apple Hill Surgical Center has adopted the following principles pertaining to patient safety at all levels and entities of the organization.

Apple Hill Surgical Center:

- Recognizes that its employees and those members of the medical staff do not purposely seek to create errors that endanger those patients under their care, and that most errors occur as a result of the complexity of the delivery of health care and the nature of the systems presently in place.
- Is committed to openly discussing patient safety at all levels of the organization and believes that all employee contributions and concerns about patient safety are valued and respected.
- Incorporates, in new employee orientation, for staff and volunteers, discussions of the importance of patient safety, the importance of surveillance for errors or potential errors, the expectations for reporting patient safety concerns and errors.
- Is committed to incorporating accountability for patient safety into job descriptions at all levels of the organization and annually evaluating all employees on the contributions that they made in the area of patient safety. Employee accountability may include any or all of the following:
 - a) Acknowledging the risks involved with complex healthcare delivery
 - b) Acknowledging that an error occurred with possible resultant injury
 - c) Providing remedial or restorative care
 - d) Assisting in possible root cause analysis of the process(es) involved
 - e) Cooperating in fixing the problem(s) in the process(es)
- Expects all employees and healthcare providers who care for patients in the center to actively use the patient safety reporting system without fear of retribution in accordance with the Whistleblower Law &/or negative feedback on performance evaluations.
- Is committed to positively recognizing employees and healthcare providers for disclosing errors, near misses, and patient safety concerns.
- Is committed to providing feedback to those employees and healthcare providers who have reported or disclosed errors. This feedback may range from acknowledgement that the report has been received to results of detailed root cause analysis performed on the process(es) in question.

- Is committed to reducing variation in patient care delivery and devising strategies to avoid reliance on memory, through the use of protocols, checklists, standardization of work processes, and well-designed automation.
- Is committed to constantly examining and reviewing research and the experiences of other organizations in developing alternatives to reduce the possibility of error and improving patient safety.
- Includes patients as active participants in their care and promotes patient and family questioning of organizational routine, procedures, and/or processes whenever something does not look or “feel right”.
- Discusses adverse outcomes with the patient and his/her family as a means to cultivate and demonstrate the organization’s commitment to patient safety to the community. (The Apple Hill Surgical Center “Policy on Disclosure of Adverse Events” covers the details of this principle)
- Keeps the Apple Hill Surgical Center Board of Directors (and other appropriate governing Boards and committees of WellSpan Health) informed of adverse outcomes, safety problems, and efforts directed at maintaining and improving patient safety.
- Supports a management style that deals with adverse outcomes without reprisals and does not create impediments to the flow of information to the reporting system.
- Recognizes the obligation to assess and manage the competency of employees and other health care providers.
- Recognizes that deliberate acts with intent to harm or deceive have no place in the patient safety culture of Apple Hill Surgical Center and will be dealt with appropriately.

Key Definitions

- **Error** - The failure of a planned action to be completed as intended (i.e., error of execution) or the use of an incorrect plan to achieve an aim (i.e., error of planning). [Institute of Medicine Report, *To Err is Human: Building a Safer Health Care System*] or an unintended act, either of omission or commission, or an act that does not achieve its intended outcome. [Joint Commission on Accreditation of Healthcare Organizations]
- **Adverse Event** - An injury caused by medical management rather than the underlying condition of the patient. An adverse event attributable to error is a "preventable adverse event." [Institute of Medicine Report, *To Err is Human: Building a Safer Health Care System*]
- **Sentinel Event** - An unexpected occurrence involving death or serious physical or psychological injury. Serious injury specifically includes loss of limb or function. Sentinel events that are subject to review by the Joint Commission on Accreditation of Healthcare Organizations include: suicide of a patient in a setting where the patient receives round-the-clock care; infant abduction or discharge to the wrong family; rape; hemolytic transfusion reaction involving the administration of blood or blood products having major blood group incompatibilities; and surgery on the wrong patient or wrong body part. [Joint Commission on Accreditation of Healthcare Organizations]
- **Near Miss** - Any process variation which did not affect the outcome, but for which a recurrence carries a significant chance of a serious adverse outcome. [Joint Commission on Accreditation of Healthcare Organizations]
- **Root Cause Analysis** - A process for identifying the basic or causal factor(s) that underlie variation in performance, including the occurrence or possible occurrence of a sentinel event. A root cause analysis focuses primarily on systems and processes, not individual performance. It

