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

F760
(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.

The error rate must be 5% or greater in order to cite F759. Rounding up of a lower rate (e.g., 4.6%) to a 5% rate is not permitted. A medication error rate of 5% or greater may indicate that systemic problems exist. The survey team should consider investigating additional potential noncompliance issues, such as F755– Pharmacy Services, related to the facility's medication distribution system.

NOTE: Significant and non-significant medication errors observed at 5% or greater during the Medication Administration Observation task should be cited at F759. However, any **significant** medication error, whether or not the error rate is 5% or greater, should be cited at F760.

Significant and Non-significant Medication Errors
Determining Significance

The relative significance of medication errors is a matter of professional judgment. Follow three general guidelines in determining whether a medication error is significant or not:

- Resident Condition - The resident's condition is an important factor to take into consideration. For example, a diuretic (fluid pill) erroneously administered to a dehydrated resident may have serious consequences, but if administered to a resident with a normal fluid balance may not. If the resident's condition requires rigid control, such as with strict intake and output measurement, daily weights, or monitoring of lab values, a single missed or wrong dose can be highly significant;
- Drug Category - If the medication is from a category that usually requires the resident to be titrated to a specific blood level, a single medication error could alter that level and precipitate a reoccurrence of symptoms or toxicity. This is especially important with a medication that has a Narrow Therapeutic Index (NTI) (i.e., a medication in which the therapeutic dose is very close to the toxic dose). Examples of medications with NTI include: phenytoin (Dilantin), carbamazepine (Tegretol); warfarin (Coumadin); digoxin (Lanoxin); theophylline (TheoDur); lithium salts (Eskalith, Lithobid); and
- Frequency of Error - If an error is occurring repeatedly, there may be more reason to classify the error as significant. For example, if a resident's medication was omitted several times, it may be appropriate, depending on consideration of resident condition and medication category, to classify that error as significant. (See Dose Reconciliation Technique to the Observation Technique below).

Significant medication errors are cited at F760 in the following circumstances:

- When the surveyor observes a significant medication error during a medication preparation and/or administration (regardless of whether the overall facility error rate is 5% or greater);
- When the surveyor identifies a significant medication error(s) during the course of a resident record review.

While observation is the preferred method for citing medication errors, the surveyor may identify medication errors based on evidence from other sources, such as documentation of a change in the resident's condition determined to be due to medication errors, reports from family members that medication was given incorrectly and investigation supports that a medication error occurred, or discrepancies in the MAR that lead to identification of a medication error. The surveyor 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 review other relevant documents. Surveyors should evaluate whether past non-compliance exists using the survey protocol.

Medication errors identified through methods other than observation are not counted in the medication pass observation and not cited at F759, but, any significant medication errors would be cited at F760 if evidence supports the citation.

Examples of Significant and Non-Significant Medication Errors
Some of the error examples are identified as significant. This designation is based on accepted clinical standards of practice without regard to the status of the resident because these error examples show a high potential for creating problems for the typical long-term care facility resident. Those errors identified as non-significant have also been designated primarily on the basis of the nature of the medication. Resident status, actual or potential resident response to the error, and frequency of error could cause such errors to be classified as significant.

Examples of Medication Errors
In the following tables, S=Significant; NS=Not Significant.

Omissions (Medication ordered but not administered at least once):

Medication Order	Significance
Metoprolol Succinate 100mg daily	S
Furosemide 40mg twice daily	S
Trazodone 25mg at bedtime	NS
Ibuprofen 400mg three times daily	NS
Artificial tears 2 drops both eyes three times daily	NS
Fiber supplement one packet twice daily	NS
Multivitamin one daily	NS
Calcium Carbonate Chewable 1 tablet three times a day after meals	NS

Unauthorized Medication (Medications administered without a physician's order):

Medication Order	Significance
Warfarin 4mg Amoxicillin 500 mg	S S
Allopurinol 100mg Ferrous Sulfate 325mg	S NS

Medication Order	Significance
Acetaminophen 325 mg	NS

Wrong Dose:

Medication Order	Administered	Significance
Digoxin 0.125mg everyday Morphine Sulfate 20mg/ml 0.25 ml	0.25mg 0.5ml	S S
Calcium Carbonate 600 mg	500mg	NS

Wrong Route of Administration:

Medication Order	Administered	Significance
Neomycin and Polymyxin B Ear Drops 4 to 5 drops to left ear four times a day	Left Eye	S

Wrong Dosage Form:

Medication Order	Administered	Significance
Dilantin Kapseals 100 mg three Kapseals by mouth at bedtime	Prompt Phenytoin 100 mg three capsules by mouth at bedtime	S*
Docusate Sodium Liquid 100mg twice daily	Capsule	NS

* Parke Davis Kapseals have an extended rate of absorption. Prompt phenytoin capsules do not.

