the Remedi Pulse

AN EVIDENCED BASED APPROACH TO MEDICATION ADMINISTRATION

Remedi SeniorCare EDUCATION Rx

A CLINICAL AND REGULATORY UPDATE FROM REMEDI SENIORCARE

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Survey Solutions

with William Vaughan, BSN, RN
VP of Education & Clinical Affairs

Medication Errors under the Mega Rule: Old Wine in a New Bottle

It's been said that nursing homes and nuclear power plants are the two most heavily regulated industries in America. The recently enacted Reform of Requirements for long-term care facilities (aka the mega rule), which garnered more than 9,800 public comments, did little to dispel that perception. While the net effect of the mega rule was an expansion of regulatory requirements, the language of two pharmacy related regulations, F759 (medication error rate) and F760 (significant medication errors), remained basically unchanged. However, the guidance to surveyors on how to interpret these regulations was revised[1]. Below, we review both existing and revised guidance to surveyors, as well as survey processes, related to medication errors.

Note: While the guidance to surveyors can be helpful in interpreting regulations, a common misconception on the part of both providers and surveyors is that it has the force of regulation; it does not. In memorandum S&C-08-10, CMS notes that "…surveyors must base all cited deficiencies on a violation of statutory and/or regulatory requirements, rather than sections of the interpretive guidelines. The deficiency citation must be written to explain how the entity fails to comply with the regulatory requirements, not how the facility fails to comply with the guidelines for the interpretation of those requirements.[2]" Providers should be mindful of this distinction when interacting with surveyors and when reviewing cited deficiencies.

- **Surveyor intervention during a medication pass (F759):** This regulation is unique in that it acknowledges that errors can occur which do not automatically rise to the level of a cited deficiency. The threshold for citing a medication error rate remains at 5% as does the definition of a medication error (i.e., preparation/administration not in accordance with the prescriber's order, manufacturer's specification, or accepted professional standards). Surveyors are now instructed to intervene during the medication pass observation if they "suspect" an error is about to occur. The surveyor will generally wait until it's clear

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Medications and Specific Administration Guidelines

Prepared by: Erin M. Foti, PharmD, BCGP, Director of Consulting Services

With the shear amount of medications that are available in today's market, it is a challenge to keep all the administration recommendations committed to memory. To crush or not to crush? Take with food or on an empty stomach? Do I need to separate certain medications from others? The FDA estimates that medications are not taken as prescribed upwards of 50% of the time, which results in overdosing, underdosing and/or increased risk for adverse effects. Understanding how to administer medications correctly results in maximizing their benefits; this includes understanding manufacturer recommendations and industry best-practice standards.

Drug manufacturer recommendations are not absolute requirements, and as such, should be evaluated on an individual basis depending on each resident's situation. It is important to note that strictly following a manufacturer's recommendation may not always be in the best interest of a resident. In fact, CMS does not consider the failure to follow a manufacturer's recommendation a medication error when observed during the medication pass. Manufacturer's recommendations should always be evaluated in the context of a resident centered care process which assesses their overall impact on the resident's well-being.

For those residents who cannot take medications according to general manufacturer recommendations, check with the prescriber or consultant pharmacist to determine if patient-specific alterations in administration are acceptable for that medication, or if an alternative option is necessary. If the prescriber determines that the general recommendations should not apply to a specific resident - or there is no alternative available - consider documenting the rationale in the medical record to ensure clear communication and avoid unnecessary scrutiny.

Medication administration staff should remain vigilant of medication recommendations and cautionary statements provided by the pharmacy, which are often printed on the medication products (PAXIT® bags, boxes, tubes, etc.) and on medication administration records.

To the right is the list of commonly used medications associated with specific recommendations for administration:

Remedi Superstar Nurse

THOMASINA NOLAN, RN

Shaker Gardens Nursing and Rehabilitation, Shaker Heights, OH

CONGRATULATIONS to Thomasina Nolan, RN, Shaker Gardens Nursing and Rehabilitation in Shaker Heights, Ohio, for being chosen as the Remedi Superstar Nurse. Thomasina was nominated by her former DON, Laura Walker. Per Laura, "Thomasina is a wonderful asset here at Shaker Gardens. She is willing to jump right in wherever needed, especially during our annual surveys and in our conversion to PCC. Thomasina doesn't complain about doing the work, she just gets it done. She has a very bubbly personality, which the residents enjoy and they miss her whenever she has a day off from work. Thomasina enjoys her job and it is obvious that she takes pride in her duties as a registered nurse. It is an honor and a privilege to have a nurse who exemplifies excellence in customer service and work performance."