progresses from special causes in clinical processes to common causes in organizational processes and identifies potential improvements in processes or systems that would tend to decrease the likelihood of such events in the future. [Joint Commission on Accreditation of Healthcare Organizations]

- **Failure Mode Effects and Criticality Analysis** - A proactive approach to assessing the intended and actual implementation of a process to identify steps in the process where there is, or may be, undesirable variation or failure modes; the possible effect on patients for each identified failure mode; and how serious or critical the possible effect could be on the patient. For the most critical effects, a root cause analysis is conducted to determine why the variation leading to that effect may occur in order to better design the process or system to minimize the risk of that failure mode or protect patients from the effects of that failure mode. [Joint Commission on Accreditation of Healthcare Organizations]
- **Action Plan** - The product of root cause analysis that identifies the strategies that the organization intends to implement to reduce the risk of similar events occurring in the future. The plan addresses responsibility for implementation, oversight, pilot testing as appropriate, time lines, and strategies for measuring the effectiveness of the actions. [Joint Commission on Accreditation of Healthcare Organizations]
- **Serious Event** - An event, occurrence, or situation involving the clinical care of a patient in a medical facility (hospital, ambulatory surgery facility, or birthing center) that results in death or compromises patient safety and results in an unanticipated injury requiring the delivery of additional health services to the patient. [Pennsylvania Act 13 of 2002, Medical Care Availability and Reduction of Error Act] Serious events are reportable to the Patient Safety Authority and Department of Health under Act 13.
- **Incident** - An event, occurrence, or situation involving the clinical care of a patient in a medical facility (hospital, ambulatory surgery facility, or birthing center) 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. [Pennsylvania Act 13 of 2002, Medical Care Availability and Reduction of Error Act] Incidents are reportable to the Patient Safety Authority under Act 13.
- **Infrastructure Failure** - An undesirable or unintended event, occurrence, or situation involving the infrastructure of a medical facility (hospital, ambulatory surgery facility, or birthing center) or the discontinuation or significant disruption of a service, which could seriously compromise patient safety. [Pennsylvania Act 13 of 2002, Medical Care Availability and Reduction of Error Act] Infrastructure failures are reportable to the Pennsylvania Department of Health (DOH) under Act 13 and other DOH regulations.
- **Patient Safety** - Freedom from accidental injury while receiving health care services.

Authority and Responsibility

Board of Directors - The overall authority for direction of the patient safety improvement and management program rests with Apple Hill Surgical Center's board of directors. The board of directors delegates its authority to implement and maintain the various components of the patient safety improvement and management program to the Director of Apple Hill Surgical Center.

Director - The Director of Apple Hill Surgical Center in collaboration with administrative, managerial, medical, and clinical staff ensures that the patient safety improvement and management 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 Director will designate a qualified individual in the organization to manage the organization-wide patient safety improvement and management program at Apple Hill Surgical Center.

Patient Safety Officer - An individual designated by the Director of Apple Hill Surgical Center who is responsible for the organization-wide patient safety improvement and management program and is accountable directly to Apple Hill Surgical Center's Board of Directors and Director. The patient safety officer will:

