of counterfeit medications and active recalls for medications and the associated active pharmaceutical ingredients.

Medications brought into the hospital by the patient or their family or prescribed within the hospital for self-administration are known to the patient's physician and noted in the patient's medical record.

The hospital implements a process for patient self-administration of medications, administration of medications by a family, and the management, use, and documentation of medication or medication samples.

Measurable Elements of MMU.06.01

1. Ⓓ The hospital defines, in writing, when medications brought into the hospital by patients or their families or brought into the hospital as samples can be administered.
2. Ⓓ If self-administration of medications is allowed, the hospital follows the written processes that guide the safe and accurate self-administration of medications or the administration of medications by a family member. The processes address training, supervision, and documentation.
3. The hospital educates patients and families involved in self-administration and documents in the patient's medical record about the following:
   - Medication name, type, and reason for use
   - How to administer the medication, including process, time, frequency, route, and dose
   - Anticipated actions and potential side effects of the medication administered
   - Monitoring the effects of the medication
   - Proper storage of the medication
4. The hospital determines that the patient or the family member who administers the medication is competent at medication administration before allowing them to administer medications.

Monitoring

Standard MMU.07.00

The hospital monitors and responds to actual or potential adverse drug events and adverse drug reactions.

Intent of MMU.07.00

The purposes of monitoring are to evaluate the medication's effect on the patient's symptoms or illness, as well as blood count, renal function, liver function, and other medication-related physical and biological effects with medications; to evaluate the patient for adverse effects; and to respond to the noted effects accordingly. Definitions of *adverse drug events* and *adverse drug reactions* are referenced in the JCI policy for sentinel events and as follows:

> *Adverse drug event:* an injury resulting from a medical intervention related to a medication, including harm from an adverse drug reaction or a medication error.
>
> *Adverse drug reaction:* a response to a medicinal product that is noxious and unintended and that occurs at doses normally used in humans for the prophylaxis, diagnosis, or treatment of disease or for the restoration, correction, or modification of physiological or psychological function.

Patients, their physicians, nurses, and other health care practitioners work together to monitor patients on medications. Based on monitoring, the dosage or type of medication can be adjusted when needed. It is appropriate to closely monitor the patient's response to the first dose(s) of a medication new to the patient. Such monitoring is intended to identify the anticipated therapeutic response as well as allergic responses, unanticipated drug-drug interactions, or a change in the patient's equilibrium raising the risk of falls, among others.

Monitoring medication effects includes observing, timely responding to, and documenting any adverse effects. The hospital has a policy that identifies all adverse effects that are to be recorded and those that must be reported. The hospital establishes a mechanism for reporting adverse events when required and the time frame for reporting.

Measurable Elements of MMU.07.00

1. Ⓓ The hospital follows a written process to monitor, respond to, and document actual or potential adverse drug events, and adverse drug reactions. (*See also* PCC.02.00, ME 3)
2. Ⓓ The hospital follows a written process addressing prescriber notification in the event of adverse drug events and adverse drug reactions.
3. The hospital complies with internal and external reporting requirements for actual or potential adverse drug events and adverse drug reactions.
4. The hospital uses a standardized process for reporting adverse drug events as part of the hospital quality and patient safety program.
5. Adverse drug events are reported as identified by the process in the time frame required.
6. The hospital conducts a root cause analysis of data when adverse drug event patterns or undesirable trends occur.
7. The hospital uses the analysis of adverse drug-related events to improve medication use processes.

Standard MMU.07.01

The hospital implements a process for identifying, reporting, managing, and tracking all medication errors and near miss events (or close calls).

Intent of MMU.07.01

JCI defines a *medication error* as "a preventable event that may cause or lead to inappropriate medication use or patient or resident harm while the medication is in the control of the health care professional, patient, resident, 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; and use."

Processes are developed and implemented for the purposes of identifying, tracking, trending, analyzing, and reporting errors and adverse events, near misses, and complications. In addition, to proactively learn where systems may be vulnerable to adverse events, the program collects data and information on "near miss" events and complications—a process variation that did not affect the outcome—and evaluates them to prevent the actual occurrence of adverse events. Routine measurement data, as well as data from intensive assessments, contribute to this understanding of where improvement should be planned and what priority should be given to the improvement.

The hospital is responsible for planning and implementing changes for improvement based on the analysis of errors or adverse events, near misses, and complications. The process includes defining a medication error and a near miss, using a standardized format for reporting, and educating staff on the process and importance of reporting. The hospital establishes a definition of a near miss and what types of events are to be reported, as well as potential complications related to the care, treatment, and services provided.

Health care organizations that foster a culture of safety focus on safe medication management practices, which include promoting the reporting of errors without fear of retribution. The documentation and reporting of errors are the first steps in learning from them and avoiding repeat occurrences. The information must be documented and reported, and the data must be analyzed to identify opportunities for improvement. Without implementing a process that includes utilization of the data for improving safety practices, hospitals face challenging barriers in their safety improvement efforts. For example, a survey in Europe showed the following results: