

Measurable Elements of MMU.01.02

1. ① The hospital implements a written policy for receiving and acting on notifications of recalled medications, including medications compounded within the hospital in which products that have been recalled have been used.
2. ① The policy includes identifying, retrieving, and returning, or safely and properly destroying, medications recalled by the manufacturer, supplier, or regulatory agency.
3. The hospital isolates recalled medications from the rest of the medication stock to prevent accidental use or distribution and clearly labels them as “Recalled.”
4. The hospital notifies patients who received recalled medication and provides them with appropriate guidance.
5. The hospital has a process to inform health care providers about the recall and advise them on alternative treatments if necessary.
6. The process includes documentation of all actions taken related to the recall of a medication, including details such as the recall notice, affected lot numbers, actions taken, communications sent, and any responses received.

Standard MMU.01.03

The hospital has a process for handling expired medications.

Intent of MMU.01.03

Hospitals must ensure that they have a process for identifying, retrieving, and returning, or safely and properly discarding, expired medications. There is a policy or procedure that addresses any use of or the destruction of medications known to be expired or outdated. An expired medication is one that is past the expiration date listed on the original packaging from the manufacturer. A “beyond use date” (BUD) is the date and/or time after which the product should not be used. A “beyond use date” medication is defined as a medication that is opened, or used not in original form or conditions that the manufacturer provides, and is typically safe and effective to use for a short period of time after opening (shelf life). This would apply to a refrigerated medication that has a usable time outside of the refrigerator or an insulin vial that is opened and used for 28 days, or a sterile admixture that is compounded using other components. These “beyond use date” medications should be marked with a date of expiration based on when they were opened so that staff know the end date of use.

Measurable Elements of MMU.01.03

1. ① The hospital establishes and implements a written process for the following:
 - Identifying, retrieving, and returning opened and unopened, expired medications and outdated medications
 - Using unopened, expired medications and outdated medications
 - Destroying medications known to be expired or outdated
2. The hospital isolates expired medications from the rest of the medication stock to prevent accidental use or distribution and clearly labels them as “Expired.”
3. The process includes documentation of all actions taken related to the expired medication.

Selection and Procurement**Standard MMU.02.00**

The hospital implements a process for the selection and procurement of medications.

Intent of MMU.02.00

The hospital has a method for overseeing the hospital's medication list, including how listed medications are used; a method for ensuring that medications for prescribing or ordering are stocked; and a process for procuring medications not stocked or normally available to the hospital or for times when the pharmacy is closed. These methods and processes exist to support the hospital's mission, patient needs, and types of services provided.

Every hospital must decide which medications to make available for prescribing and ordering by the health care practitioners. The hospital develops a list (often referred to as a formulary) of all the medications it stocks or that are readily available from contracted services. In some cases, laws and regulations may determine the medications on the list or the source of those medications. Medication selection is a collaborative process that includes patient need and safety as well as economics. Medications are occasionally out of stock due to delayed delivery, national shortages, or other reasons not anticipated through normal inventory control.

The hospital has a method, such as designating an interdisciplinary team, to maintain and to monitor the medication list and to monitor the use of medications in the hospital; for example, monitoring the use of antimicrobials. Those involved in the oversight of the list include health care practitioners involved in the ordering, dispensing, administering, and monitoring processes for medications. The interdisciplinary team reports its findings, recommendations, and program status to hospital leaders. Criteria for selecting medications include, at a minimum, the following:

- Indications for use
- Effectiveness
- Drug interactions
- Potential for errors and abuse
- Adverse drug events
- Sentinel event advisories
- Population(s) served (for example, pediatrics, geriatrics)
- Other risks
- Costs

There is a process or mechanism to monitor patient response to newly added medications. For example, when the decision is made to add a new type of medication or a new class of drugs to the list, there is a process to collect, aggregate, and monitor data related to appropriateness of indication, how the drug is prescribed (dosage or route, for example), and any unanticipated adverse events or conditions associated with the new drug during the introductory period. The list is reviewed at least annually based on emerging safety and efficacy information and information on usage and adverse events.

On occasion, medications not stocked or readily available to the hospital are needed, and there is a process to approve and procure such medications. For example, patients who are on home infusions who become inpatients may not have enough medication to continue the infusion while in the hospital. Such specialty medications may include lifesaving infusions for pulmonary hypertension and those used in insulin pumps. There is a process to approve and procure such medications. Also, there are occasions when medications are needed during the night or when the pharmacy is closed. Each hospital needs to plan for these occurrences and educate staff on procedures to follow in the event they occur.

Measurable Elements of MMU.02.00

1. The interdisciplinary team collaborates with hospital leaders to develop criteria for determining how decisions are made for which medications are available for dispensing or administering. (*See also* IPSPG.03.00, ME 1; IPSPG.03.01, ME 1)
2. © The list of medications by both brand name and generic name, stocked in the hospital or readily available from contracted services is reviewed annually.
3. The process used to develop and monitor the list (unless determined by regulation or an authority outside the hospital) is developed by the interdisciplinary team in collaboration with hospital leaders.
4. There is a process for procuring medications during the following:
 - At night or when the pharmacy is closed
 - When a medication is not on the formulary, stocked, or readily available in the hospital

Storage

Standard MMU.03.00

Medications are properly and safely stored.

Intent of MMU.03.00

The oversight of medication storage includes all locations where medications are stored to ensure consistency with product stability and protection from loss or theft. Medications may be stored within a storage area, in a pharmacy or pharmaceutical service, on the patient care units, in unit pharmacies, or the nursing station in the clinical unit.

There are some types of medications that require special handling, as with the following examples:

- Radioactive medications pose a safety risk.
- Antineoplastic and other hazardous medications carry a risk to health care workers who handle, prepare, dispense, administer, or dispose of these drugs.
- Investigational medications may require special storage and/or consent.

Measurable Elements of MMU.03.00

1. Medications are stored under conditions suitable for product stability, including medications stored on individual patient care units and ambulances, as applicable. (*See also* IPSPG.03.02, ME 2)
2. The hospital stores all medications, including biologicals and controlled (scheduled) medications, in a secured area to prevent diversion, and locked, as applicable, in accordance with laws and regulations. These medications are accurately accounted for according to applicable laws and regulations. (*See also* IPSPG.03.02, ME 2; FMS.05.00, ME 2)
3. © There is a written process for managing medications or products requiring special handling, such as hazardous medications, radioactive medications, and investigational medications. (*See also* MMU.06.00, ME 6)
4. Medications and chemicals used to prepare medications are accurately labeled with contents, expiration dates, and applicable warnings.
5. All medication storage areas, including medication storage areas on patient care units and ambulances (as applicable), are periodically inspected to ensure that medications are stored properly.
6. Medications are protected from loss or theft throughout the hospital. (*See also* FMS.04.00, ME 2)