- Oversee the creation, review, and refinements to the patient safety improvement and management program.
- Coordinate and prioritize the activities of the patient safety committee.
- Develop and implement adequate information and management systems to support the activities of the patient safety improvement and management program.
- Identify and secure the necessary resources to fully implement the patient safety improvement and management 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 the investigation of serious events and as appropriate identified incidents.
- Ensure that disclosure of serious events to patients and/or families is carried out in accordance with organizational policy and law/regulations.
- Take such action as is immediately necessary to ensure patient safety as a result of any investigation.
- Report to the patient safety committee regarding any action taken to promote patient safety as a result of any investigation.
- Devise strategies to enlist medical staff, employee, and patient family input into the organization's patient safety improvement and management plan.
- Serve as the direct link to the Apple Hill Surgical Center Board of Directors and Director on all matters related to patient safety.
- Ensure that the organization conducts proactive hazard analyses using Lean Daily Management System (LDMS) principles.
- Serve as a member of the WellSpan Health Patient Safety Committee to assure coordination, optimum learning and dissemination of information throughout WellSpan Health.

Management Staff – Apple Hill Surgical Center's managers will ensure that the patient safety improvement and management program will be given high priority and will support the program. Managers will:

- Assure allocation of adequate resources for organizational and departmental patient safety initiatives.
- Assign staff to participate in risk reduction activities.
- Ensure that sufficient time is available for staff participation in patient safety activities.
- Reinforce reporting expectations and management of an adverse event resulting from an error that has reached the patient resulting in harm.

- Establish a non-punitive culture that encourages reporting.
- Make sure that staff attends all required patient safety education programs.
- Supplement mandatory education programs with other patient safety education and training that relates directly to the jobs performed by employees in that area of the organization.
- Ensure safe practice by all staff through observation and use of other appropriate evaluative processes.

Medical Staff – Members of Apple Hill Surgical Center’s Medical Staff are responsible for actively participating in the Surgical Center’s patient safety improvement and management program. An active participant will:

- Assume responsibility for identifying processes or systems that could potentially lead to errors and adverse events.
- Know and follow organizational and departmental policies and procedures applicable to assigned duties.
- Avoid taking shortcuts or encouraging others in the organization to shortcut established policies and procedures as a means of facilitating patient care.
- 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 judgment and awareness of potential hazards before taking action.
- Promptly report serious events and incidents in accordance with the Center’s policy and procedure.
- Assume responsibility for one's own professional development and education to improve individual performance and promote patient safety.

Surgical Center Employees and Volunteers – Apple Hill Surgical Center’s employees and its volunteers are responsible for actively participating in the Surgical Center’s patient safety improvement and management program. An active participant will:

- Assume responsibility for identifying processes or systems that could potentially lead to errors and adverse events.
- Know and follow organizational and departmental policies and procedures applicable to assigned duties.
- Avoid taking shortcuts or encouraging others in the organization to shortcut established policies and procedures as a means of facilitating patient care.
- 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 judgment 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.
- Promptly report serious events and incidents in accordance with established Surgical Center’s policy and procedure.
- Assume responsibility for one's own professional development and education to improve individual performance and promote patient safety.

Patients and Families – Apple Hill Surgical Center recognizes that patients and their families play a critical role in ensuring patient safety. In particular, the patient and family can often serve as the final checkpoint to avoid an error and adverse outcome. As such, Apple Hill Surgical Center will provide appropriate education to patients and families to make sure patients and families:

- 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.
- Encourage completion of any specific questionnaires related to satisfaction, quality, or patient safety.

Patient Safety Committee

Composition - The Apple Hill Surgical Center Patient Safety Committee is an interdisciplinary committee comprised of individuals with organizational responsibility for quality, safety, and risk management. Apple Hill Surgical Center's Patient Safety Committee will include the patient safety officer (Medical Director of Apple Hill), one resident of the community (**will not be an agent, employee, or contractor of the facility**), WellSpan Health Corporate Patient Safety representative, one nurse from the facility, the Director and Nurse Manager. All members of the committee will be required to sign a confidentiality attestation, which outlines their responsibilities relative to the sharing or discussion of information dealt with in the committee. The committee shall elect a chairperson who shall periodically report the work of the committee to the Center's Board of Directors.

Frequency of Meetings – The Patient Safety Committee will meet quarterly and minutes will be taken at all meetings.

Goals of the Patient Safety Committee – The patient safety committee will:

- Create an ideal patient safety culture for Apple Hill Surgical Center that is:
 - Just Culture*
 - Educational*
 - Analyzing/Reporting*
 - Continuously Improving*
- Inform and educate Apple Hill Surgical Center staff and patients on patient safety issues and topics
- Create a clinical error reporting system which is easy to use, able to track, trend and identify problems proactively which will be completed in an accurate and timely manner. The above system will include but not be limited to the following factors:
 1. Care of the affected patient(s)
 2. Containment of risk to others
 3. Preservation of factual information for subsequent analysis
 4. Review proactivity sentinel alerts and document appropriate action plans.

Functions – The Patient Safety Committee:

- Provides the oversight and management of the patient safety program. This includes making recommendations to organization leaders and the board of directors about the adequacy of resources allocated to support patient safety activities.
- Guides the development and revision of organization-wide and departmental-specific patient safety policies and procedures to ensure compliance with law, regulation, and accreditation standards and to foster a non-punitive environment for error reporting.
- Establishes and maintains systems for the reporting, tracking, and trending of incidents and other risk management investigations, activities.
- Establishes appropriate mechanisms for the review and analysis of incidents, near misses, serious events, sentinel events, and infrastructure failures, including the appointment of teams to conduct root cause analysis.
- Reviews summaries of all serious and sentinel event root cause analyses to determine whether the review has been thorough and credible in ascertaining the causal factors for the event.
- Recommends corrective action resulting from review and analysis related to any type of event to appropriate Surgical Center and medical staff committees.
- Integrates information gleaned from patient complaints, concerns, and other opinion/feedback as well as employee and medical staff feedback that is directly related to patient safety, either an event that has already occurred or as part of the proactive hazard analyses.
- Identifies opportunities for sharing appropriate information within the organization to demonstrate the impact of the patient safety program to medical staff, employees, and board of directors.
- Reviews and acts on recommendations issued by the Joint Commission on Accreditation for Healthcare Organizations, the Accreditation Association for Ambulatory Health Care, the National Quality Forum, the Food and Drug Administration, the Centers for Disease Control and Prevention, the Patient Safety Authority, the Pennsylvania Department of Health, the Institute for Safe Medication Practices, the Occupational Safety and Health Administration, the Agency for Healthcare Research and Quality, and other groups as appropriate.
- Researches and implements best practice ideas gained from networking and literature reviews.
- Recommends patient safety education and training opportunities for employees based on information developed in the committee and may include case studies, communication skill development, and team training.
- Coordinates all patient safety activities across the organization.
- Develops an annual evaluation process with employees to assess progress in developing a culture of safety in the organization.
- Submits **quarterly** reports on the activities and results of the patient safety program to the Apple Hill Surgical Center Board of Directors.

Scope of the Program

Leadership and Continuous Improvement – The leadership of Apple Hill Surgical Center supports a systematic, coordinated, and continuous approach to the improvement and management of patient safety. This will be achieved through the establishment of policies, procedures, and protocols to support effective responses to actual adverse events: ongoing proactive risk reduction activities to minimize the occurrence of errors or the probability that those errors will reach the patient; involvement of the medical staff, employees, and patients, families; and designing or redesigning processes and systems on the basis of what has been learned internally and externally through patient safety initiatives.

Internal Reporting – In order to have an effective patient safety improvement and management program, there must be an emphasis on reporting all types of events that may harm or have harmed patients. Apple Hill Surgical Center has adopted a non-punitive approach in its management of adverse events and reporting. All members of the medical staff and employees are required to report suspected and or identified medical errors and should do so without the fear of reprisal in relationship to their employment. Apple Hill Surgical Center focuses first and foremost on system process improvements and will not blame the individual(s) involved in the event or seek retribution against the individual for reporting the event. Apple Hill Surgical Center will accept anonymous reports submitted, and will make available to staff anonymous reporting forms established by the PA DOH.

