UPMC Presbyterian Shadyside Hospital and South Surgery Center
PATIENT SAFETY PLAN
September 2013

I. Purpose: To improve the health and safety of hospital patients through the establishment and implementation of a comprehensive Patient Safety Program.

II. Definitions:

A. Just Culture: from Agency for Healthcare Research and Quality (AHRQ)

- Supports a culture where frontline personnel feel comfortable disclosing errors (including their own) while maintaining professional accountability.
- Recognizes that individual practitioners should not be held accountable for system failings over which they have no control.
- Does not tolerate reckless behavior, conscious disregard of clear risks to patients, or gross misconduct (e.g., falsifying a record, performing professional duties while intoxicated).
- Realizes that competent professionals make errors and acknowledges development of unhealthy norms (shortcuts, "routine rule violations").
- Focuses on fair, consistent and predictable organizational responses to errors.

B. Corrective Action: Any action recommended or taken to promote patient safety as a result of retrospective investigations and/or analyses or Reportable Patient Events or prospective analyses of existing practices, procedures, policies or systems.

C. Healthcare-Associated Infection: A localized or systemic condition that results from an adverse reaction to the presence of an infectious agent or its toxins that:

(1) Occurs in a patient in a health care setting;

(2) Was not present or incubating at the time of admission, unless the infection was related to a previous admission to the same setting; and

(3) If occurring in a hospital setting, meets the criteria for a specific infection site as defined by the Centers for Disease Control and Prevention and its National Health Care Safety Network.

D. Incident: An event, occurrence or situation involving the clinical care of a patient who 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. This term does not include a serious event. (See Section V.B.3 for criteria used to determine if an event is an "Incident").

E. Infrastructure: Structures related to the physical plan and service delivery systems necessary for the provision of health care services in a medical facility.

F. 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.

G. Mcare: Pennsylvania's Medical Care Availability and Reduction of Error Act.

H. Medication Event: Any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient or consumer. Such events may be related to professional practice, health care products, procedures and systems, including prescribing; order communication; product labeling, packaging and nomenclature; compounding, dispensing, distribution, administration, education, monitoring or use. A medication event may be either an incident or serious.

I. National Healthcare Safety Network (NHSN): A secure internet based data collection system managed by the Division of Healthcare Quality Promotion at the Centers for Disease Control and Prevention.

J. Peer Review Organization: A committee or organization consisting of health care providers and/or hospital administrators who evaluate the quality and efficiency of services ordered or performed by a hospital or other health care provider and/or the compliance of a hospital or other health care facility with standards set by an association of health care providers and with applicable laws, rules and regulations.

K. Reportable Patient Event: Any Incident, Medication Event, Sentinel Event or Serious Event.

L. Sentinel Event: A sentinel event is defined by the Joint Commission as an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof. Serious injury specifically includes loss of limb or function. The phrase "or the risk thereof" includes any process variation for which a recurrence would carry a significant chance of a serious adverse outcome.

M. 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. (See Section V.B.2 for criteria used to determine if an event is a "Serious Event").

N. TJC: The Joint Commission.

O. Preventable Serious Adverse Events (PSAE): A preventable serious adverse event is defined as an event that occurs in a health care facility that is within the health care provider's control to avoid, but that occurs because of an error or other system failure and results in a patient's death, loss of body part, disfigurement, disability or loss of bodily function lasting more than seven days or still present at the time of discharge from a health care facility.

III. Scope of Patient Safety Program: Patient safety is a priority for the leadership of UPMC Presbyterian Shadyside and the South Surgery Center with support for a culture of safety and a systematic, coordinated and continuous approach to the improvement and management of patient safety. UPMC Presbyterian Shadyside and the South Surgery Center established and will continue to establish and implement through this Patient Safety Program and through supporting policies and procedures such as:

- Clearly defined roles of the Governing Body, administrators and clinicians who will create, manage and implement the Patient Safety Program
- An effective and timely organization-wide system for the internal report of Reportable Patient Events and Infrastructure Failures
- Protocols for the immediate clinical and non-clinical responses to Serious Events
- A timely system for the reporting of appropriate information to external governmental agencies, regulatory bodies and other patient safety organizations
- Protocols and tools for investigating and analyzing Reportable Patient Events and Infrastructure Failures
- Proactive risk reduction activities through ongoing review of incidents and events identify opportunities to improve patient safety and implement/revise processes and procedures
- Design and implementation of processes to meet TJC's National Patient Safety Goals
- Protocols and tools for the creation and implementation of corrective actions designed to reduce Serious Events and Incidents
- Protocols to encourage and support staff to participate in all aspects of the Patient Safety Program through education and a Just Culture climate for reporting of reportable patient events
- Periodic reports to the Governing Body concerning patient safety
- Mechanisms for receiving and considering the input of employees, patients and patient families concerning patient safety issues
- Protocols for the communication to patients and/or guardians and family members of the significant aspects of patient care, including disclosure and notification of Serious Events in compliance with Mcare and TJC standards
- Procedures to ensure compliance to Act 52 of 2007; health-associated infections and amendments to the Mcare Act.

IV. Authority and Responsibility:

A. Board of Directors: The overall authority for creation and implementation of the Patient Safety Program rests with each Hospital's Governing Body, which shall follow applicable policies and procedures set by UPMC. The Governing Body has delegated its authority to implement and maintain the various components of the Patient Safety Program to the Hospital's Chief Executive Officer.

B. Chief Executive Officer: The Chief Executive Officer, in collaboration with the Patient Safety Officer and administrators and medical staff leaders, is charged with the creation and implementation of the Patient Safety Program. This Program will be integrated with other Hospital and UPMC activities such as performance improvement, environmental safety and risk management.