Wrong Medication:

Medication Order	Administered	Significance
Vibramycin	Vancomycin	S
Tums	Oscal	NS

Wrong Time:

Medication Order	Administered	Significance
Oxycodone 5mg 2 Tabs 20 min. before painful treatment	2 Tabs given after treatment	S
Losartan 50mg daily at 8 a.m.	At 9:30 am	NS

Medication Errors Due to Failure to Follow Manufacturers Specifications or Accepted Professional Standards

Failure to "Shake Well" or Mix a Suspension

The failure to "shake" a medication that is labeled "shake well" may lead to a diluted dose or overly concentrated dose depending on the product and the elapsed time since the last "shake." Some medications, for example phenytoin, require correct preparation to achieve the desired therapeutic effect. Surveyors may also observe facility staff mixing

suspensions that should not be shaken vigorously but instead "rolled." Any rolling motion used is acceptable as long as the suspension appears uniformly milky and the rolling action has not created bubbles which can affect measurement and administration of the correct dose.

Crushing Medications

The crushing of tablets or capsules for which the manufacturer instructs to "do not crush" requires further investigation by the surveyor. The Institute for Safe Medication Practices website provides a list of oral dosage forms that should not be crushed which may be helpful. http://www.ismp.org/tools/DoNotCrush.pdf. Some exceptions to the "Do Not Crush" instruction include:

- If the prescriber orders a medication to be crushed which the manufacturer states should not be crushed, the prescriber or the pharmacist must explain, in the clinical record, why crushing the medication will not adversely affect the resident. Additionally, the pharmacist should inform the facility staff to observe for pertinent adverse effects.
- If the facility can provide literature from the medication manufacturer or from a peer-reviewed health journal to justify why modification of the dosage form will not compromise resident care.

The standard of practice is that **c**rushed medications should not be combined and given all at once via feeding tube. Crushing and combining medications may result in physical and chemical incompatibilities leading to an altered therapeutic response, or cause feeding tube occlusions when the crushed medications are combined and administered via feeding tube. Flushing the feeding tube between each medication is also standard of practice.

A facility is not required to flush the tubing between each medication if there is a physician's order that specifies a different flush schedule because of a fluid restriction. For a resident who requires fluid regulation, the physician's order should include the amount of water to be used for the flushing between crushed medications and administration of medications.

Before giving medications via feeding tube, the placement of the feeding tube should be confirmed in accordance with the facility's policy based on current standards of practice. Concerns related to placement and function of the feeding tube should be evaluated under the requirements at §483.25(g)(4)-(5), F693, Enteral Nutrition.

Lastly, the administration of enteral nutrition formula and administration of phenytoin (Dilantin) must be separated to minimize interaction, according to drug and enteral formula manufacturer recommendations. The surveyor should consider the simultaneous administration of phenytoin and enteral nutrition formula as a medication error.

NOTE: Additional information related to administering medications via feeding tube may be found in ASPEN Safe Practices for Enteral Nutrition Therapy at https://www.ismp.org/tools/articles/ASPEN.pdf (2009) and

http://pen.sagepub.com/content/early/2016/11/09/0148607116673053.full.pdf (2016). References to non-CMS sources do not constitute or imply endorsement of these organizations or their programs by CMS or the U.S. Department of Health and Human Services and were current as of the date of this publication.

Crushing Oral Medications – To address concerns with physical and chemical incompatibility and complete dosaging, best practice would be to separately crush each medication and separately administer each medication with food.

However, separating crushed medications may not be appropriate for all residents and is generally not counted as a medication error unless there are instructions not to crush the medication(s). Facilities should use a person-centered, individualized approach to administering all medications. If a surveyor identifies concerns related to crushing and combining oral medications, the surveyor should evaluate whether facility staff have worked with the resident/representative and appropriate clinicians (e.g., the consultant pharmacist, attending physician, medical director) to determine the most appropriate method for administering crushed medications which considers each resident's safety, needs, medication schedule, preferences, and functional ability.