However, in the event that a member of the medical staff or employee participates in willful or malicious misconduct, sabotage, substance abuse, criminal activity, fails to report the event truthfully or in a timely fashion, or makes an egregious error demonstrating a lack of fundamental knowledge necessary to carry-out his/her job responsibilities, Apple Hill Surgical Center may institute disciplinary or corrective action. Failure to report may also cause Apple Hill Surgical Center to report a licensed health care professional to his/her respective state professional licensure board in accordance with Pennsylvania's Medical Care Availability and Reduction of Error Act (Act 13).

Retrospective Analysis – The following types of events may be addressed by the patient safety program:

- Near-Miss and Actual Medication Errors (wrong dose, wrong route, missed dose, wrong drug, wrong patient, wrong administration time)
- Adverse Drug Events (defined as patient harm related to medication use)
- No Harm, Near Miss Events or Incidents (Unintended acts or process variations which do not affect the outcome, but recurrences may lead to adverse outcomes)
- Adverse Clinical Events
- Sentinel Events
- Patient Restraint and Seclusion Events (those resulting in patient injury)
- Selected Administrative Incidents (patient identification, discharge problems, documentation, informed consent issues, advance directives)
- Other Situations or Incidents (other situations which may involve infrastructure/environmental issues, work design, patient care products or equipment)

Employee Education – The Patient Safety Committee will assure that all employees and medical staff members receive appropriate and timely education related to improving patient safety. The committee will assure:

- All new employees of Apple Hill Surgical Center receive an orientation to the Apple Hill Surgical Center Patient Safety Program within one month of their hire.
- Members of the medical staff receive information on the Surgical Center’s Patient Safety Program at the time of initial credentialing.
- Periodically, the committee will assess attitudes of employees regarding patient safety by conducting audits of opinions that seek to assess staff attitudes and knowledge regarding safe practices.
- Every employee or staff member of Apple Hill Surgical Center has the opportunity to attend a patient safety presentation.
- Ongoing education will occur with the adverse events reporting system. The current system is RL Solutions CRS/SRS, a web-based reporting tool used at all facilities of WellSpan Health.
- Staff Annual Performance Evaluations include language on patient safety on which employees or staff members are assessed. Standard language on patient safety is being incorporated into each job description at Apple Hill Surgical Center as well.
- Each staff member is personally responsible for reporting adverse events and potential events to prevent future adverse outcomes.

Patient and Family Education – The committee shall promote patient and family education to enhance their ability to intercept errors before they reach the patient. This education may include:

- Published brochures provided to patients at the time of admission.
- Published brochures for distribution through the offices of medical staff members to their outpatients.
- Educational programs to the community designed to foster appropriate questioning of health care providers.

Patients and families are responsible for providing complete and accurate information and for asking questions when they do not understand what they have been told about the patient’s care or what they are expected to do.

Disclosure – Apple Hill Surgical Center has an ethical obligation to honestly inform patients and appropriate family members of adverse events that result in harm to the patient. It is the policy of Apple Hill Surgical Center that all patients who sustain a serious event will receive notification of the nature of the adverse event. A serious event is equivalent to an “E &/or through I” event in the Apple Hill Surgical Center RL Solutions CRS/SRS. In compliance with PA Act 13, the patient will receive written notification within 7 days of the Surgical Center’s determination of this serious event.

The patient’s attending physician, or his/her designee, shall be informed of the need for this disclosure by Surgical Center staff prior to informing the patient. If the attending physician, or his/her designee, disagrees with the decision to inform the patient, the Medical Director of Apple Hill Surgical Center shall be asked to determine if the patient should be notified of a serious event. If the Medical Director is not available, the Surgical Center will ask the WellSpan Health Corporate Patient Safety Officer to assist with the decision. If that individual is unavailable, the

Director of Apple Hill Surgical Center or his/her designee shall be asked to make the final determination of whether to notify the patient of a serious event.

The attending physician, or his/her designee, shall be strongly encouraged to be present along with the Surgical Center's Medical Director or appointed designee when the patient, and when appropriate, their family, receive verbal and written notification of the serious event. An electronic copy of the patient's written notification of a serious event is maintained.

External Reporting – Depending on the severity of the event or incident, the appropriate authorities, including the Pennsylvania Patient Safety Authority and/or the Department of Health will be notified utilizing the required reporting format. (*Refer to Well Span's Manual of Administrative Policy, Sentinel Event and Other Event Reporting Policy(ies)*)

Management of Events and Reporting

Immediate Management of Event

Upon identification of an error, incident, or event, the patient care provider should:

- Take appropriate steps to care for the patient and minimize negative outcomes.
- Contact the patient's attending physician and other physicians as appropriate to report the error, incident, or event and implement any additional therapy or treatment as ordered by the physician.
- As appropriate, implement steps to contain the risk to others as in possibly a drug or medical device recall.
- Preserve any information or evidence that may be helpful in analyzing the error, incident, or event. This includes physical evidence such as preservation of IV tubing, fluid bags, equipment such as pumps, the unit of blood, or medication labels.
- Report the error, incident, or event immediately to the staff member(s) immediate manager(s).
- Complete the required incident report forms using the RL Solutions CRS/SRS tool. If not available, use downtime procedures.
- Obtain appropriate support for staff members involved in the error, incident, or event as needed.

Internal Reporting

Apple Hill Surgical Center, through its parent WellSpan Health, has contracted with a private vendor (RL Solutions CRS/SRS) who is providing it with an electronic information system for reporting adverse events from Apple Hill Surgical Center using Internet technology. Every employee or staff member will have a password to access the reporting system which is easily accessible from every PC device throughout Apple Hill Surgical Center. Each employee or staff member will undergo training in the use of the reporting system. It has an option for anonymous reporting as well as an identified reporting option. Managers have access to all the adverse event reports and have the capability to modify a report from one of their employees as well. Each manager can generate a report for their area of responsibility based on any time frame.

The Apple Hill Surgical Center Patient Safety Committee will analyze reports from RL Solutions CRS/SRS. Trending will be evaluated and action plans for correction requested as needed. The Patient Safety Committee will maintain an on-going log of these trends. The Apple Hill Surgical Center Performance Improvement Committee and Patient Safety Committee will make quarterly reports to the Board of Directors of Apple Hill Surgical Center and to other WellSpan Health Board and Committees as applicable.

External Reporting

A serious event report or incident as defined in Act 13 must be submitted to the Patient Safety Authority and/or the Department of Health no later than 24-hours after the occurrence or discovery of the serious event or incident. All external reporting shall be coordinated by the Surgical Center's patient safety officer and/or designee. Reports shall be submitted in the format specified by the Patient Safety Authority and/or the Department of Health.

Program Review

In addition, the Apple Hill Surgical Center Patient Safety Committee will periodically perform one or more of the following audits or other such audits deemed appropriate:

- **Organizational Assessment Tool-** this is a AHRQ Survey to assess annually the progress of developing a patient safety culture and processes in Apple Hill Surgical Center. This data will be presented in trended format.
- **Employee Survey-** this is a survey sent out to randomly chosen employees annually to assess the development of a culture of blamelessness and patient safety

Confidentiality

The Apple Hill Surgical Center Patient Safety Program reviews and evaluates patient safety data in a confidential manner. Records, data, and knowledge collected by or for the Committee to review shall be confidential and maintained in a confidential manner. Unauthorized disclosure is absolutely prohibited by Apple Hill Surgical Center. Unauthorized disclosure of Committee information by a Committee member may result in discipline including loss of Committee membership or termination of employment or corrective action including loss of Committee membership, reprimand or non-reappointment for any Medical Staff Committee member.

APPROVED:

BY THE APPLE HILL SURGICAL CENTER
BOARD OF DIRECTORS

DATE:
