

By
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There are portions of the interpretive guidelines that specify such things as permissive duties or tools that facilities may be using to care for residents.*



DEPARTMENT OF HEALTH & HUMAN SERVICES Centers for Medicare & Medicaid Services 7500 Security Boulevard, Mail Stop S2-12-25 Baltimore, Maryland 21244-1850



Center for Medicaid and State Operations/Survey & Certification Group

Ref: S&C-08-10

DATE: January 18, 2008

TO: State Survey Agency Directors

FROM: Director

Survey and Certification Group

SUBJECT: Use of Interpretive Guidance by Surveyors for Long Term Care Facilities

Memorandum Summary

- The Centers for Medicare & Medicaid Services (CMS) has been asked to clarify the use of the Interpretive Guidance to Surveyors for Long Term Care Facilities in reviewing for compliance with the regulatory requirements for nursing homes.
- Surveyors must cite all deficiencies based on a violation of statutory and/or regulatory requirements.

Background: The Social Security Act mandates the establishment of minimum health and safety standards that providers and suppliers must meet in order to participate in the Medicare and/or Medicaid programs. Specific provision of the nursing home regulations at 42 C.F.R. Part 483 further refine this statutory obligation. CMS' authoritative interpretation of the regulatory language is found in the State Operations Manual (SOM). The SOM specifies that the interpretive guidelines serve as, and also provide surveyors with, specific survey protocols such as investigative protocols, definitions of regulatory terms, and interview probes that they can use during surveys to evaluate compliance with the regulations.

Discussion: The survey process is the best assurance we have that protections set forth in the nursing home requirements are being met and that residents are receiving quality services. CMS continuously investigates ways to improve the long term care survey process with the goal of improving the quality of care and quality of life of nursing home residents. Providing updated interpretive guidance to nursing home surveyors is one method used by CMS to improve the survey process. The interpretive guidance facilitates surveyors' consistent regulatory interpretation and determination of the gravity and pervasiveness of identified deficiencies; ultimately providing a consistent approach to the manner in which surveyors assess a nursing home's compliance with the requirements.

Permissive duties are **not** requirements, and lack of use of any particular tool does not, by itself, constitute sufficient grounds for the citation of a deficiency.*

Page 2 - State Survey Agency Directors

In providing new interpretive guidance, CMS is careful not to prescribe new requirements. Instead, the focus is on relaying to surveyors information consistent with the regulations and accepted standards of care. There are portions of the interpretive guidelines that specify such things as permissive duties or tools that facilities may be using to care for residents. Permissive duties are not requirements, and the lack of use of any particular tool does not, by itself, constitute sufficient grounds for the citation of a deficiency.

*CMS January 18, 2008

SHOULD

Words like "should" or "may" create permissive standards, vs. words like "shall" and "must" that indicate requirements*...



An example of a permissive duty is found in the guidance for 42 C.F.R. § 483.25(c) Pressure Sores. One section of this Guidance refers to repositioning as a common and effective intervention for individuals with a pressure sore or who are at risk of developing one. The Guidance provides, "The care plan for a resident at risk of friction or shearing during repositioning may require the use of lifting devices for repositioning." This sentence indicates a permissive action by the facility but does not create a requirement that facilities use lift devices in order to prevent pressure sores, as the facility may have other interventions in place to avoid shearing and friction. The lack of use, by itself, does not create a deficient practice for a facility. Words like "should" or "may" create permissive standards, vs. words like "shall" and "must" that indicate requirements.

Conclusion: Surveyors should refer to SOM Section 2712 "Use of Survey Protocols in the Survey Process" and Principle #5 in the Principles of Documentation found in Exhibit 7A for clarification in using a triangle of the interpretive guide.

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.*

*CMS January 18, 2008

Conclusion: Surveyors should refer to SOM Section 2712 "Use of Survey Protocols in the Survey Process" and Principle #5 in the Principles of Documentation found in Exhibit 7A for clarification in using information found in the interpretive guidelines. Both sources make it clear 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.

 F332 - The facility must ensure that it is free of medication error rates of Five percent or greater*...

• F333 - The facility must ensure that residents are free of any significant medications error. *If one or more significant errors are identified then a F333 deficiency exists.**

^{*} CMS SOM 12/06

State	F-Tag 332	F-Tag 333
United States	11.0%	6.6%
AR	41.8%	35.3%
NM	28.6%	10.0%
WA	19.7%	5.9%
TN	19.1%	11.3%
CA	14.9%	10.0%
AZ	10.5%	15.0%
MD	7.4%	31.3%

CMS OSCAR Current Survey, December 2008

F-Tag 332 Medication Errors

F - Tag 332

From 07/07 thru 12/08

53% Omission of a Drug

43% involved a vitamin or OTC item

41 % Wrong Dose

33% Dose not given with food

20% not enough fluids with dose

18% involved MDI - puffs

17% involved eye drops

F-Tag **333**Medication Errors

F – Tag 333

From 07/07 thru 12/08

41% Omission of a drug

37% Wrong dose

27% Not following MD orders

15% Wrong Drug administered

13% Administered DC'ed drug

F-Tag 332 and F-Tag 333 Medication Errors Did you know?

The administration of nutritional and dietary supplements should not be included in the calculation of the facility's medications error rate.*

*CMS September 28 2007

DEPARTMENT OF HEALTH & HUMAN SERVICES Centers for Medicare & Medicaid Services 7500 Security Boulevard, Mail Stop S2-12-25 Baltimore, Maryland 21244-1850



Center for Medicaid and State Operations/Survey and Certification Group

Ref: S&C-07-39

DATE: September 28, 2007

TO: State Survey Agency Directors

FROM: Director

Survey and Certification Group

SUBJECT: Nursing Homes - Medication Pass Clarification for Surveying F Tags 332 and

333 During Nursing Home Surveys

Memorandum Summary

A nursing home's noncompliance with the administration of <u>nutritional</u> and <u>dietary</u>
supplements should not be included in the calculation of the facility's medication
error rate at F332 or as a significant medication error at F333.

- We expect that the nursing home 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.
- Medication errors involving <u>vitamins and/or minerals should</u> be documented at F332 and counted towards the 5 percent error rate but <u>would not be considered to be a</u> <u>significant medication error</u> unless the criteria at F333 were met.

Background

Because some facilities may record the administration of nutritional and dietary supplements on the medication administration record (MAR) and as a result, these products may have been interpreted as medications, we are providing the following clarifications as to:

- Whether nutritional and dietary supplements should be evaluated as medications during the medication pass review performed during survey; and
- Whether to include nutritional and/or dietary supplements that are not administered according to physician's orders, in the calculation of the facility's medication error rate.



Dietary Supplements – herbal and alternative products are considered to be dietary supplements.

They are **NOT** regulated by the FDA and their composition is not standardized.

* CMS September 28, 2007

"Dietary Supplements" - 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, given to a resident between meals, 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. Keep in mind that, 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."

Because strong act supplement and to be strong for humanassa

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* CMS September 28, 2007

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cause nutrit and and dietas supplements are not considered to be medications for purposes of

Because nutritional and dietary supplements are not considered to be medications for the purpose of federal nursing home surveys, noncompliance with the administration of these products should **NOT** be included in the calculation of the facility's medication error rate at F332 or as a significant medication error at F333.

* CMS September 28, 2007

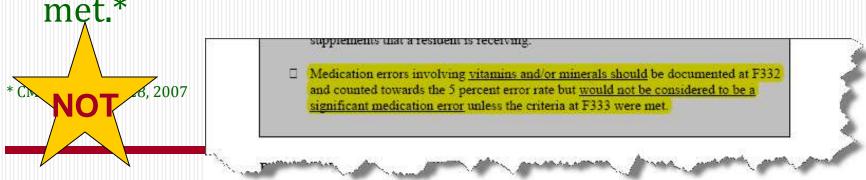
Because nutritional and dietary supplements are not considered to be medications for purposes of federal nursing home surveys, noncompliance with the administration of these products should not be included in the calculation of the facility's medication error rate at F332 or as a significant medication error at F333.

It is expected that the facility staff, along with the prescriber and consulting pharmacist, are aware of review for, and domment any potential adverse consequences between medications.

F-Tag 332 and F-Tag 333 Medication Errors SHOULD Did you know?

Medication errors involving vitamins and/or minerals should be documented at F332 and counted towards the **Five** percent error rate.

But would not be considered to be a significant medication error unless the criteria at F333 were met.*



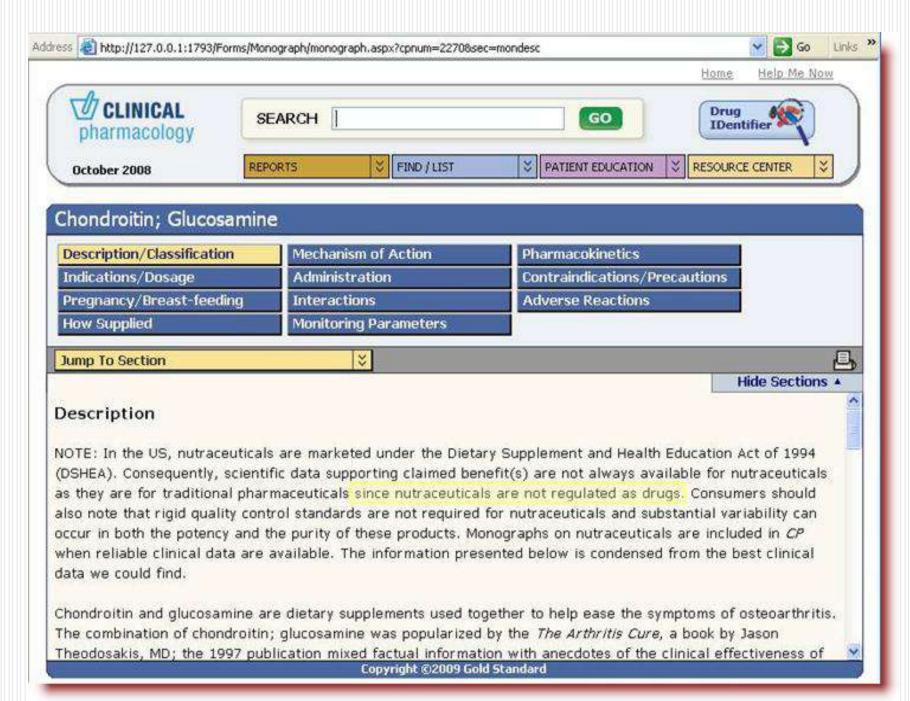
Is **Chondroitin and Glucosamine** a medication error if administered incorrectly during a medication pass?

No,

Chondroitin and Glucosamine are dietary supplements and are not regulated as drugs. They are marketed under the Dietary Supplement and Health Education Act of 1994 (DSHEA)*

^{*&}quot;Clinical Pharmacology Oct 2008"

^{*}CMS September 28 2007



Is a One A Day Multi-Vitamin with Iron a medication error if administered incorrectly during a medication pass?

YES

In most cases as an insignificant error and counted toward the 5% error rate.

