



Center for Clinical Standards and Quality/ Survey & Certification Group

Ref: S&C: 13-02-NH

DATE: November 2, 2012

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Nursing Homes - Clarification of Guidance related to Medication Errors and Pharmacy Services

Memorandum Summary

We are providing clarification on three specific topics related to medication errors and pharmacy services:

- **Medication Errors:** Potential medication errors related to medication administration via feeding tube and administration timing for metered dose inhalers and proton pump inhibitors and survey implications.
- **Medication Administration Practices:** The practice of “borrowing” medications and issues related to diversion, control, reconciliation and disposal of medications, including fentanyl patches.
- **Medication Regimen Reviews for Stays under 30 days and/or Changes in Condition:** The need for pharmacist medication regimen reviews when a resident experiences a change in condition and/or for residents admitted for less than 30 days.

Background

Medications are an integral part of the care provided to nursing home residents. They are administered to achieve positive outcomes, such as curing an illness, diagnosing a disease or a condition, modifying a disease process, reducing or eliminating symptoms, or preventing a disease or symptom. However, any medication or combination of medications may result in adverse consequences. Therefore residents must only receive medications when there are clear clinical indications and when the potential benefits outweigh the risks.

To improve the review of the requirements regarding medications and pharmacy services, the Centers for Medicare & Medicaid Services (CMS) implemented revised interpretive guidance for tag F329- Unnecessary medications and for Pharmacy services at F425, F428, and F431 on

December 18, 2006. Since the 2006 guidance release, we have received several requests for clarifications regarding:

- Medication errors;
- Medication administration practices; and
- Medication regimen reviews for stays under 30 days and changes in resident condition.

I. Medication errors

- *Administration of Medications via a Feeding Tube (collectively refers to Nasoenteric i.e. nasogastric or nasointestinal, or Gastrostomy tubes)*

Surveyors have identified problems regarding safe administration of medications via a feeding tube (such as incorrectly crushing time-released oral medications) or not flushing the tube before, in between and after administration of a medication. In accordance with F425- Pharmacy Services, the facility, in consultation with the pharmacist, must provide procedures for the accurate administration of all medications. The procedures must reflect current standards of practice, including but not limited to; types of medications that may be safely administered via a feeding tube; appropriate dosage forms; techniques to monitor and verify that the feeding tube is in the right location (e.g., stomach or small intestine, depending on the tube) before administering medications; preparing drugs for enteral administration, administering drugs separately, diluting drugs as appropriate, and flushing the feeding tube before, between, and after drug administration¹; and that medications with known incompatibilities must not be given at the same time.

Survey Implications:

Refer to F322- Nasogastric Tubes, if placement of the feeding tube is not checked prior to medication administration. For a resident who requires fluid regulation, the physician's order should include the amount of water to be used for the flushing and administration of medications.

For administering medications via tube feeding, the standard of practice⁵ is to administer each medication separately and flush the tubing between each medication. An exception would be if there is a physician's order that specifies a different flush schedule for an individual resident, for example because of a fluid restriction. Failure to flush before and in between each medication administration is considered a single medication error and would be included in the calculation for medication errors exceeding 5 percent. If noncompliance with the administration of medication(s) via a feeding tube has been identified at F332- Medication Errors, additional requirements should be investigated such as F425- Pharmacy Services to assure that the facility has policies for administration of medications via feeding tube that meet current standards of practice.

Also consider F520 - Quality Assessment and Assurance (QAA), in order to determine whether the QAA committee monitors for safe medication administration practices including the administration of medications via feeding tubes in order to assure that facility policy and

standards of practice are implemented. The committee and the medical director and pharmacist are expected to be involved in the oversight of safe medication administration practices.

- ***Metered Dose Inhalers (MDIs)***

Updates in asthma and chronic obstructive pulmonary disease (COPD) practice guidelines have prompted us to clarify the use of metered dose inhalers to administer medications, and more specifically the timing between puffs. If more than one (1) puff is required, (whether the same medication or a different medication), current guidelines, and/or manufacturer product information indicate there should be a waiting time of approximately one (1) minute between puffs except for short acting beta agonists such as albuterol, where a shorter wait time of 15-30 seconds is acceptable.² Ensuring that a device is administered correctly is vital to optimizing inhalation therapy. Numerous educational resources on the storage and administration of various inhalation therapies (e.g., diskus, nebulizer, MDI) are available. Some examples include:

- http://www.nhlbi.nih.gov/health/prof/lung/asthma/nurs_gde.pdf;
- <http://www.aafa-md.org/thumbdrive.htm> (under pharmacy file- handouts);
- You Tube Video: http://www.youtube.com/watch?v=Z_95ni8DJwU

Survey Implications:

If surveyors identify concerns related to the administration of medications at F332- Medication Errors, then additional requirements may also be considered and investigated such as F425- Pharmacy Services.

- ***Proton Pump Inhibitors (PPI)***

This clarification provides surveyors directions for further investigation if they have identified concerns related to the circumstances and timing of PPI administration. Section 483.60(a), Pharmacy Services, requires the facility to establish procedures that assure the accurate administration of medications to meet the needs of each resident. The facility must have policies that address the timing for medications that are required to be administered with regard to food intake (for example, with food or on an empty stomach). PPIs, such as lansoprazole (Prevacid) and omeprazole (Prilosec), are routinely used in nursing home settings. For optimal therapeutic benefit, most PPIs should be administered on an empty stomach, ideally 30-60 minutes before meals. The rationale is that in order for the medication to provide the maximum benefit it needs to be present in the system before food activates the acid pumps so that the peak concentration of the PPI will coincide with maximal acid secretion.³ Some residents may report benefits of this medication being administered outside the 30-60 minutes prior to a meal and this needs to be determined and documented to justify the continued administration times.

As with any class of medication, it is important to identify the indication for use as well as continued need to ensure appropriate use. This is particularly important with new resident admissions, since many patients are placed on a PPI after an acute care stay, but may not require long-term therapy with these agents. The Food and Drug Administration requires adding information to the PPI prescription label as well as to the over the counter (OTC) PPIs. They

noted that patients who take higher doses and/or remain on PPIs longer (at least one year) were reported to have a higher incidence of hip, wrist or spine fractures.^{4a} This warning, as well as the increased risk for infections such as pneumonia and *Clostridium difficile*,^{4b} reinforces the importance of evaluating each resident for continued medication use.

Survey Implications:

If concerns related to the administration of medications have been identified at F332- Medication Errors, then additional requirements may also be considered and investigated such as F281- Professional Standards of Quality, F329- Unnecessary Medications or F425- Pharmacy Services.

II. Concerns regarding medication administration practices

A. “Borrowing Medications”

Nurses have reported situations in which a medication is not available in the resident’s supply or in the facility’s emergency medication kit or supply. Nursing staff may then decide to “borrow” medications from another resident’s supply in order to relieve pain or ensure timely administration of an antibiotic or cardiac medication for the benefit of a resident. This practice of borrowing medications from other residents’ supplies is not consistent with professional standards and contributes to medication errors⁶.

If permitted under State law, a contracted pharmacy provider may establish an emergency supply of medications in collaboration with the medical director and the director of nurses. The surveyor should investigate whether policies and procedures are in place for emergency kit use and if they are being implemented. The facility may use an automated medication distribution system and should have procedures for both routine and emergency use of medications.

Survey Implications:

The surveyor should interview staff responsible for medication administration in order to determine:

- How they assure each resident has a sufficient supply of their prescribed medications (for example, a resident who is on pain management to assure an adequate supply of medication is available to meet the resident’s needs). At a minimum the system is expected to include a process for the timely ordering and reordering of a medication;
- Who monitors to assure that the medications are delivered when ordered; and
- What they do if a resident’s prescribed medication is not available for administration.

If the staff borrows medications to administer to a resident due to the failure of the staff to order the medication and not following the facility’s system for reordering medications, refer to F281- Professional Standards of Quality.

In addition, interview the pharmacist, director of nurses, and/or medical director as appropriate in order to determine if they have a system in place to assure each resident has a sufficient supply

of their prescribed medications for timely administration and monitor that the system is followed. (See F425- Pharmacy Services)

Determine whether the nursing staff contacted the prescriber if an ordered medication was not available. Review the resident's record for documentation regarding the notification and orders from the prescriber on how to address the non-availability of the medication. If the prescriber was not available, determine if the medical director was contacted for orders or further action (See F501- Medical Director, and F514 - Accuracy of medical record.)

Determine whether the QAA committee monitors to assure the timely provision and administration of each resident's prescribed medications. (See F520 - Quality Assessment and Assurance).

B. Fentanyl Patches

Tag F431- Service Consultation requires a licensed pharmacist, who is employed by or provides services to a facility, to establish a system of records of receipt and disposition of all controlled medications. The system should enable periodic, accurate reconciliation and accounting of all controlled drugs. Fentanyl transdermal patches are a controlled substance commonly used in nursing homes for pain medication. These patches present a unique situation given the multiple boxed warnings, the potential for abuse, misuse and diversion, and the substantial amount of fentanyl remaining in the patch after use. The facility's policies must address safe and secure storage, limited access and reconciliation of controlled substances in order to minimize loss or diversion, and provide for safe handling, distribution and disposition of the medications.

One benefit of the patch is the continuous delivery of fentanyl over 72 hours. This slow-release of fentanyl from the transdermal reservoir allows for more consistent pain control in patients with chronic pain. This unique delivery system, however, is not impervious to diversion, even after the fentanyl patch has been used, removed and/or disposed. One study determined that even after three days of use, 28 to 84.4% of the original fentanyl dose was still present in the patch. The study noted that the dose remaining in the patch was within the limits of a lethal fentanyl dose.⁷

The remaining fentanyl in a used patch is a potential vehicle of abuse and accidental overdose and warrants implementation of adequate disposal policies. Fentanyl products contain several boxed warnings related to potential abuse, misuse, and diversion, and specifically, the contraindication of fentanyl transdermal patch use in individuals who are not opioid tolerant.

Staff should dispose of fentanyl patches in the same manner as wasting of any other controlled substances, particularly because the active ingredient is still accessible. Wasting must involve a secure and safe method, so diversion and/or accidental exposure are minimized. Tag F425 requires the facility's procedures to address the disposition of all medications. This includes but is not limited to:

- Timely identification and removal of medications from the current supply of medications for disposition;
- Identification of storage method for medications awaiting final disposition;

- Control and accountability of medications awaiting final disposition;
- Documentation of actual disposition for both full dose and any other remaining partial dose; and
- A method of disposition consistent with applicable state and federal requirements, local ordinances, and standards of practice.

Survey Implications:

If surveyors identify misuse or diversion of a controlled substance, they should consider and investigate these requirements:

- F309 - Quality of care, for evidence and/or potential outcomes, such as unrelieved pain. For example, evidence that on a particular shift, or when a particular staff member is working, that the resident's pain symptoms are not relieved to the extent possible but the pain symptoms are met to the extent possible on other shifts;
- F425 - Pharmacy Services, for policies for safeguarding and access, monitoring, administration, documentation, reconciliation and destruction of controlled substances;
- F431 - Pharmacy service consultation, for drug records and reconciliation of controlled drugs;
- F514 - Clinical Records, accuracy of medical record and for the documentation of the administration of the medication and outcomes; or
- F520 - Quality assessment and assurance, for how the QAA committee monitors the administration, reconciliation and disposition of controlled substances in the facility.

In addition, if the investigation identifies diversion of a resident's medication, the surveyor must review for F224- Misappropriation of Resident's Property. If it is determined that a resident's medications were diverted for staff use, the State Agency must make referrals to appropriate agencies, such as local law enforcement; Drug Enforcement Administration; State Board of Nursing; State Board of Pharmacy; and possibly the State licensure Board for Nursing Home Administrators.

III. Medication Regimen Reviews for Stays under 30 days and Changes in Condition

Consultation (including medication regimen review) by the pharmacist can promote safe and effective medication use. The regulation at F428-Medication Regimen Review requires that a licensed pharmacist review each resident's medication regimen at least once a month.

The facility is expected to have a proactive, systematic and effective approach to monitoring, reporting, and acting upon the effects, risks, and adverse consequences of medications. The pharmacist may need to conduct the medication regimen review more frequently (for example weekly), depending on the resident's condition and the risks for adverse consequences related to current medications. The requirement for the medication regimen review applies to all residents, including residents receiving respite care, residents at the end of life or who have elected the hospice benefit, residents with an anticipated stay of less than 30 days, or residents who have experienced a change in condition. Complex residents generally benefit from a pharmacist's review during the transition from hospital to skilled nursing facility.⁸ This review may prevent

errors due to drug-drug interactions, omissions, duplication of therapy or miscommunication during the transition from one team of care providers to another.

The current guidance at F425-Pharmacy Services provides examples of how the facility, in collaboration with the pharmacist and medical director, can establish procedures to address medication regimen reviews for residents whose anticipated stay is less than 30 days. According to the guidance, facility procedures are expected to address how and when the need for a consultation will be communicated, how the medication review will be handled if the pharmacist is off-site, how the results or report of the pharmacist's findings will be communicated to the provider, the expectations for the provider's response and follow up, and how and where this information will be documented.

Survey Implications:

Both the previous and the current guidance at F428-Medication Regimen Review have identified that the pharmacist may need to review a medication regimen more frequently, depending on the resident's condition and the risk for adverse consequences associated with the medications. Efforts to prevent medication-related adverse consequences and to recognize existing or emerging complications are a significant focus of clinical care in nursing homes. If there is evidence the pharmacist should have conducted more frequent reviews, surveyors should consider consulting an advanced practitioner, pharmacist or physician at the State Survey Agency or Regional Office to review cases in which this practice may be considered deficient.

If non-compliance has been identified at F428, then additional requirements may also be considered and investigated such as F385-Physician Supervision; F329-Unnecessary Medications; or F501-Medical Director.

For questions on this memorandum, please contact alice.bonner@cms.hhs.gov.

Effective Date: Immediately. This policy should be communicated with all survey and certification staff, their managers and the State/Regional Office training coordinators within 30 days of this memorandum.

References:

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4. a. FDA (Federal Drug Administration) drug safety communication: possible increased risk of fractures of the hip, wrist and spine with the use of proton pump inhibitors. 3/23/2011.

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7. Marquardt KA, Tharratt RS, Musallam NA. Fentanyl remaining in a transdermal system following three days of continuous use. *Ann Pharmacother*. 1995; 29: 969-971.

8. Boockvar KS, Carlson LaCorte H, Giambanco V, Fridman B, Siu A. Medication reconciliation for reducing drug discrepancy adverse effects. *Am J Geriatr Pharmacother*. 2006 Sep; 4(3): 236-43.

/s/

Thomas E. Hamilton

cc: Survey and Certification Regional Office Management