WHEN IS A MEDICATION ERROR CLINICALLY SIGNIFICANT?

An important aspect of the long term care survey process consists of evaluating the safety and effectiveness of the facility's system for preparing and administering medications to its residents. This is accomplished by conducting the medication pass observation, otherwise known as “Task 5-E”. While it is not unusual to identify medication errors during this process, fortunately the majority of errors are deemed non-significant in nature, posing no reasonable risk to the resident.

Many times, the notion of a “significant medication error” comes into play. The State Operations Manual under 483.25(m)(2) F333 states that residents of the nursing facility must be free of significant medication errors. CMS defines a significant medication error as an error which “causes the resident discomfort or jeopardizes his/her health and safety”. Thus, a significant medication error may present as an actual negative outcome, or it may present as a potential for a negative outcome. The question then becomes “how do you distinguish between significant and non-significant medication errors”? Many times, the answer will be quite simple. Any error causing the resident harm in any way would be deemed a significant medication error. Put another way, if the error causes a change in the resident’s therapy (e.g., if it caused the resident to be sent to the ER or admitted to the hospital, or resulted in an injury or death), it would quite obviously be viewed as a significant error. If the error resulted in the resident experiencing pain, becoming nauseated or to vomit, to become sedated, to become uncoordinated and to sustain a fall, or to become constipated, that would be viewed as being a significant medication error.

At other times, there may be no obvious negative outcome from a medication error, but the error may place the resident at a reasonable risk for sustaining an injury or otherwise place the resident’s health and safety at risk. In such situations, the surveyor will be called upon to use his/her professional judgment. Quite often, such a situation will require survey team consensus. Under the guidelines of F333, CMS instructs the surveyor to consider three factors in determining the significance of a medication error: Resident Condition; Drug Category; and Frequency of the Error. For example:

Resident Condition- In general, a medication error involving a resident who is relatively medically-stable would appear to be less problematic than if the same error involved another resident who was more medically-unstable. For example, an unordered dose of Ibuprofen given to a medically stable resident from a gastrointestinal standpoint (e.g., no history of gastric ulcer, GERD, etc.) would seem much less problematic that if the same unordered medication were given to another, less stable individual diagnosed with a bleeding ulcer. Likewise, an unordered dose of Amoxicillin given to an individual with no history of drug allergies would be viewed much less problematic than if it were administered in error to an individual known to be allergic to Penicillin.

Drug Category: An essential factor in determining the significance of a medication error would be to consider the nature or properties of the medication in question. At the top of any list of medications most likely to cause harm when used in error would be medications with a “narrow therapeutic index” (NTI). Examples of NTI medications would include those which require close titration to achieve a safe and effective dosage, or those medications whose therapeutic dose closely approaches its toxic dose. CMS guidelines associated with F333 list NTI drug categories that include anticoagulants, anticonvulsants, antiarrhythmics, antiasthmatics, and antimanic drugs. With any general conversation of NTI drugs, two drugs should come quickly to
mind- Warfarin (Coumadin) and Insulin, two relatively common medications used in the LTC environment. There should be little argument that any instance of either Insulin or Warfarin being used in error (e.g., given without an order, ordered but omitted, or administered as either an over-dose or under-dose) would constitute a significant medication error.

A number of other factors not elaborated upon in the CMS guidance may need to be considered when determining the clinical significance of a medication error. For example, the inappropriate crushing of certain “sustained-release” or “long-acting” dosage forms may be deemed significant, especially with certain long-acting antihypertensive or opioid formulations. Failure to administer a medication by its appropriate route will often be viewed as a significant error. Occasionally, the frequency of dosing may need to be considered.

Surveyors should rely on CMS’s guidelines under F333 as their most important information resource regarding significant medication errors. However, numerous professional organizations also provide valuable information on the subject. Among the most notable organizations that would address this issue would be the Institute for Safe Medication Practices (ISMP), the Joint Commission, the American Society for Consultant Pharmacists (ASCP), and many others. All of these sources may be accessed on the internet.

Several professional organizations point-out that a frequent source of medication errors (and especially significant errors) involves transitions from hospitals to LTC facilities. Medications listed as more likely to cause resident harm include the “high risk” medications Warfarin, Insulin, Opioids, and cardiovascular agents.

**Frequency of the Error:** Quite often, a simple medication error discovered during the medication pass observation will be deemed an isolated incident and often judged to be non-significant. However, further investigation of the error may reveal the error had persistently recurred over a period of time. In certain situations, the surveyor, through a reconciling technique that compares the number of tablets delivered to the number of doses administered, may be able to prove (for example) that the medication had been omitted for five of the previous seven days, thus yielding credence to the assessment of a significant error. Such a conclusion, however, should be made in concert with the condition of the resident and the nature of the medication.

Surveyors are reminded that significant medication errors are to be cited under the following circumstances:

- When observed during the medication administration observation: A significant medication error observed during a medication administration observation should be cited, regardless of whether the facility error rate is 5% or greater;

- When identified during the course of a resident record review, including a revisit survey or a complaint investigation: A surveyor may cite a deficiency at F333 based upon either a resident record review and/or an observation of a medication preparation or administration. Surveyors must conduct any follow up investigation to obtain corroborating information regarding the error, such as interviews with the nurse, Director of Nursing, or the pharmacist, and document that information and facts as required by the Principals of Documentation. Also, it may be necessary to apply the past non-compliance when determining a deficient practice or citation.