C. Patient Safety Officer: The Patient Safety Officer shall be that individual designated by each Hospital's Chief Executive Officer to be responsible to coordinate the Patient Safety Program and to carry out specific aspects of the Program. The Patient Safety Officer will be accountable to the Chief Executive Officer, and Hospital Governing Body. The Patient Safety Officer for UPMC will provide direction to each hospital's Patient Safety Officer. The duties of the hospital's Patient Safety Officer, either alone or in cooperation with the Patient Safety Committee shall include:

- Overseeing the creation of, and reviewing, evaluating and refining the Patient Safety Program on an ongoing basis

- Serving as a member of and coordinating and prioritizing the activities of the Patient Safety Committee

- Overseeing the Hospital's system for internal reporting of Reportable Patient Events and Infrastructure Failures

- Overseeing and ensuring the reasonable investigations of Reportable Patient Events

- Fostering a culture of proactive risk assessment and analysis

- Fostering the development/revision of processes to enhance patient safety

- Coordinating communications with patients and families about significant aspects of patient care, including the disclosure of Serious Events in accordance with Hospital Policy, Mcare and TJC standards

- Analyzing investigations of Reportable Patient Events and taking such action as is immediately necessary to ensure patient safety

- Reviewing and monitoring Corrective Actions

- Creating and presenting to the Patient Safety Committee reports of investigations of Serious Events and Incidents and Corrective Actions taken as a result of such investigations

- Serving as a link to the Governing Body, and Chief Executive Officer, and various Hospital and UPMC peer review organizations on matters related to patient safety

D. Patient Safety Committee: The Patient Safety Committee shall meet at least monthly to oversee the Patient Safety Program and carry out the duties described in Sections 307(b)(2) and 310(a) of Mcare.

- The Patient Safety Committee shall be composed of:
  Vice President, Medical Staff Affairs/designee;
  Vice President, Patient Care Services/designee – Presbyterian Campus/designee;
  Vice President, Patient Care Services/designee – Shadyside Campus/designee;
  Vice President, Inpatient and Emergency Service, Western Psychiatric Institute and Clinic Vice President, Patient Care Services/designee – Western Psychiatric Institute and Clinic
  Director of Patient Safety & Innovation/Patient Safety Officer
  Patient Safety Specialist – Presbyterian Campus
  Patient Safety Specialist – Shadyside Campus
  Director of Regulatory and Compliance, Presbyterian/ ShadysideAccreditation and Regulatory Specialist – Presbyterian Campus
  Accreditation and Regulatory Specialist – Shadyside Campus
  Risk Management Specialist – Western Psychiatric Institute and Clinic

Senior Director of Operations, Hillman/designee
Senior Director of Clinical Operations/designee (Network Cancer Centers)
Director, South Surgery Center/Patient Safety Officer
Clinical Coordinator, South Surgery Center
Professional RN, South Surgery Center
Three (3) Community Members which includes one (1) for South Surgery Center

a. The community members shall not be agents, employees or contractors of Hospital.
b. No more than one (1) member shall be a member of the Governing Body.

- The Patient Safety Committee shall:
  a. Receive, review and evaluate:
     1) Serious Event, Incident reports, PSAEs, and Sentinel Events;
     2) Reports from the Patient Safety Officer/designee, including reports regarding trends, investigations and Corrective Actions;
     3) Reports from any Data Collection Agency appointed by the Pennsylvania Patient Safety Authority advising of immediate changes that can be instituted to reduce Serious Events and Incidents.
  b. Receive and act upon notices and reports received from the Pennsylvania Patient Safety Authority concerning the investigations of Serious Events reported anonymously to the Authority.
     1) The Patient Safety Committee shall delegate to the Patient Safety Officer the obligation to send the results of investigations to the Patient Safety Authority and to do all things necessary to cooperate with the Authority and comply with care.
  c. Make recommendations to eliminate future Serious Events, Incidents and Sentinel Events.
  d. Report on a quarterly basis to each Hospital's Chief Executive Office and the Governing Body regarding the number of Serious Events and Incidents and its recommendations to eliminate future Serious Events and Incidents.
     1) This obligation may be carried out on behalf of the Patient Safety Committee by the Patient Safety Officer or Vice President, Patient Care Services.

- The South Surgery Center as defined in section 310 (a) (2) as an ambulatory surgery facility will utilize the Presbyterian/Shadyside Patient Safety Committee forum for the reporting of their incidents/events to the listed South Surgery membership of the Patient Safety Committee. This report of events/incidents will be completed by the Director South Surgery Center who is the Patient Safety Officer or designee.

E. Patient Safety and Quality Peer Review Committee: The Patient Safety and Quality Peer Review Committee shall be comprised solely of health care providers from varying disciplines throughout the Hospital and shall be organized and operated as a Peer Review Organization under the Pennsylvania Peer Review Protection Act. The Patient Safety and Quality Peer Review Committee, in cooperation with the Patient Safety

Officer, shall coordinate all peer review activities related to the reporting, investigation and analysis of Reportable Patient Events.

1. The Patient Safety and Quality Peer Review Committee, in conjunction with the Patient Safety Officer, shall:
   a. Review and evaluate Reportable Patient Events.
   b. Oversee and monitor reporting to external organizations.
   c. Receive and evaluate information and reports relating to patient safety from other Peer Review Organizations; complaints and feedback from patients and patient families; reports from staff employees and relevant safety literature.
   d. Investigate or delegate to another Peer Review Organization for investigation, all Incidents, Serious Events and Sentinel Events.
   e. Determine what Reportable Patient Events qualify as Serious and/or Sentinel Events.
   f. Complete or delegate to another Peer Review body for completion, root cause, intensive or other analyses of appropriate Reportable Patient Events.
   g. Receive, evaluate and act upon recommendations relating to patient safety made by the Pennsylvania Patient Safety Authority, TJC, the Pennsylvania Department of Health, the Center for Disease Control, the United States Food and Drug Administration and other governmental, regulatory and private patient safety organizations.
   h. Develop, help to implement and monitor appropriate Corrective Actions.
   i. Develop procedures for and oversee the implementation of communications with patients, guardians and patient family members, as appropriate, of all significant aspects of patient care, including written notification of Serious Event (procedures for communications and notices shall comply with Mcare and TJC standards).

   j. Coordinate proactive risk reduction activities, including the selection and assessment of at least one (1) high-risk process every 18 months.

V. Summaries of Key Elements of Patient Safety Program:

A. Internal Reporting System:

1. Hospital has in place a system for reporting Reportable Patient Events and Infrastructure Failures 24 hours a day, 7 days a week.

2. The basic elements of the reporting system are:
   a. An Initial Incident/Event Report is generated by the individual discovering any Reportable Patient Event.
   b. Managers/Supervisors receive notifications that an event/incident was reported in their department/area.
   c. Staff may communicate any potentially Reportable Patient Event to their manager or directly to the Patient Safety Officer.

3. In accordance with the Pennsylvania Whistleblower Law, 43 P.S. 1421, et. Seq., no adverse action, including discharge discrimination or retaliation regarding compensation, terms, conditions, location or privileges of employment or staff membership, shall be taken against any staff member or employee for the sole reason

that the staff member or employee has or is about to report a Reportable Patient Event.

4. Staff members or employees may be subject to disciplinary action if they knowingly make false statements in a report, knowingly cause a false report to be filed or fail to report a Serious Event with knowledge of the event and the obligation to report.

5. Employees and staff shall be educated about and encouraged to actively participate in the reporting process as outlined by the established policy. However, any health care worker, including physicians who have concerns about the safety or quality of care provided by the hospital may report these concerns to The Joint Commission without fear of retaliatory disciplinary action because of such reporting.

B. Determination of Serious Events and Incidents. The Patient Safety Officer, the PQPR Committee and others involved in implementing this Safety Plan shall identify "Serious Events" and "Incidents" reportable to the Patient Safety Authority in accordance with the following criteria:

1. **The event occurs in a Medical Facility of UPMC Presbyterian Shadyside or the South Surgery Center.** A Medical Facility is defined by MCARE as a Hospital or hospital-based ambulatory surgical facility (ASF).
    1) An event is **not** considered to occur in a Medical Facility just because it occurs in a facility owned by or affiliated with UPMC. For example, an event that occurs in a physician's private office, even if located on property owned by UPMC, does not occur in a Medical Facility as defined by MCARE.
2. A Reportable Patient Event shall be considered a **Serious Event** if all of the following exist:
    a. The event involves the clinical care of a patient.
        (1) An event is **not** considered to involve clinical care merely because the patient is in a Medical Facility of UPMC. The event must be related to some aspect of medical care, treatment, observation, diagnosis or examination.
    b. **The event results in death or compromises patient safety.**
    c. **The event results in unanticipated injury.**
    An injury is **NOT** unanticipated if it is a recognized and accepted risk of the clinical care that can occur without any deviation from the standard of care and either occurs on a not infrequent basis to patients in general or is well understood to be a likely outcome for a particular patient
    d. **The event required the delivery of additional health care services.** The following are **NOT** considered additional health care services:
        i) Steps taken to determine if there are any injuries, such as x-rays or other diagnostic tests,
        ii) Minor acts of first aid that do not need to be performed by a professional health care provider, such as cleansing of a cut or abrasion, application of a topical antibiotic, application of a bandage, etc.

3 A Reportable Patient Event shall be considered an **Incident** if the following exist:
    a. **The event involves the clinical care of the patient: and**
    b. **If one or more of the following criteria are <u>NOT</u> met:**
        1) results in death <u>or</u> compromises patient safety;

2) results in unanticipated injury
3) Required delivery of additional health care services.

C. Determination of Sentinel Events

The Patient Safety Officer, the Patient Safety Peer Review Committee will identify sentinel events using TJC definition of a sentinel event and TJC Sentinel Event Policy as references.

D. Determination of Preventable Serious Adverse Events (PSAE)

The Patient Safety Officer, the Patient Safety Peer Review Committee will identify "Preventable Serious Adverse Events: using the process outlined in Policy "HS-PT1204" Preventable Serious Adverse Events.

1. The following principles will be used in making this determination:
   a. **The error or event must be within the control of the facility.** Errors that may have occurred in the manufacture of drugs, devices, or equipment, well before the materials reached a facility's doors, are examples of events that would be outside of the UPMC's control.
   b. **The error or event must be the result of a mistake made by UPMC.** These include errors in which UPMC failed to successfully carry out a practice that would have, in all probability, prevented harm to the patient.
   c. **The error or event must result in significant harm.** The list of events should be limited to those that yield very serious results.
   d. **The error or event must be clearly and precisely defined.** A great level of specificity is required to identify events that could result in a facility foregoing payment.

2. PSAEs will be coded as such in Riskmaster to facilitate communication with fiscal services and Health Information Management.

F. Identification, Reporting and Disclosure of Healthcare-Associated Infections (HAI)

1. Identification of HAI

Infections identified during hospitalization or after a procedure will be reviewed by an infection control practitioner (ICP) to determine whether or not the infection is healthcare associated (HA) as defined by CDC criteria. If criteria are met, the infection is confirmed to be HA. Should the ICP be unable to determine whether the infection is HA, the case will be referred to an infectious disease physician specialist for confirmation.

2. Reporting of HAI

a. Each identified case of HAI will be entered into CDC's National Health Care Safety Network (NHSN) within 24 hours of confirmation.
b. The Patient Safety Authority (PSA) and the Department of Health (DOH) have been given the right to access NHSN to meet serious event reporting requirements under MCARE.
c. HAI identified at any Surgery Center will be directly entered into the PA PSRS as serious events within 24 hours of determination.
d. Where denominator data is required for surgical site infections, such data will be entered into NHSN 30 days after the monthly plan date (i.e. February data will be

entered no later than March 30.) See Addendum (page 15) Act 52 of 2007 Medical Care Availability and Reduction of Error (MCARE) Act.

3. Disclosure of HAI

a. HAI will be considered serious events under Mcare.

b. Letters of disclosure will be sent to the patient/significant other within 7 days of confirmation of the infection.

G. Peer Review Investigations:

1. Reportable Patient Events will be reviewed and categorized by or on behalf of the Patient Safety and Quality Peer Review Committee.

2. Serious Events, Incidents and sentinel events will be appropriately investigated by or on behalf of the Patient Safety and Quality Peer Review Committee or another designated Peer Review body.

H. Peer Review Analyses:

1. Retrospective Analyses:
   a. Based upon information gathered during investigations and any other relevant information, the Patient Safety and Quality Peer Review Committee and/or other Peer Review body shall determine the need for and conduct appropriate root cause, intensive or other analyses to identify the cause or causes of Serious Events, Sentinel Events and selected Incidents.

2. Prospective Risk Assessments:
   a. The Patient Safety and Quality Peer Review Committee and/or other Peer Review body shall, either individually or collaboratively:
      1) carry out ongoing prospective risk assessments of Hospital/ASF practices, policies, procedures, systems and organizations utilizing failure mode analyses or other methodologies to identify need for improvement;
      2) conduct a focused prospective assessment of at least one (1) high-risk process within the Hospital/ASF every 18 months;
      3) serve as resources and consultants concerning patient safety for administrators and clinicians who are creating new practices, policies, procedures and systems.
   b. The Patient Safety Officer or delegated individual shall individually or collectively compare current policies, procedures and processes to published risk reduction activities and revise internal processes accordingly.

I. Process Improvements:

1. Based upon ongoing peer review investigations and analyses, the Patient Safety and Quality Peer Review Committee and other Peer Review bodies shall strive to develop recommended Process Improvements which shall be forwarded to the Patient Safety Officer.

2. Based upon its review of reports from the Patient Safety Officer, reports from the Pennsylvania Patient Safety Authority and reports of Serious Events, Incidents and

Sentinel Events, the Patient Safety Committee shall make recommendations for Corrective Actions/Process Improvements and communicate such recommendations to the Hospital/ASF through the Patient Safety Officer.

3. The Patient Safety Officer in collaboration with other members of one or more Peer Review bodies shall analyze recommended Process Improvements and determine the scope and timing of any Corrective Actions to be implemented by the Hospital/ASF

4. The Patient Safety Committee or other designated Peer Review body shall monitor and evaluate implemented Corrective Actions on an ongoing basis to determine their effectiveness.

J. Patient Safety Education:

1. Hospital/ASF has focused on patient safety education to the Board, Hospital leaders, medical leadership, Hospital staff and patients.

2. The Hospital/ASF routinely participate in local, regional and national coalitions to improve patient safety. Several examples include the Patient Safety Authority, Hospital and Health System Association of Pennsylvania, Agency for Healthcare Research and Quality, Institute for Safe Medication Practices, American Hospital Association, and TJC.

3. Hospital/ASF has built quality improvement and patient safety policies into staff orientation and continuing education materials and patient and family educational materials.

4. Patient safety has been incorporated in the annual education requirements of all staff members.

K. Communications with Patients and Patient Families:

1. Hospital/ASF will work collaboratively with its clinical staff to inform patients, and when appropriate, their families, about the patient's plan of care and outcome of care, including unanticipated results.
   a. Communications should be made in language appropriate to the patient's educational level and cultural status.

2. Hospital/ASF will coordinate the process by which patients, family members and/or designees are provided written notices within 7 days of the discovery of a Serious Event.
   a. All written notices to patients shall be created and communicated in the manner and form approved by the Patient Safety and Quality Peer Review Committee and or its designee(s) as coordinated by the Patient Safety Officer.
      1) Notices shall go to the patient and any family member(s) and/or designee(s) authorized by the patient.
      2) If the patient is unable to give consent, notification will be given to an adult member of the patient's immediate family, or if none known, to the closest adult family member.
      3) For a minor patient, notification will be given to a parent or guardian.

4) If there is no family or designated representative a copy of the letter will be placed on file.

L. External Reporting:

1. The Patient Safety Officer, in collaboration with the Patient Safety and Quality Peer Review Committee, shall oversee all reporting to external organizations. The Patient Safety Officer may delegate the actual creation and forwarding of such reports to one (1) or more Peer Review bodies or individual members of such Peer Review bodies.
   a. Serious Events shall be reported to the Pennsylvania Department of Health and Patient Safety Authority within 24 hours of confirmation using the Pennsylvania – Patient Safety Reporting System (PA-PSRS).
   b. Incidents shall be reported to the Patient Safety Authority using the PA-PSRS.
   c. Infrastructure Failures shall be reported to the Department of Health within 24 hours of confirmation using the PA-PSRS.
   d. Reports to the Food and Drug Administration, the Center for Disease Control, Pennsylvania Department of Health and other organizations shall be made in accordance with applicable laws and Hospital policy.
   e. HAI will be reported to the National Healthcare Safety Network as required by Act 52 of 2007.

2. Licensed County Office of Behavioral Health programs will have local definitions and practices for reporting.

M. Anonymous Reporting to the Patient Safety Authority

1. A healthcare worker who believes that a serious event has occurred and has reported the event through the hospitals/ASF's internal reporting system may file an anonymous report with the Patient Safety Authority.

2. The healthcare worker must submit the event on the form designated for this purpose by the Patient Safety Authority.
   - This form is available to staff on the UPMC Infonet.

Revised: September 2013

Addendum
UPMC Presbyterian Shadyside
and South Surgery Center
Patient Safety Plan

Allegheny County
Process for Root Cause Analysis (RCA) of Sentinel Events
Pertains to Western Psychiatric Institute and Clinic Only

Overview

As an integral component of the Mayview Closure procedures, the Allegheny County Department of Human Services Office of Behavioral Health (OBH) shall be required by the Pennsylvania Office of Mental Health and Substance Abuse Services (OMHSAS) to complete a Root Cause Analysis (RCA) on all incidents identified as meeting the definition of a sentinel event. OBH has arranged for Community Care Behavioral Health to be its agent in facilitating these RCAs.

This requirement serves to help ensure a culture of consumer safety priorities and appropriate action/reaction when a sentinel event occurs. This methodology has a positive impact on the provision of care and services; assists in the prevention of similar incidents in the future; establishes a benchmark for improvement opportunities; and helps assert and maintain public trust in the services provided.

Root Cause Analysis is an investigative process that began in the airline industry to determine the underlining cause of airplane accidents. It was transposed to the health care setting in the mid-1990s by The Joint Commission. OMHSAS has utilized this process in the state hospital system since the mid-1990s.

The basic concept of a RCA is to conduct a detailed investigation of the circumstances of an event until the specific cause(s) and the relevant system cause(s) are identified. If at any time during the investigation, critical issues that require immediate intervention are discovered, such issues must be addressed as quickly as possible. Ultimately, the goal of the RCA is to reduce risk and promote safety, and to arrive at recommendations on how to best prevent sentinel events from happening again.

A sentinel event is defined as an unexpected occurrence involving death or serious physical or psychological injury, or risk thereof, unrelated to the natural course of an individual's illness or underlying condition. For this process, the sentinel event will involve one or more persons who receive or have received mental health services from a contracted provider of the Allegheny County Department of Human Services or Community Care Behavioral Health, or an event that impacts in a significant manner on the entire mental health system. Examples of sentinel events involving person(s) include:

- Allegation/confirmation of rape or homicide
- A consumer being the victim or alleged perpetrator of a serious crime (major felony)
- An unexplained/unexpected death of a consumer
- Serious injury (loss of limb or function), depending on the circumstances
- Apparent suicide/serious suicide attempt

Examples of systems sentinel events include:

- An unexplained fire at a residence
- A hostage situation
- An unexplained and significant increase in adverse events associated with one particular provider or the system as a whole

Process

OBH and Community Care have established policies and procedures to ensure the reporting, prompt review and needed follow-up of significant incidents involving mental health consumers in Allegheny County. Some significant incidents will also be determined as sentinel events and a RCA investigation may be a part of the needed follow-up activities. This process will outline the steps for identifying, initiating and conducting RCAs for sentinel events in Allegheny County:

1. OBH and Community Care will meet on a weekly basis to review significant incidents that have been reported involving mental health consumers in Allegheny County. After the review, when it is determined that a sentinel event has occurred in the community, Community Care will notify the individual's lead provider (Outpatient, Service Coordination or Community Treatment Team) that they will need to complete a RCA investigation of the identified sentinel event and will need to submit a RCA report and action plan upon completion of their investigation. For high profile and/or very serious incidents, OBH and Community Care may initiate the RCA process immediately upon learning of the incident, prior to the weekly review. Alternatively, a Joint Commission accredited provider may initiate a RCA investigation prior to a request from Community Care and OBH and will be responsible for notification to Community Care and OBH. Also, a non-Joint Commission accredited provider may request that Community Care/OBH initiate a RCA.

2. Community Care will be available to provide technical assistance on the RCA process for providers as needed.

3. OBH, Community Care and OMHSAS may request to participate with the provider in their internal RCA meetings and investigation.

4. Providers will be required to submit initial RCA reports and action plans within one month of notification from Community Care that a RCA investigation is needed. Completed RCA reports and action plans will be reviewed jointly by OBH and Community Care.

5. For sentinel events that require further analysis as determined by the OBH/Community Care review, a system RCA meeting will be convened. Criteria for holding a system RCA meeting is as follows:

    a. Level 1 (system RCA meeting required): unexplained/unexpected death, arrest for felony, serious injury or other serious negative event involving a person who is actively connected with mental health services. Actively connected with mental health services is defined as participating in 3 or more outpatient service events within the past 12 months, or any combination of mental health inpatient and mental health outpatient services within the past 12 months.
    b. Level 2 (need for system RCA meeting will be assessed): unexplained/unexpected death, arrest for felony, serious injury or other serious negative event involving a person who has had one or more assessments or other brief encounters with the mental health system

within the past 12 months, without actively connecting with mental health services. Review will include efforts made to engage the person in services/supports.

c. Level 3 (system RCA meeting not needed): an anticipated death due to a known medical illness/condition, exacerbation of illness that follows the normal or expected course of illness, or death/injury that is clearly accidental and unrelated to a person's mental illness.

6. For providers accredited through The Joint Commission, the system RCA meeting will be facilitated by the lead provider and will include representatives from OBH, Community Care, OMHSAS, AHCI, and other involved providers. For providers not accredited by The Joint Commission, the system RCA meeting will be facilitated by Community Care and will also include representatives from the provider(s), OBH, OMHSAS and AHCI. During the system RCA meetings, additional recommendations/action steps may be identified and providers will be asked to incorporate these into their final report.

7. Providers will be required to submit final reports and action plans to Community Care within two weeks of the system RCA meeting. Once final reports are received from providers, Community Care will prepare a summary report of recommendations. The summary report and specific action steps identified will be forwarded to OBH. OBH will review the summary recommendations with behavioral health providers at the monthly Allegheny Behavioral Health Providers Meeting. OBH will also forward these summary recommendations to OMHSAS.

8. OBH will be responsible for meeting with providers on a regular basis to monitor the progress of the identified action steps on the final provider RCA reports.

ACT 52 OF 2007
MEDICAL CARE AVAILABILITY AND REDUCTION OF ERROR (MCARE) ACT
CHAPTER 4. HEALTH CARE-ASSOCIATED INFECTIONS
40 P.S. § 1303.401 – 1303.411 (2007)

§ 1303.401. Scope of chapter

This chapter relates to the reduction and prevention of health care-associated infections.

§ 1303.402. Definitions

The following words and phrases when used in this chapter shall have the meanings given to them in this section unless the context clearly indicates otherwise:

"AMBULATORY SURGICAL FACILITY." An entity defined as an ambulatory surgical facility under the act of July 19, 1979 (P.L. 130, No. 48), known as the Health Care Facilities Act.

"ANTIMICROBIAL AGENT." A general term for drugs, chemicals or other substances that kill or slow the growth of microbes, including, but not limited to, antibacterial drugs, antiviral agents, antifungal agents and antiparasitic drugs.

"AUTHORITY." The Patient Safety Authority established under this act.

"CENTERS FOR DISEASE CONTROL AND PREVENTION" or "CDC." The United States Department of Health and Human Services Centers for Disease Control and Prevention.

"COLONIZATION." The first stage of microbial infection or the presence of nonreplicating microorganisms usually present in host tissues that are in contact with the external environment.

"COUNCIL." The Pennsylvania Health Care Cost Containment Council established under the act of July 8, 1986 (P.L. 408, No. 89), known as the Health Care Cost Containment Act.

"DEPARTMENT." The Department of Health of the Commonwealth.

"FUND." The Patient Safety Trust Fund as defined in section 305

"HEALTH CARE-ASSOCIATED INFECTION." A localized or systemic condition that results from an adverse reaction to the presence of an infectious agent or its toxins that:

1) occurs in a patient in a health care setting;

2) was not present or incubating at the time of admission, unless the infection was related to a previous admission to the same setting; and

3) if occurring in a hospital setting, meets the criteria for a specific infection site as defined by the Centers for Disease Control and Prevention and its National Healthcare Safety Network.

"HEALTHCARE FACILITIES ACT." The act of July 19, 1979 (P.L. 130, No. 48), known as the Health Care Facilities Act.

"HEALTH CARE FACILITY." A hospital or nursing home licensed or otherwise regulated to provide health care services under the laws of this Commonwealth.

"HEALTH PAYOR." An individual or entity providing a group health, sickness or accident policy, subscriber contract or program issued or provided by an entity, including any one of the following:

1) The act of June 2, 1915 (P.L. 736, No. 338), known as The Workers' Compensation Act.

2) The act of May 17, 1921 (P.L. 682, No. 284), known as The Insurance Company Law of 1921

3) The act of December 29, 1972 (P.L. 1701, No. 364), known as The Health Maintenance Organization Act.

4) The act of May 18, 1976 (P.L. 123, No. 54), known as The Individual Accident and Sickness Insurance Minimum Standards Act.

5) 40 Pa.C.S. Ch. 61 (relating to hospital plan corporations).

6) 40 Pa.C.S. Ch. 63 (relating to professional health services plan corporations).

"MEDICAL ASSISTANCE." The Commonwealth's medical assistance program established under the act of June 13, 1967 (P.L. 31, No. 21), known as The Public Welfare Code.

"METHICILLIN-RESISTANT STAPHYLOCOCCUS AUREUS" or "MRSA." A strain of bacteria that is resistant to certain antibiotics and is difficult to treat medically.

"MULTIDRUG-RESISTANT ORGANISM" or "MDRO." Microorganisms, predominantly bacteria, that are resistant to more than one class of antimicrobial agents.

"NATIONAL HEALTHCARE SAFETY NETWORK" or "NHSN." A secure Internet-based data collection system managed by the Division of Healthcare Quality Promotion at the Centers for Disease Control and Prevention.

"NATIONALLY RECOGNIZED STANDARDS." Standards developed by the Department of Health and Human Services Centers for Disease Control and Prevention (CDC) and its National Healthcare Safety Network.

"NURSING HOME." An entity licensed as a long-term care nursing facility under the act of July 19, 1979 (P.L. 130, No. 48), known as The Health Care Facilities Act.

"SURVEILLANCE SYSTEM." An ongoing and comprehensive method of measuring health status, outcomes and related processes of care, analyzing data and providing information from data sources within a health care facility to assist in reducing health care-associated infections.

§ 1303.403. Infection control plan

a) DEVELOPMENT AND COMPLIANCE. – Within 120 days of the effective date of this section, a health care facility and an ambulatory surgical facility shall develop and implement an internal infection control plan that shall be established for the purpose of improving the health and safety of patients and health care workers and shall include:

1) A multidisciplinary committee including representatives from each of the following if applicable to that specific health care facility:

    a. Medical staff that could include the chief medical officer or the nursing home medical director.
    b. Administration representatives that could include the chief executive officer, the chief financial officer or the nursing home administrator.
    c. Laboratory personnel.
    d. Nursing staff that could include a director of nursing or a nursing supervisor.
    e. Pharmacy staff that could include the chief of pharmacy.
    f. Physical plant personnel.
    g. A patient safety officer or designee
    h. Members from the infection control team, which could include an epidemiologist.
    i. The community, except that these representatives may not be an agent, employee or contractor of the health care facility or ambulatory surgical facility.

2) Effective measures for the detection, control and prevention of health care-associated infections.

3) Culture surveillance processes and policies.

4) A system to identify and designate patients known to be colonized or infected with MRSA or other MDRO that includes:

    a. The procedures necessary for requiring cultures and screenings for nursing home residents admitted to a hospital.
    b. The procedures for identifying other high-risk patients admitted to the hospital that necessitate routine cultures and screening.

5) The procedures and protocols for staff who may have had potential exposure to a patient or resident known to be colonized or infected with MRSA or MDRO, including cultures and screenings, prophylaxis and follow-up care.

6) An outreach process for notifying a receiving health care facility or an ambulatory surgical facility of any patient known to be colonized prior to transfer within or between facilities.

7) A required infection-control intervention protocol which includes:

    a. Infection control precautions based on nationally recognized standards, for general surveillance of infected or colonized patients.
    b. Intervention protocols based on evidence-based standards.
    c. Isolation procedures.
    d. Physical plant operations related to infection control.
    e. Appropriate use of antimicrobial agents.
    f. Mandatory educational programs for personnel.
    g. Fiscal and human resource requirements.

8) The procedure for distribution of advisories issued under section 405(b)(4) so as to ensure easy access in each health care facility for all administrative staff, medical personnel and health care workers.

b) DEPARTMENT REVIEW. – No later than 14 days after implementation of its infection control plan, a health care facility and an ambulatory surgical facility shall submit the plan to the department. The department shall review each health care facility's and ambulatory surgical facility's infection control plan to ensure compliance under the Health Care Facilities Act and section 408(3) If, at any time, the department finds that an infection control plan does not meet the requirements of this chapter or any applicable laws, the health care facility or ambulatory surgical facility shall modify its plan to come into compliance.

c) NOTIFICATION. – Upon submission to the department of its infection control plan, a health care facility and an ambulatory surgical facility shall notify all health care workers, physical plant personnel and medical staff of the facility of the infection control plan. Compliance with the infection control plan shall be enforced by the facility.

§ 1303.404. Health care facility reporting

a) NURSING HOME REPORTING. – In addition to reporting pursuant to The Health Care Facilities Act, a nursing home shall also electronically report health care-associated infection data to the department and the authority using nationally recognized standards based on CDC definitions, provided that the data is reported on a patient-specific basis in the form, with the time for reporting and format as determined by the department and the authority.

b) HOSPITAL REPORTING. – A hospital shall report health care-associated infection data to the CDC and its National Healthcare Safety Network no later than 180 days following the effective date of this section. A hospital shall:

1) Report all components as defined in the NHSN Manual, Patient Safety Component Protocol and any successor edition, for all patients throughout the facility on a continuous basis.

2) Report patient-specific data to include, at a minimum, patient identification number, gender and date of birth. The patient identification number must be compatible with the patient identifier on the uniform billing forms submitted to the council.

3) Report data on a monthly basis in accordance with protocols defined in the NHSN Manual as updated by the CDC.

4) Authorize the department, the authority and the council to have access to the NHSN for facility-specific reports of health care-associated infection data contained in the NHSN database for purposes of viewing and analyzing that data.

c) STRATEGIC ASSESSMENTS. – Each hospital, other than those currently using a qualified electronic surveillance system, shall by December 31, 2007, conduct a strategic assessment of the utility and efficacy of implementing a qualified electronic surveillance system pursuant to subsections (d) and (e) for the purpose of improving infection control and prevention. The assessment shall also include an examination of financial and technological barriers to implementation of a qualified electronic surveillance system pursuant to subsections (d) and (e). The assessment shall be submitted to the department within 14 days of completion.

d) QUALIFIED ELECTRONIC SURVEILLANCE SYSTEM. – A qualified electronic surveillance system shall include the following minimum elements:

1) Extractions of existing electronic clinical data from health care facility systems on an ongoing, constant and consistent basis.

2) Translation of nonstandardized laboratory, pharmacy and/or radiology data into uniform information that can be analyzed on a population-wide basis.

3) Clinical support, educational tools and training to ensure that information provided under this subsection will assist the hospital in reducing the incidence of health care- associated infections in a manner that meets or exceeds benchmarks.

4) Clinical improvement measurements designed to provide positive and negative feedback to health care facility infection control staff.

5) Collection of data that is patient-specific for the entire facility.

e) ELECTRONIC SURVEILLANCE SYSTEM IMPLEMENTATION. – Except as otherwise provided in this subsection, a hospital shall have a qualified electronic surveillance system in place by December 31, 2008. The following apply:

1) If a determination has been made under subsection (c) that a qualified electronic surveillance system can be implemented, the hospital shall comply with subsection (f) until implementation.

2) If a determination has been made under subsection (c) that a qualified electronic surveillance system cannot be implemented, by December 31, 2008, the hospital shall comply with subsection (f) until such time as a qualified electronic surveillance system is implemented.

f) SURVEILLANCE SYSTEM. – Until a hospital implements a qualified electronic surveillance system, the facility shall use a surveillance system that includes:

1) A written plan of the elements of the surveillance process to include, but not be limited to, definitions, collection of surveillance data and reporting of information.

2) Identification of personnel resources that will be used in the surveillance process.

3) Identification of information or technological support needed to implement thesurveillance system.

4) A process for periodic evaluation and validation to ensure accuracy of surveillance.

g) CONTINUED REPORTING. – Until hospitals begin reporting to NHSN and have authorized access to the department, the authority and the council, hospitals shall continue to meet reporting requirements pursuant to Chapter 3 of this act and section 6 of the act of July 8, 1986 (P.L. 408, No. 89), known as The Health Care Cost Containment Act.

§ 1303.405. Patient Safety Authority jurisdiction.

a) HEALTH CARE FACILITY REPORTS TO AUTHORITY. – The occurrence of a health care-associated infection in a health care facility shall be deemed a serious event as defined in section 302 The report to the authority shall also be subject to all of the confidentiality protections set forth in section 311 The occurrence of a health care-associated infection shall only constitute

a serious event for hospitals if it meets the criteria for reporting as defined by the current CDC and NHSN Manual, Patient Safety Component Protocol and any successor edition.

b) DUTIES. – In addition to its existing responsibilities, the authority is responsible for all of the following:

1) Establishing, based on CDC definitions, uniform definitions using nationally recognized standards for the identification and reporting of health care-associated infections by nursing homes.

2) Publishing a notice in the Pennsylvania Bulletin stating the uniform reporting requirements established pursuant to this subsection and the effective date for the commencement of required reporting by hospitals consistent with this chapter, which, at a minimum, shall begin 120 days after publication of the notice.

3) Publishing a notice in the Pennsylvania Bulletin stating the uniform reporting requirements established pursuant to this subsection and section 404(a) and the effective date for the commencement of required reporting by nursing homes consistent with this chapter, which, at a minimum, shall begin 120 days after publication of the notice.

4) Issuing advisories to health care facilities in a manner similar to section 304(a)(7).

5) Including a separate category for providing information about health care-associated infections in the annual report under section 304(c).

6) Creating and conducting training programs for infection control teams, health care workers and physical plant personnel about the prevention and control of health care- associated infections. Nothing in this act shall preclude the authority from working with the department or any organization in conducting these programs.

7) Appointing an advisory panel of health care-associated infection control experts, including at least one representative of a not-for-profit nursing home, at least one representative of a for-profit nursing home, at least one representative of a county nursing home and at least two representatives of a hospital, one of which must be from a rural hospital, to assist in carrying out the requirements of this chapter.

c) PUBLIC COMMENT. – Prior to publishing a notice under subsection (b)(2) and (3), the authority shall solicit public comments for at least 30 days. The authority shall respond to the comments it receives during the 30-day public comment period.

§ 1303.406. Payment for performing routine cultures and screenings.

The cost of routine cultures and screenings performed on patients in compliance with a health care facility's and ambulatory surgical facility's infection control plan shall be considered a reimbursable cost to be paid by health payors and medical assistance upon Federal approval. These costs shall be subject to any copayment, coinsurance or deductible in amounts imposed in any applicable policy issued by a health payor and to any agreements between a health care facility, ambulatory surgical facility and payor.

§ 1303.407. Quality improvement payment.

a) GENERAL RULE. – Commencing on January 1, 2009, the Department of Public Welfare in consultation with the department shall make a quality improvement payment to a health care facility that achieves at least a 10% reduction for that facility in the total number of reported health care-associated infections over the preceding year pursuant to section 408(7)(i) For calendar year 2010 and thereafter, the Department of Public Welfare shall consult with the department to establish appropriate percentage benchmarks for the reduction of health care- associated infections in each health care facility in order to be eligible for a payment pursuant to this section.

b) ADDITIONAL QUALITY IMPROVEMENT PAYMENTS. – Nothing in this section shall prevent the Department of Public Welfare in consultation with the department from providing additional quality improvement payments to a health care facility that has implemented a qualified electronic surveillance system and has achieved or exceeded reductions in the total number of reported health care-associated infections for that facility over the preceding year as provided in subsection (a).

c) ELIGIBILITY. – In addition to meeting the requirements contained in this section, to be eligible for a quality improvement payment, a health care facility must be in compliance with health care-associated reporting requirements contained in this act and the Health Care Facilities Act.

d) DISTRIBUTION OF FUNDS. – Funds for the purpose of implementing this section shall be appropriated to the Department of Public Welfare and distributed to eligible health care facilities as set forth in this section. Quality improvement payments to health care facilities shall be limited to funds available for this purpose.

§ 1303.408. Duties of Department of Health.

The department is responsible for the following:

a) The development of a public health awareness campaign on health care-associated infections to be known as the Community Awareness Program. The program shall provide information to the public on causes and symptoms of health care-associated infections, diagnosis and treatment prevention methods and the proper use of antimicrobial agents.

b) The consideration and determination of the feasibility of establishing an active surveillance program involving other entities, such as athletic teams or correctional facilities for the purpose of identifying those persons in the community that are colonized and at risk of susceptibility to and transmission of MRSA bacteria.

c) The review of each health care facility's and ambulatory surgical facility's infection control plan. This review shall be performed pursuant to the department's authority under the Health Care Facilities Act and the regulations promulgated thereunder.

d) The development of recommendations and best practices that implement and effectuate improved screenings and cultures and other means for the reduction and elimination of health care-associated infections.

e) The development of recommendations regarding evidence-based screening protocols for an individual with MRSA and MDRO prior to admission to a hospital.

f) The review of strategic assessments under section 404(c) and the provision of assistance to hospitals in implementing a qualified electronic surveillance system pursuant to the requirements of section 404(d) and (e).

g) The development of a methodology, in consultation with the authority and the council, for determining and assessing the rate of health care-associated infections that occur in health care facilities in this Commonwealth. This methodology shall be used:

   1) to determine the rate of reduction in health care-associated infection rates within a health care facility during a reporting period;

   2) to compare health care-associated infection rates among similar health care facilities within this Commonwealth; and

   3) to compare health care-associated infection rates among similar health care facilities nationwide.

h) The development, in consultation with the authority and the council, of reasonable benchmarks to measure the progress health care facilities make toward reducing health care-associated infections. Beginning in 2010, all health care facilities shall be measured against these benchmarks. A health care facility with a rate of health care-associated infections that does not meet the benchmark appropriate to that type of facility shall be required to submit a plan of correction to the department within 60 days of receiving notification that the rate does not meet the benchmark. After 180 days, a facility that has not shown progress in reducing its rate of infection shall consult with and obtain department approval for a new plan of correction that includes resources available to assist the health care facility. After an additional 180 days, a facility that fails to show progress in reducing its rate of infection may be subject to action under The Health Care Facilities Act.

i) Publishing a notice in the Pennsylvania Bulletin of the specific benchmarks the department shall use to measure the progress of health care facilities in reducing health care-associated infections. Prior to publishing the notice, the department shall seek public comments for at least 30 days. The department shall respond to the comments it receives during the 30-day public comment period.

§ 1303.409. Nursing home assessment to Patient Safety Authority.

a) ASSESSMENT. – Commencing July 1, 2008, each nursing home shall pay the department a surcharge on its licensing fee as necessary to provide sufficient revenues for the authority to perform its responsibilities under this chapter. The total annual assessment for all nursing homes shall not be more than an aggregate amount of $1,000,000. The department shall transfer the total assessment amount to the fund within 30 days of receipt.

b) BASE AMOUNT. – For each succeeding calendar year, the authority shall determine the appropriate assessment amount and the department shall assess each nursing home its proportionate share of the authority's budget for its responsibilities under this chapter. The total assessment amount shall not be more than $ 1,000,000 in fiscal year 2008-2009 and shall be increased according to the Consumer Price Index in each succeeding fiscal year.

c) EXPENDITURES. – Money appropriated to the fund under this chapter shall be expended by the authority to implement this chapter.

d) DISSOLUTION. – In the event that the fund is discontinued or the authority is dissolved by operation of law, any balance paid by nursing homes remaining in the fund, after deducting administrative costs of liquidation, shall be returned to the nursing homes in proportion to their financial contributions to the fund in the preceding licensing period.

e) FAILURE TO PAY SURCHARGE. – If, after 30 days' notice, a nursing home fails to pay a surcharge levied by the department under this chapter, the department may assess an administrative penalty of $ 1,000 per day until the surcharge is paid.

f) REIMBURSABLE COST. – Subject to Federal approval, the annual assessment amount paid by a nursing home shall be a reimbursable cost under the medical assistance program. The Department of Public Welfare shall pay each nursing home, as a separate, pass-through payment, an amount equal to the assessment paid by a nursing home multiplied by the facility's medical assistance occupancy rate as reported in its annual cost report.

§ 1303.410. Scope of reporting.

For purposes of reporting health care-associated infections to the Commonwealth, its agencies and independent agencies, this chapter sets forth the applicable criteria to be utilized by health care facilities in making such reports. Nothing in this act shall supersede the requirements set forth in the act of April 23, 1956 (1955 P.L. 1510, No. 500), known as the Disease Prevention and Control Law of 1955, and the regulations promulgated thereunder.

§ 1303.411. Penalties.

a) VIOLATION OF HEALTH CARE FACILITIES ACT. – The failure of a health care facility to report health care-associated infections as required by sections 404 and 405 or the failure of a health care facility or ambulatory surgical facility to develop, implement and comply with its infection control plan in accordance with the requirements of section 403 shall be a violation of the Health Care Facilities Act.

b) ADMINISTRATIVE PENALTY. – In addition to any penalty that may be imposed under the Health Care Facilities Act, a health care facility which negligently fails to report a health care- associated infection as required under this chapter may be subject to an administrative penalty of $1,000 per day imposed by the department.