Email your Superstar Nurse nomination(s) to Rebecca.Ogden@RemediRx.com

Medication	Diagnosis for Use	Medication Administration Instructions/Special Considerations
Levoxyl, Synthroid, Levothroid (Levothyroxine)	Hypothyroidism	Administer on an empty stomach
Linzess (Linaclotide)	IBS, constipation pre-dominant or chronic idiopathic constipation	Give greater than 30 minutes before first meal; May open capsule-do not crush or chew contents
Amitiza (Lubiprostone)	IBS, constipation pre-dominant or chronic idiopathic constipation, Opioid induced constipation	Give with food and water; do not open capsule
Movantik (Naloxegol)	Opioid induced constipation	Give one hour before or two hours after a meal
Actonel (Risedronate) Fosamax (Alendronate)	Osteoporosis	Give with water greater than 30 minutes before first meal, remain upright for 30 minutes
Boniva (Ibandronate)	Osteoporosis	Give with water 60 minutes before first food/drink/medication, remain upright for 60 minutes
Carafate (Sucralfate)	Duodenal ulcer treatment and maintenance therapy; gastric erosion	Give one hour before meals; Due to numerous interactions give other medications two hours before or four hours after Carafate
Exelon patch (Rivastigmine transdermal)	Alzheimer's dementia Parkinson's dementia	Do not use same location for patch within a 14 day period
Prilosec (Omeprazole) Prevacid (Lansoprazole)	GERD, Gastric/Duodenal ulcers	Give before meals
Nexium (Esomeprazole)	GERD, Hypersecretory conditions, Gastric ulcer prophylaxis	Give greater than one hour before meals
Protonix (Pantoprazole)	GERD, Hypersecretory conditions, Upper GI bleeding	Give with or without food
Dexilant (Dexlansoprazole)	GERD	Give with or without food
Renvela/Renagel (Sevelamer)	Hyperphosphatemia, dialysis patients	Numerous drug interactions; give other medications two hours before or six hours after Sevelamer; give with meals
PhosLo (Calcium acetate)	Hyperphosphatemia, ESRD	Numerous drug interactions; give other medications two hours before or six hours after PhosLo
Comtan (Entacapone)	Adjunct treatment to Parkinson's disease	Give each dose with Carbidopa/Levodopa
Steroid Inhalers	COPD, Asthma	Rinse mouth after each use
Glucotrol (Glipizide)	Diabetes Type 2	Give 30 minutes before meals
Amaryl (Glimepiride)	Diabetes Type 2	Give with first main meal
DiaBeta/Micronase (Glyburide)	Diabetes Type 2	Give with meals
Glucophage (Metformin)	Diabetes Type 2	Give with meals
Questran (Cholestryramine)	Hyperlipidemia	Give other oral medications one hour before or four to six hours after cholestyramine to prevent delayed or decreased absorption

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- the staff member is committed to administering the medication, intervene before they do, and then discuss their concern with the staff member. CMS cautions surveyors not to involve the resident in this discussion. Errors prevented by surveyor intervention are counted in the facility's medication error rate.
- **Administering crushed medications orally:** Perhaps no other guidance caused such controversy as CMS' initially published stance on orally administered crushed medications. In the June, 2017, advance copy of Appendix PP, CMS noted that "The standard of practice is that crushed medications should not be combined and given all at once, either orally (e.g., in pudding or other similar food) or via feeding tube." Surveyors were instructed to count as an error every crushed medication that was not administered individually. Rationale provided by CMS in support of this guidance included potential "physical and chemical incompatibilities leading to an altered therapeutic response," as well as the inability to determine which medications were administered should a resident be unwilling or unable to ingest all the crushed medications. With a lack of evidence to support the incompatibility argument and a resident centered approach as the best solution to address the concern related to partial ingestion of combined medications, CMS softened its stance. In the current Appendix PP (revised 11/22/17), the guidance now reads "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." The message here is clear. If a resident demonstrates difficulty with ingesting all the crushed medications provided, it's entirely appropriate to care plan the issue and consider administering the medications individually. The consultant pharmacist should be part of this care planning process to determine if alternatives to the resident's current drug regimen exist. Otherwise, F759 does not prohibit the combining and administration of crushed medications orally to other residents.
- **Timing errors:** Another long-standing misconception is that under F759, an error should be cited if a medication is administered more than one hour before or after it is scheduled to be given. Provided that a specific time or other instruction (i.e., AC, PC, etc.,) is not included in the actual order, CMS has clear guidance on this issue:

  "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)."***

  Facilities should examine their policies and procedures to make sure they are not demanding that their staff meet these arbitrary and clinically non-significant administration timelines. The consultant pharmacist is an invaluable resource in determining the appropriateness of medication administration schedules.
- **Defining a medication:** For F759 and/or F760 to be applicable, the substance administered must be a medication. Guidance on this point reads as follows:

  "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 should be documented at F759 and counted towards the error rate calculation. Medication errors involving vitamins and minerals would not be considered to be a significant medication error unless the criteria at F760 were met."

  Facilities should be clear on what contributed to their medication error rate and confirm that a supplement was not included in the calculation. To that end, surveyor instructions include "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."

The above discussion of medication related guidance is not exhaustive. As medication management will continue to be scrutinized as a regulatory priority, facilities should be familiar with the additional information provided in the guidance to surveyors under F759 and F760.

Note: Bill was a surveyor with the Maryland State Survey Agency from 1988 until 2001. He became Chief Nurse of the agency in 2001 and remained in that position until joining Remedi SeniorCare in 2013.

[1] https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/GuidanceforLawsAndRegulations/Downloads/Appendix-PP-State-Operations-Manual.pdf

[2] https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/downloads/SCLetter08-10.pdf