Attachment 1.H

Policy for a Nonpunitive, System-Based Adverse Drug Event Reporting Program

This attachment provides an example of a policy that details a blame-free reporting program. Clear definitions, severity classifications, and steps for staff to follow when reporting an error are included as well as guidelines for trending the information and using it to improve the medication use systems.

Policy for a Non-Punitive, System-Based Adverse Drug Event Reporting Program

These guidelines are intended to assist in the delivery of patient care or management of hospital services. They are not intended to replace professional judgment.

Policy Title

Adverse Drug Events

1.0 Purpose

To provide a standardized mechanism for identifying, reporting, and monitoring adverse drug events (ADEs) and to provide a consistent mechanism for improving the medication use process.

2.0 Scope

This policy applies to medication therapy for all patients cared for in hospital departments, main campus outpatient services, and physician practices regardless of where the medication was originally prescribed.

3.0 Definitions

Adverse Drug Event (ADE) - a deviation in the medication use process (prescribing, dispensing, administering, monitoring) or undesirable clinical manifestation that is consequent to and caused by the administration or omission of medications, or IV fluids as outlined in hospital policies and procedures or within the scope of accepted medical practice.

Significant ADE – An ADE categorized with severity category 6 or 7 (see below). It should be considered a sentinel event by hospital policy.

Adverse Drug Reaction (ADR) - is a subset of ADEs that includes any clinical manifestation that is undesired, unintended, or unexpected that is consequent to and caused by the administration of medications or IV fluids.

Preventable ADR - An ADR that resulted from a deviation in the medication use process that could be reasonably anticipated based upon existing policies and procedures, patient data, medical literature or accepted medical practice.

Medication Safety Improvement Committee - a subcommittee of the Pharmacy and Therapeutics (P&T) Committee that reviews errors, trends, and significant ADEs and makes recommendations for system-based changes to improve the medication use process (ie Fredrick Memorial's "Saf-Med Committee").

ADE Hotline - phone line to report possible ADEs.

ADE Report Form - Form completed by any member of hospital staff to document a possible ADE.

ADE Review Form - Form used by ADE Reviewers to assess and document to identify causative factors in preparation for entry into data base.

ADE Reviewer - Member of clinical staff (pharmacist, nurse, radiology technologist, respiratory therapist, physician) appointed by the P&T Committee who reviews/assesses reported ADEs, completes documentation, and serves on the Medication Safety Improvement Committee.

Clinical Interventions - Routines in the Pharmacy computer system that allow pharmacists to document interventions made to clarify or optimize medication therapy, such as, dosage adjustments, or nonformulary requests.

Severity:

Category 1: Circumstances or processes that have the potential to cause an adverse drug event.
Category 2: An event occurred but the patient was not harmed.
Category 3: An event occurred that resulted in the need for increased patient assessments but no change in vital signs and no patient harm.
Category 4: An event occurred that resulted in the need for treatment and/or intervention and caused temporary patient harm.
Category 5: An event occurred that resulted in initial or prolonged hospitalization, affected patient participation in an investigational drug study, and/or caused temporary patient harm.
Category 6: An event occurred that resulted in permanent patient harm or near death event, such as anaphylaxis.
Category 7: An event occurred that resulted in patient death.

4.0 Policy

4.1 Fredrick Memorial Healthcare System (FMH) encourages the reporting of adverse drug events, and potential adverse drug events as a means to assess and improve the medication use process and provide a safe environment for patient care. Thus, the focus of the program is quality improvement, not punishment. FMH assumes that practitioners are doing their very best and that errors and ADEs are not the result of gross negligence. Therefore, employees are not subject to disciplinary action when making or reporting errors except in the following circumstances:

- The employee consistently fails to participate in the detection, reporting, and the system-based remedies to prevent errors.
- There is reason to believe criminal activity or criminal intent may be involved in the making or reporting of an ADE.
- False information is provided in relation to the ADE report or investigation.

4.2 The reporting program is coordinated through the Pharmacy and Therapeutics Committee, as part of the hospital's performance improvement and peer review function, with participation by Nursing and Pharmacy departments and the medical staff.

4.3 Pharmacists report ADRs to the FDA if they are serious, associated with a new drug, or not mentioned in the drug's labeling.

4.4 ADEs are reported by physicians, nurses, pharmacists, patients, medical records/QA personnel or any member of the FMH staff. An ADE report form is completed or a call is made to the ADE Hotline within 24 hours of the event's identification.

4.5 Staff members identifying an ADE in severity category 6 or 7 above or classified as a sentinel event reports the event, contacts the Administrator on call and follows the steps outlined in the FMH Sentinel Event Policy and Procedure. A Root Cause Analysis is conducted in these cases as outlined by standing FMH procedures.

5.0 Procedures and Responsibilities

5.1 Identifying an ADE

- Staff who receive a report of or suspect an ADE notify prescriber immediately if the event is significant or may alter the patient's plan of care.
- Staff assess the patient.
- Staff collaborate with clinical and supervisory resource personnel if unsure how to proceed.
- Staff implement adjustments in patient's treatment as ordered.
- Staff document the factual description of the ADE, notification of physician and subsequent monitoring in the progress record.

5.2 Reporting an ADE

- Staff calls the ADE hotline, completes the ADE reporting form or enters an ADE clinical intervention in the Meditech Pharmacy-module within 24 hours of the ADE identification. ADE forms are mailed, confidentially, to the Saf-Med Committee in the Pharmacy or put in an ADE drop box. Pharmacy staff take ADE reports off Hotline seven days a week and complete ADE Report forms.
- No copies are made of the ADE forms. Clinical interventions are migrated into a secure database. Forms and data are secured in the Pharmacy and accessed by key or password.

5.3 Reviewing ADEs

- Supervisor/manager completes timely evaluation of the circumstances surrounding the event.
- ADE Reviewers assess all reports, to verify and collect additional data, and assign severity level. In the case of significant ADEs or medication-related sentinel events, reviewers confirm notification of department director or manager, as well as compliance with sentinel event policy. (see above 4.5).
- ADE reports are reviewed using published criteria and categorized by: location, severity, product information and therapeutic classification, type, causes and contributing factors.
- ADR's get an additional level of review. ADR's are evaluated to determine: 1) appropriateness of medication for patient's condition; 2) predisposing contraindications to medication; 3) appropriate documentation of allergies; and 4) appropriate management and monitoring of ADR.

5.4 Trending/Reporting/Improving the Medication Use Process

- The Pharmacy Department performs the data entry, trending, and report distribution. The Pharmacy prepares a quarterly analysis of ADE's.
- The Pharmacy forwards quarterly ADE trending reports to FMH managers. Managers are responsible for analyzing their department data and responding with performance improvement activities.
- ADEs are tabulated monthly and reported to the Saf-Med Committee. Reports include ADE and ADR rates.
- The Saf-Med Committee reviews the monthly report, significant events, results of root cause analysis and completion of consequent recommendations and makes recommendations for improvements to the medication use process.
- Saf-Med Committee reports and recommendations are made to the P&T Committee. Minutes are distributed to the Safety Committee, P&T Committee Chair and Nursing management. P&T Committee recommendations are forwarded to the medical staff Quality Assurance Coordinating Committee.
- Medication use improvements and recommendations are communicated to FMH staff via e-mail, P&T minutes, Pharmacy Newsletter, educational offerings at medical staff and other department meetings.

6.0 Documentation

Use ADE Report and Review forms.

7.0 Quality Assessment

ADE reports are trended monthly and reviewed at the Pharmacy and Therapeutics Committee and Saf-Med Committee. The Committees make recommendations on surveillance, formulary changes, educational efforts, and policy changes as necessary.

8.0 Exceptions

Adverse reactions that occur following the administration of investigational drugs are reported according to the specific protocol for that drug by contacting the principle investigator. A probationary employee may be terminated if basic competencies related to the medication use process are not demonstrated.

9.0 The following resources were used to prepare the above policy:

Best Practices for Health-System Pharmacy Position and Practice Standards of ASHP 1998-1999. Bethesda, MD: American Society of Health-System Pharmacists, 1998.

Chesapeake General Hospital. *Medication System Analysis Policy and Procedure.* Chesapeake, VA: Chesapeake General Hospital, 1997.

Coe, Charles P. *Preparing the Pharmacy for a Joint Commission Survey*. 4th ed. Bethesda, MD: American Society of Health System Pharmacists, 1998.

Frederick Memorial Hospital. "Discipline Process." *FMH Housewide Manual, HR.510.* Frederick, MD: Frederick Memorial Hospital, 1999.

Frederick Memorial Hospital. "Procedure for Conducting a 'Root Cause Analysis' (RCA)." *FMH Housewide Manual, PI.112.* Frederick, MD: Frederick Memorial Hospital, 1999.

Frederick Memorial Hospital. "Sentinel Events." *FMH Housewide Manual, PI.111.* Frederick, MD: Frederick Memorial Hospital, 1999.

National Coordinating Council for Medication Reporting and Prevention. *NCC MERP Taxonomy of Medication Errors.* Rockville, MD: National Coordinating Council for Medication Reporting and Prevention, 1998. Available at: http://www.nccmerp.org/taxo0731.pdf Accessed November 12, 2002.

Newton-Wellesley Hospital. *Medication Error and Adverse Drug Event Policy.* Newton, MA: Newton-Wellesley Hospital, 2000.