Giving Adequate Fluids with Medications

Administering medications without adequate fluid when the manufacturer specifies that adequate fluids be taken with the medication requires further investigation. Taking medications with inadequate fluid may interfere with the medication working properly. Most medications can be taken with water, but there are exceptions, as further explained below. If the resident declines to take adequate fluid, the facility is not at fault so long as they made a good faith effort to offer fluid, and provided any assistance that may be necessary to drink the fluid. Additionally, the surveyor should look for evidence that the IDT considered other medication options or routes of administration for residents who decline to take adequate fluids or who are fluid restricted. For example, the surveyor would count fluids consumed during meals or snacks (such as coffee, juice, milk, soft drinks, etc.) as fluids taken with the medication, as long as they have consumed within a reasonable time of taking the medication (e.g., within approximately 30 minutes).

Medications that are recommended to be given with adequate fluid include, but are not limited to:

- Bulk laxatives (e.g., Metamucil, Fiberall, Serutan, Konsyl, Citrucel);
- Alendronate—should be taken with 6-8 ounces of plain water only.
- Potassium supplements (solid or liquid dosage forms) such as: Kaochlor, Klorvess, Kaon, K-Lor, K-Tab, K-Dur, K-Lyte, Slow K, Klotrix, Micro K, or Ten K should be administered with or after meals with a full glass (e.g., approximately 4 - 8 ounces of water or fruit juice). This will minimize the possibility of gastrointestinal irritation and saline cathartic effect.

Medications that must be taken with food or antacids

The administration of medications without food or antacids when the manufacturer specifies that food or antacids be taken with or before the medication is considered a

medication error. The most commonly used medications that should be taken with food or antacids are the Nonsteroidal Anti-Inflammatory Drugs (NSAIDs). There is evidence that older individuals living with multiple diagnoses are at greater risk of gastritis and GI bleeds. Determine if the time of administration takes into account the need to give the medication with food.

Nutritional and Dietary Supplements

Nutritional supplements are medical foods that are used to complement a resident's dietary needs. Examples of these are total parenteral products, enteral products, and meal replacement products (e.g., Ensure, Glucerna and Promote.)

Herbal and alternative products are considered to be dietary supplements. They are not regulated by the Food and Drug Administration (e.g., they are not reviewed for safety and effectiveness like medications) and their composition is not standardized (e.g., the composition varies among manufacturers). If a dietary supplement is given to a resident between meals and has a vitamin(s) as one or more of its ingredients, it should be documented and evaluated as a dietary supplement, rather than a medication. For clinical purposes, it is important to document a resident's intake of such substances elsewhere in the clinical record and to monitor their potential effects, as they can interact with other medications.

NOTE: Because nutritional and dietary supplements are not considered to be medications for purposes of the medication administration observation, noncompliance with the administration of these products should not be included in the calculation of the facility's medication error rate. The exception to this would be vitamins and minerals which are generally considered a category of dietary supplements. Medication errors involving vitamins and/or minerals <u>should</u> be documented at F759 and counted towards the error rate calculation. Medication errors involving vitamins and minerals <u>would not</u> be considered to be a significant medication error unless the criteria at F760 were met.

It is expected that the facility staff, along with the prescriber and consulting pharmacist, are aware of, review for, and document any potential adverse consequences between medications, nutritional supplements, and dietary supplements that a resident is receiving.

Medications Administered into the Eye

Facility staff must follow the manufacturer's product information for administration instructions. Facility staff must verify the eye(s) into which eye medication will be administered. When observing the administration of eye drops, confirm that the medication makes full contact with the lower conjunctival sac, so that the medication is washed over the eye when the resident closes eyelid; the eye drop(s) should not fall onto the cornea and the tip of the eye drop bottle should not touch any portion of the eye. The eye drop must contact the eye for a sufficient period of time before the next eye drop is administered. The time for optimal eye drop absorption is approximately 3 to 5 minutes. Systemic effects of eye medications may be reduced if the nurse or resident presses the tear duct for one minute after eye drop administration or gently closes the eye for

approximately three minutes after the administration. For additional information related to administration of eye drops, see http://www.aaaai.org/Aaaai/media/MediaLibrary/PDF%20Documents/Libraries/NEW-WEBSITE-LOGOeyedropinstruction_orig_HI.pdf and http://journals.lww.com/nursing/Citation/2007/05000/Administering_eyedrops.14.aspx

NOTE: References to non-CMS sources do not constitute or imply endorsement of these organizations or their programs by CMS or the U.S. Department of Health and Human Services and were current as of the date of this publication.

