I. POLICY

It is the policy of the UPMC to encourage and promote a philosophy of performance improvement and meet the patient safety requirements of federal and state laws and regulations, including but not limited to the (a) Centers for Medicare & Medicaid Services’ Conditions of Participation and (b) Pennsylvania Medical Care Availability and Reduction of Error Act (“Mcare”), 40 P.S. §1301.101, et. seq. All reported “Medication Events” (see definition in Section IV below) will be investigated and analyzed as part of each entity’s quality improvement initiative and in accordance with relevant laws and regulations governing operations of peer review organizations and the protection of peer review information.

Links to policies referenced within this policy can be found in Section VII.

II. PURPOSE

The purpose of this policy is to promote consistent documentation, reporting and follow-up of Medication Events; promote safe prescribing, transcription, dispensing, administration, and monitoring of medications to patients; provide a mechanism for monitoring Medication Events and provide useful information to identify trends and indicate opportunities for performance improvement.

III. SCOPE

This policy applies to all United States based UPMC hospitals and clinics. It excludes senior communities and home care services. Similar policies exist for other care settings within UPMC and are contained in setting-specific policy manuals.

IV. DEFINITIONS

A. “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.

Medication events also include intravenous (IV) medication incompatibility (i.e., involving an IV admixture, syringe or Y-site), which may occur when intravenous medications interfere with one another chemically or physiologically. (6)

B. **Adverse Event (AE)**: Is defined as any negative patient events that are expressed as symptoms, signs or laboratory abnormalities. (1)

C. **Adverse Drug Event (ADE)**: Is defined as any untoward occurrence that may be present during treatment with a pharmaceutical product which does not necessarily have a causal relationship. (2)

D. **Adverse Drug Reaction (ADR)**: Is defined as any response to a drug that is noxious and unintended and occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease, or for modification of physiological function. (3)

![Diagram showing the relationship between Adverse Event (AE), Adverse Drug Event (ADE), and Adverse Drug Reaction (ADR)]

**Figure 1**: World Health Organization/Naranjo Model of Adverse Drug Reactions.

Figure 1 summarizes the relationship between adverse events (AEs), adverse drug events (ADEs), and adverse drug reactions (ADRs). When a relationship between an AE and a drug is suspected and plausible, then an adverse drug event (ADE) is assumed. When an ADE is determined to be causally related to a drug, then an ADR is assumed. This model delineates differing levels of certainty that an event is caused by a drug. (4,5)

E. **“Peer Review Organization”**: Any organization comprised of health care providers (physicians, nurses, pharmacists and hospital administrators), the purpose of which is to improve the quality of patient care through process improvement or other means.

F. **“Peer Review Proceeding”**: Any investigation, deliberation, communication or other proceeding or function of an MER process, P & T Committee or other peer review organization.

V. **FORM**

A. **The Initial Investigation Event Report (IIER) Form**: The IIER Form, whether in electronic or paper form, is the initial and primary form used to report all patient incidents at UPMC facilities, including Medication Events. Any staff
member or employee should report each Medication Event on the standard IIER Form with information regarding the event.

VI. PROCEDURE

A. When a Medication Event or Adverse Drug Reaction occurs, the IIER Form should be completed by the staff member (physician, nurse, pharmacist or other clinician or person) who discovers the event. The report should be completed in accordance with the established procedure (Policy HS-RI1305, “Initial Incident/Event Reporting). The event may also be reported on the institution’s medication or adverse event telephone hotline (if available). If the event is reported via the hotline, the reporter does not need to complete the IIER since it will be confidentially completed by the recipient of the message.

Notification:

1. If a Medication Event or Adverse Drug Reaction reaches the patient, the attending physician must be notified. When the attending physician is not available, notification to the covering physician must occur. When the covering physician must be notified, the patient’s attending physician must be notified as soon as he/she is available. Notification will be documented in the medical record. (6)

2. Immediate notification is to occur: (a) in those cases where harm to the patient has already occurred; or (b) there is a known potential for harm as a result of the medication event or adverse drug event; or (c) if the outcome of the medication event or adverse drug event is unknown. (6)

Documentation: The medication event or ADR as well as notification of the physician(s) is to be documented in the medical record.

B. As soon as possible upon completion, any IIER Form relating to a Medication Event or Adverse Drug Reaction shall go through the entity’s medication review process for investigation and appropriate further action.

C. The results of the medication event review should be shared with appropriate peer review organizations within the entity and UPMC such as a P & T Committee, Patient Safety Committee or Quality Improvement Committee or Council. All such sharing of information shall be done in a way that maintains the confidentiality and peer review protection of the information.

D. Any Medication Event determined to be an Adverse Drug Reaction shall be forwarded to the appropriate peer review organization for review if such review is conducted by a peer review organization other than the MER process reviewing Medication Events.
VII. POLICIES REFERENCED WITHIN THIS POLICY

HS-RI1305  Initial Incident/Event Reporting

SIGNED: Holly Lorenz, RN MSN
Chief Nursing Executive

ORIGINAL: December 13, 2001

APPROVALS:
Policy Review Subcommittee: August 9, 2012
Executive Staff: August 30, 2012

PRECEDE: November 18, 2011

SPONSOR: Corporate Nursing Operations

* With respect to UPMC business units described in the Scope section, this policy is intended to replace individual business unit policies covering the same subject matter. In-Scope business unit policies covering the same subject matter should be pulled from all manuals.

References: