

F759

(Rev. 173, Issued: 11-22-17, Effective: 11-28-17, Implementation: 11-28-17)

§483.45(f) Medication Errors.

The facility must ensure that its—

§483.45(f)(1) Medication error rates are not 5 percent or greater; and

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(Rev. 173, Issued: 11-22-17, Effective: 11-28-17, Implementation: 11-28-17)

The facility must ensure that its—

§483.45(f)(2) Residents are free of any significant medication errors.

DEFINITIONS

“Medication Error” means the observed or identified preparation or administration of medications or biologicals which is not in accordance with:

1. The prescriber’s order;
2. Manufacturer’s specifications (not recommendations) regarding the preparation and administration of the medication or biological; or
3. Accepted professional standards and principles which apply to professionals providing services. Accepted professional standards and principles include the various practice regulations in each State, and current commonly accepted health standards established by national organizations, boards, and councils.

“Significant medication error” means one which causes the resident discomfort or jeopardizes his or her health and safety. Criteria for judging significant medication errors as well as examples are provided below. Significance may be subjective or relative depending on the individual situation and duration, e.g., constipation that is unrelieved because an ordered laxative is omitted for one day, resulting in a medication error, may cause a resident slight discomfort or perhaps no discomfort at all. However, if this omission leads to constipation that persists for greater than three days, the medication error may be deemed significant since constipation that causes an obstruction or fecal impaction can directly jeopardize the resident’s health and safety.

“Medication error rate” is determined by calculating the percentage of medication errors observed during a medication administration observation. The numerator in the ratio is the total number of errors that the survey team observes, both significant and non-significant. The denominator consists of the total number of observations or “opportunities for errors” and includes all the doses the survey team observed being administered plus the doses ordered but not administered. The equation for calculating a medication error rate is as follows:

Medication Error Rate = Number of Errors Observed divided by the Opportunities for Errors (doses given plus doses ordered but not given) X 100.

- Facility failure to monitor for response or for the emergence or presence of adverse consequences for a resident who has not yet experienced an adverse consequence or decline in function, such as by monitoring hydration status and basic metabolic profile for a resident receiving diuretics or ACE inhibitors.

Severity Level 1:

Severity Level 1 does not apply for this regulatory requirement because the failure of the facility to provide appropriate care and services to manage the resident's medication regimen to avoid unnecessary medications and minimize negative outcome places residents at risk for more than minimal harm.

RESOURCES AND TOOLS

The following resources and tools provide information on medications including box warnings, appropriate dosing, medication categories, drug interactions, and medication safety information. Some of these resources also assist in identifying the correct class of a medication. Additionally, the list includes some of the recognized clinical resources available for understanding the overall treatment and management of medical problems, symptoms and medication consequences and precautions.

- U.S. Department of Health and Human Services, National Institute of Mental Health Web site, which includes publications and clinical research information, www.nimh.nih.gov
- MedlinePlus, <https://www.nlm.nih.gov/medlineplus/druginformation.html>
- National Library of Medicine Drug Information Portal, <http://druginfo.nlm.nih.gov/drugportal/drug/categories> (medication class information).
- The Food and Drug Administration (FDA) webpage, Medwatch: The FDA Safety Information and Adverse Event Reporting Program, <http://www.fda.gov/Safety/MedWatch/default.htm>
- *Post-Acute and Long-Term Care Medical Association*, <https://paltmed.org/>
- American Society of Consultant Pharmacists, <https://www.ascp.com/>

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