Sublingual Medications
If the resident persists in swallowing a sublingual tablet (e.g., nitroglycerin) despite efforts to train otherwise, the facility should endeavor to seek an alternative.

Metered Dose Inhalers (MDI)
Ensuring that a device is administered correctly is vital to optimizing inhalation therapy. The surveyor would observe the administration of MDIs for the following:

- Shake the container well;
- Position the inhaler in front of or in the resident's mouth. Alternatively a spacer or valved holding chamber may be used;
- For cognitively impaired residents, many clinicians believe that the closed mouth technique is easier for the resident and more likely to be successful. However, the open mouth technique often results in better and deeper penetration of the medication(s) into the lungs, when this method can be used.
- If more than one puff is required (whether the same medication or a different medication), follow the manufacturer's product information for administration instructions including the acceptable wait time between inhalations.

NOTE: If the person administering the medication follows all the procedures outlined above, and there is an isolated failure to administer the medication because the resident is unable to understand the procedure (for example, a resident with dementia), this should not be counted as a medication error. The surveyor would evaluate the facility's responsibility to assess the resident's circumstance, and possibly attempt other dosage forms such as oral dosage forms or nebulizers. If the facility staff repeatedly fail to administer the inhaler due to circumstances related to the resident's condition, then the surveyor would cite a medication error. The surveyor should look for evidence of staff communication with the prescriber and/or the consultant pharmacist to address inability to administer a resident's medication(s) as prescribed. The surveyor should also investigate appropriate tags related to the circumstances which prevent the administration of an inhaler or other medication(s), such as care of residents with dementia.

For concerns related to care of residents with dementia, the surveyor should also consider the requirements at §483.40 Behavioral Health Services.

Determining Medication Errors
Timing Errors

If a medication is prescribed before meals (AC) and administered after meals (PC), always count this as a medication error. Likewise, if a medication is prescribed PC and is given AC, count as a medication error. Count a wrong time error if the medication is administered 60 or more minutes earlier or later than its scheduled time of administration, but **only** if that wrong time error can cause the resident discomfort or jeopardize the resident's health and safety. Counting a medication with a long half-life (e.g., digoxin) as a wrong time error when it is 15 minutes late is improper because this medication has a long half-life (beyond 24 hours) and 15 minutes has no significant impact on the resident. The same is true for many other wrong time errors (except AC AND PC errors).

To determine the scheduled time, examine the facility's policy relative to dosing schedules. The facility's policy should dictate when it administers a.m. doses, or when it administers the first dose in a 4-times-a-day dosing schedule.

Residents have the right to choose health care schedules consistent with their interests and preferences, and the nursing home should gather this information in order to be proactive in assisting residents to fulfill their choices. The adjustment of medication administration times, to meet the individual needs and preferences of residents, must be considered by the nursing home. However, medication administration scheduling must still consider physician prescription, manufacturer's guidelines, and the types of medication, including time-critical medications. Some medications require administration within a narrow window of time to ensure resident safety or achieve a therapeutic effect while other medications are not affected by a more flexible schedule. Additionally, a facility may, for example, set up a medication ordered twice a day (BID) on a different schedule for one resident than for another resident, based upon individual preferences.

Prescriber's Orders
The latest recapitulation of medication orders is sufficient for determining whether a valid order exists provided the prescriber has signed the "recap." The signed "recap," if the facility uses the "recap" system and subsequent orders constitute a legal authorization to administer the medication.

Omitted Dose
One of the most frequent types of errors is a dose of medication that is ordered but not given (omitted). If a surveyor detects an omitted dose, investigate the omission further through interviews with the responsible person(s) (and/or his/her supervisor) and all relevant individuals if a medication cart is shared. Ask the person administering medications, if possible, to describe the system for administering the medications given. Occasionally, a respiratory therapist may administer inhalers, a designated treatment person may only administer topical treatments, a hospice nurse may administer hospice medications, another person may administer eye drops or as needed medications, etc.

INVESTIGATIVE PROCEDURES
Use the Medication Administration Observation Facility Task, as appropriate, along with the interpretive guidelines, when determining if the facility meets the requirements for, or

investigating concerns related to, Medication Administration and Medication Errors.

Medication Administration Observation Methodology
The survey team should observe the administration of medications on several different medication "passes" to capture different staff members who administer medications as well as multiple routes and times of administration. However, when observing medication pass for one resident at a specific time, plan to observe all of the medications prescribed to be given at that time for that resident. Following this process will help to identify if omissions have occurred.
Record what is observed; and reconcile the record of observation with the prescriber's medication orders to determine whether or not medication errors have occurred.

Paper review may help identify possible errors, however detection of blank spaces on a medication administration record does not alone constitute the occurrence of actual medication errors. The surveyor(s) conducting medication observation will need to follow-up on any observed concerns through additional record review and interviews.

Observation Technique
The survey team must know what medications, in what strength, dosage forms, and administration route are being administered. This is accomplished prior to medication administration and may be done in a number of ways depending on the medication distribution system used (e.g. unit dose, vial system, punch card).

Medication Preparation and Administration Observation
1. Identify the medication by observing the label. When a punch card or unit dose system is used, the survey team can usually observe the label and adequately identify the medication. For multi-medication packet systems, staff identify medications by dose and descriptions provided by the pharmacy. Ask the nurse how medication(s) being administered is identified so the resident receives the correct medication(s).
2. Observe and record the administration of medications ("pass"). Findings at this juncture should be focused on what the surveyor observes, not what the medication administration record states. Follow the person administering medications and observe residents receiving medications (e.g., actually swallowing oral dosage forms). Be neutral and as unobtrusive as possible during this process.
    - The surveyor should ask appropriate staff to explain the facility policy or system for the identification of residents.
    - Multiple tablets or capsules required to deliver a dose of a single medication count as one observation and one opportunity for error;
    - If medications are crushed prior to administration:
        - Ask staff how they know the medication is permitted to be crushed.
        - Observe whether the crushed medications are combined for administration via feeding tube and flushed between each medication. If so, the number of errors would equal the number of medications that were combined. For example, if four medications were crushed and combined to be administered all at once via feeding tube, then four errors have occurred before the medications have been administered.

- Observe infection prevention practices by staff administering medications, including the procedures used for insulin pens and single dose vial use, in addition to the disinfection of blood glucose monitors (BGMs). If the staff administering medications fail to use appropriate infection prevention and control standards of practice, it should also be evaluated under §483.80, Infection Prevention and Control Program.

3. Reconcile the surveyor's record of observation with physician or prescribing practitioner orders.
   - Compare the record of observation with the most current orders for medications.
   - For each medication on the surveyor's record of observation, determine if the medication was administered:
     - According to a valid prescriber's order(s);
     - To the correct resident;
     - At the correct time;
     - In the correct dose;
     - By the correct route; and
     - According to correct accepted standards of practice and manufacturer's specifications.
   - For medications not on the surveyor's list: Examine the record for medication orders that were not administered and should have been. Such circumstances may represent omitted doses, one of the most frequent types of errors.
   - The surveyor should now have a complete record of what was observed and what should have occurred according to the prescribers' orders. Determine the number of errors by adding the errors on each resident. Before concluding for certain that an error has occurred, discuss the apparent error, if possible, with the person who administered the medications, as there may be a logical explanation for an apparent error. For example, the surveyor observed that a resident had received Lasix 20 mg, but the order was for 40 mg. This was an apparent error in dosage. But the nurse showed the surveyor another more recent order which discontinued the 40 mg order and replaced it with a 20 mg order.
4. Reporting Errors -- At the exit conference, the survey team describes to facility staff each error that they detected. The survey team is not required to analyze the errors and come to any conclusions on how the facility can correct them. Do not attempt to categorize errors into various classifications (e.g., wrong dose, wrong resident). Stress that an error occurred and that future errors must be avoided.

Intervening During Medication Administration -- There may be times when the surveyor should intervene before the person administering the medication makes a suspected medication error. This would occur in the event the surveyor becomes aware of the concern before reconciling the medication administration observations with the physician's orders.

Examples of this may include, but are not limited to, situations where the surveyor understands that the resident is about to receive:

- An unusually large dose of medication;
- A medication via the wrong route, such as ear drops in the eyes; or