Principles of a Fair and Just Culture

Background

It is inevitable that people will make mistakes or experience misunderstandings in any work environment. When events occur that cause harm or have the potential to cause harm to patients or staff members, or that place the XXXXXXX at legal, financial or ethical risk, a choice exists: to learn or to blame. The XXXXXXX is committed to creating a work environment that emphasizes learning rather than blame.

The XXXXXXX recognizes the complexity and interdependence of the work environment in all aspects of its operations, including patient care, clinical operations, research, support services and administration. The intent is to promote an atmosphere where any employee can openly discuss errors of commission or omission, process improvements, and/or systems corrections without the fear of reprisal.

It is well documented that most errors, whether or not they cause harm, are due to breakdowns in organizational systems; however, when an error takes place, individual culprits are often sought. Blaming individuals creates a culture of fear and defensiveness that diminishes both learning and the capacity to constantly improve systems.

Most errors take place within systems that themselves contribute to the error. In spite of this, it is difficult to create an institutional culture that integrates the understanding that systems failures are the root cause of most errors. Learning from errors often points to beneficial changes in systems and management processes as well as in individual behavior.

In the context of promoting a fair and just culture, what does it mean? A fair and just culture means giving constructive feedback and critical analysis in skillful ways, doing assessments that are based on facts, and having respect for the complexity of the situation. It also means providing fair-minded treatment, having productive conversations, and creating effective structures that help people reveal their errors and help the organization learn from them. A fair and just culture does <u>not</u> mean non-accountable, nor does it mean an avoidance of critique or assessment of competence. Rather, when incompetence or sub-standard performance is revealed after careful collection of facts, and/or there is reckless or willful violation of policies or negligent behavior, or behavior that intimidates others and creates a hostile work environment, will not be tolerated. Corrective or disciplinary action may be appropriate, following the process outlined in the Professional Behavior and Reporting Procedures Policy.

Applying these principles creates an opportunity to enact the core values of the XXXXXXX. In order to have the greatest impact and achieve the highest level of excellence, staff must be able to speak up about problems, errors, conflicts and misunderstandings in an environment where it is the shared goal to identify and discuss problems with curiosity and respect. To achieve excellence, unwanted or unexpected outcomes and inefficiencies of practice must be used as the basis for a learning process. Respect must be shown to all people at every level of the organization.

Principles of a Fair and Just Culture

1. **The XXXXXXX strives to create a learning environment and a workplace that supports the core values of impact, excellence, respect/compassion and discovery in every aspect of work at the XXXXXXX.**

2. **The XXXXXXX supports the efforts of every individual to deliver the best work possible. When errors are made and/or misunderstandings occur, the XXXXXXX strives to establish accountability in the context of the system in which they occurred**.

We commit to creating an institutional work environment that is least likely to cause or support error.
We are proactive about identifying system flaws.

3. **The XXXXXXX commits to holding individuals accountable for their own performance in accordance with their job responsibilities and The XXXXXXX's core values. However, individuals should not carry the burden for system flaws over which they had no control.**

4. **The XXXXXXX promotes open interdisciplinary discussion of untoward events (errors, mistakes, misunderstandings or system failures resulting in harm, potential harm or adverse outcome) by all who work, visit or are cared for at the XXXXXXX.**

We commit to developing and maintaining easily available and simple processes to discuss untoward events.
We commit to eliciting different points of view to identify sources of untoward events and to use the information to improve the working and care environment.
We commit to fostering an interdisciplinary teamwork approach to the analysis of untoward events and to the actions taken to address them.
We believe that individuals are responsible for surfacing untoward events and for contributing to the elimination of system flaws.
We commit to analyzing episodes of institutional or patient harm or potential harm in an unbiased fashion to best determine the contributions of system and individual factors.
We seek solutions that promote simplification and standardization wherever possible.

5. **The XXXXXXX acts to improve all areas of the workplace by implementing changes based on our analysis of problems and potential or actual harm.**

We know that actions designed to address the root causes of untoward events will improve the effectiveness of our work environment and the safety of care. We commit to identifying and assigning responsibility for implementing those actions to specific individuals or groups.
We commit to developing timely and effective follow-up and an effective organizational culture through education and systems for ensuring on-going competency.

6. **The XXXXXXX commits to a culture of inclusion and education.**

We commit to fostering a culture that is concerned with safety in research, clinical care and administration through continuous education, proactive interventions and safety-based leadership.
We believe that patient input is indispensable to the delivery of safe care and we commit to promoting patient and family participation.

7. **The XXXXXXX will assess our success in promoting a learning environment by evaluating our willingness to communicate openly and by the improvements we achieve.**

We commit to monitoring actions and attitudes for their effectiveness in supporting a culture of safety and modifying actions as needed.

[Principles adapted from Allan Frankel, M.D. and the Patient Safety Leaders at Partners Healthcare System]