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CENTERS for MEDICARE & MEDICAID SERVICES

Center for Medicaid and State Operations / Survey and Certification Group

Ref: S&C-06-30

DATE: **September 29, 2006**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Nursing Homes – Exceptions to the Observation Requirement When Determining Significant Medication Errors

Letter Summary

Current interpretive guidance in the State Operations Manual at F333 directs surveyors to observe a medication preparation or administration before citing significant medication errors.

This letter revises that guidance and clarifies that it is acceptable for nursing home surveyors to cite a significant medication error at F333 based upon either resident review, and/or observation of medication preparation or administration.

The purpose of this memorandum is to clarify that it is acceptable to cite a significant medication error at F333 (CFR §483.25(m)(2)) in the absence of a medication pass observation, under certain circumstances. This clarification will soon be reflected in new surveyor guidance for unnecessary medications and pharmacy services.

The "Guidance to Surveyors" located in the State Operations Manual (SOM), Appendix PP, at F332 and F333 categorizes medication errors as either "significant" or "non-significant." A "Significant medication error" is defined at F333 as one that causes the resident discomfort or jeopardizes his or her health and safety. The guidance indicates that professional judgment is used in the determination of whether a medication error is significant based on:

- The resident's condition;
- The drug category; and
- The frequency of the error.

Current guidance provides direction for surveyors to cite medication errors at F332 and F333 when the preparation or administration is observed. Surveyors therefore have not cited F333 for medication errors, even if those errors were significant, unless they occurred during an observed medication pass. Instead, surveyors have cited tags that are more general and less appropriate for the nature of the non-compliance, such as F309 "Quality of Care."

The underlying principle for identifying any medication error is the presence of evidence that the medication was delivered, administered, or managed in a manner not in accordance with physician's orders, manufacturer's specifications, or acceptable professional standards of practice. Citation of a deficiency at F333 requires the presence of evidence, whether based on reviews, interviews, observations or any combination. While observation is the preferred measure for citing medication errors, it is possible to cite medication errors based on a collection of supportive corroborating evidence from other sources. One example would be the result of a hospital's investigation that found that the wrong medication was administered to the resident in the nursing home by nursing home staff, contrary to physician's orders. Another example of the type of evidence that would support a finding of medication error at F333 would be the identification of an uncharacteristic change in the resident's condition that was determined to be the result of an error in the medication administration practice of the facility. In addition, the evidence supporting the medication error would be further substantiated by literature published by professional organizations, accreditation bodies, or other regulatory agencies.

The following three examples illustrate situations when observation of a medication pass would not be necessary to identify **significant** medication errors:

- A surveyor investigation found that a resident's family member reported to the local ombudsman that their family member received the wrong dose of Synthroid over a period of 10 days. The resident had an order for Synthroid 50mcg/day, however the pharmacist filled the prescription with Synthroid 0.5mg/day and the nurse administered the Synthroid 0.5mg (equivalent of 500 mcg/day), ten times the ordered dose, to the resident daily for ten doses. The resident complained of uncharacteristic palpitations and gastrointestinal upset and required hospitalization for symptom resolution.

  Synthroid has a narrow therapeutic index requiring careful dosage titration to avoid the consequences of over-medicating. Adverse effects of such over-medication may include alterations in cardiovascular function, bone metabolism, cognitive function, emotional state, and gastrointestinal function. Although the error was not observed in a medication pass by the surveyor, the surveyor identified considerable evidence of the error through interviews with the staff, the resident and their representative, and review of the resident's medical record. Such evidence well supported a finding of non-compliance related to a significant medication error, even without observing a medication pass.

- During a complaint investigation, record reviews and interviews with staff revealed that a resident was administered medications prescribed for her roommate in addition to her own. The resident was administered 15 medications in error, including furosemide, potassium, prednisone, amlodipine, metoprolol, lisinopril, isosorbide dinitrate, gabapentin. Some of the medications may cause adverse reactions such as hypotension, feeling lightheaded or dizzy and increased confusion. An interview with the medication nurse confirmed that she had administered the above medications in error, had not reported the error, but had monitored the resident. The nurse stated that later in the day, she assessed the resident who was exhibiting increased confusion, was cold and clammy and had low blood pressure and pulse oximetry of 90%-91% on room air. The resident was transferred to the hospital for observation and treatment for low blood pressure due to the medication error.

- A review of a resident's medical record revealed that the physician ordered Dilantin 200 mg to be given by mouth daily in divided doses (100 mg given every a.m. and 100 given every p.m.). The surveyor found no other orders for Dilantin followed this order in the resident's medical record. A review of the resident's Medication Administration Record (MAR) identified written directions to give Dilantin 200 mg at 8 a.m. and 8 p.m., every day. The MAR also identified the medication administration nurses' initials recorded by every Dilantin 200 mg in the 8 a.m. and 8 p.m. column for every day from the date ordered until the date of the surveyor's visit. The surveyor interviewed the resident's physician, and together they reviewed the physician's orders. The interview and review confirmed that the order was for 100 mg of Dilantin twice a day. The physician also confirmed that no changes to the order occurred followed the original order. The surveyor interviewed the facility pharmacy supplier and learned that a transcription error 17 days earlier resulted in the Dilantin order being filled at the dose and frequency of 200 mg twice a day. The pharmacy confirmed that the resident's medication drawer was supplied less than twenty four hours prior to the surveyor visit with four 100 mg capsules. The surveyor observed the resident's medication drawer immediately following the interview with the pharmacist and found no Dilantin capsules. The surveyor interviewed one of the medication nurses who initialed and signed the MAR indicating he gave the Dilantin to the resident nine times over the course of seventeen days. The medication nurse confirmed that he gave two 100 mg Dilantin capsules to the resident each time he administered the medication. Although all staff could not confirm or deny giving the wrong dose over the entire course of seventeen days; the interviews with the physician, pharmacist and nurse, along with the review of the medical record, and the observation of the resident's medication drawer, provided the supporting evidence that collectively confirmed the medication error.

  While in this example the resident may have received the wrong dose multiple times before the error was identified, Dilantin given above the prescribed dose for even **one dose potentially** has adverse consequences to the resident affecting the central nervous system, gastrointestinal system, and cardiovascular system to name a few. Dilantin given above the prescribed dose may also increase or decrease various lab values. Providers are cautioned to monitor elderly individuals receiving Dilantin because they tend to metabolize Dilantin slowly and may require reduced dosages.

Although there was no observation of a medication pass in any of the above examples, the record reviews and interviews corroborated the presence of significant medication errors.

This memorandum clarifies that a surveyor may cite a deficiency at F333 based upon either resident review, and/or observation of a medication preparation or administration.

Note: Significant and non-significant medication errors observed at 5% or greater should continue to be cited at F332. However, any **significant** medication error included in the F332 (5% or greater) citation should also be cited at **F333**.

For questions on this memorandum, please contact Debra Swinton-Spears at 410-786-7506 or via email at debra.swinton-spears@cms.hhs.gov.

Effective Date: This policy is effective immediately. Please ensure that surveyors and all other appropriate staff are fully informed within 30 days of the date of this memorandum. This policy will be reflected in the next update to the SOM.

Training: The information contained in this announcement should be shared with all State and Regional Office nursing home surveyors and supervisors.

/s/
Thomas E. Hamilton

cc: Survey and Certification Regional Office Management (G-5)