*CMS September 28 2007

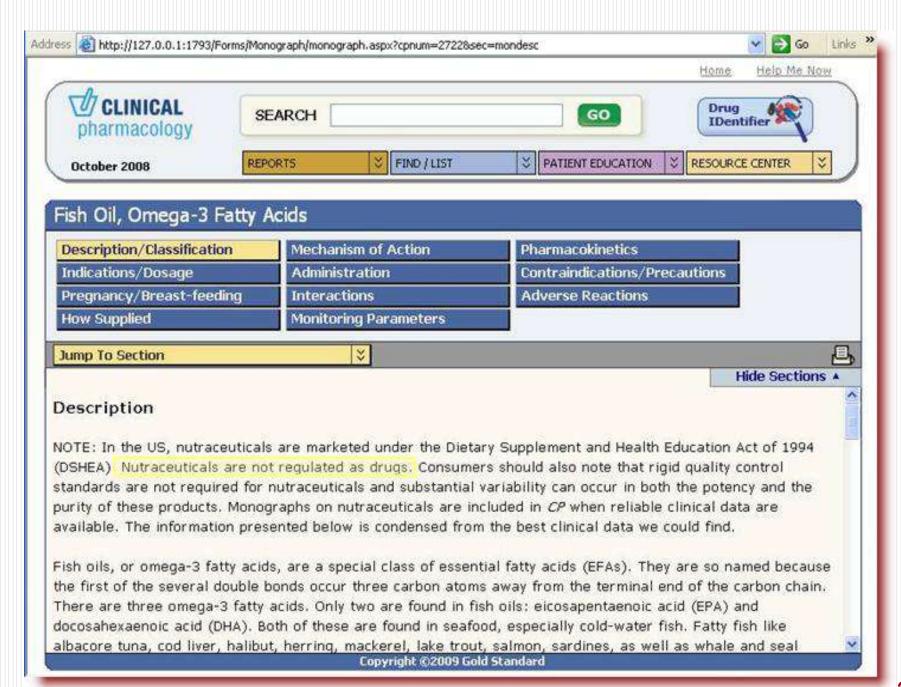
Is **Omega-3** a medication error if administered incorrectly during a medication pass?

No.

Omega-3 fatty acids are dietary supplements and are not regulated as drugs. They are marketed under the Dietary Supplement and Health Education Act of 1994 (DSHEA)*

^{*&}quot;Clinical Pharmacology Oct 2008"

^{*}CMS September 28 2007



What is a Medication Error?

- The observed preparation or administration of drugs or biologicals which is not in accordance with:
 - Physicians Orders
 - Manufacturer's specifications (not recommendations)
 regarding the preparation and administration of the
 drug or biological.
 - Accepted professional standards and principles...

^{*} CMS SOM 12/06

True or False

It is a medication error if the patient does not rinse their mouth after administering **Advair Diskus**?

Maybe...

Advair Diskus Package Insert under Dosage and Administration,

"After inhalation, the patient SHOULD rinse the mouth with water without swallowing."*

*Advair Diskus, Dosage and Administration 2.0 Package Insert

True or False

2 DOSAGE AND ADMINISTRATION

ADVAIR DISKUS should be administered twice daily every day by the orally inhaled route only. After inhalation, the patient should rinse the mouth with water without swallowing [see Patient Counseling Information (17.4)].

More frequent administration or a higher number of inhalations (more than 1 inhalation twice daily) of the prescribed strength of ADVAIR DISKUS is not recommended as some patients are more likely to experience adverse effects with higher doses of salmeterol. Patients using ADVAIR DISKUS should not use additional long-acting beta2-agonists for any reason.

[See Warning 1] Descriptions (5-2, 5-12) 10

water without swallowing."*

*Advair Diskus, Dosage and Administration 2.0 Package Insert



What is a significant medication error?

Answer: An error which causes the resident discomfort or jeopardizes his or her health and safety.

Determining Significance

The relative significance of medication errors is a matter of professional judgment following **three** general guidelines.

- Resident Condition
- Drug Category
- Frequency of error

The following situations in drug administration "MAY" be considered medications errors

- Failure to "Shake Well"
- Mixing insulin suspensions
- Crushing medications that should not be crushed.
- Adequate fluids with medications
- Medications that must be taken with food or antacids
- Medications administered with enteral nutritional formulas

The following situations in drug administration "MAY" be considered medications errors cont.

- Medications instilled into the eye
- Allowing resident to swallow sublingual tablets
- Medication administered via metered dose inhalers

* CMS SOM 12/06

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

The following situations in drug administration may be considered medication errors:

Failure to "Shake Well": The failure to "shake" a drug product that is labeled
"shake well." This may lead to an under dose or over dose depending on the
drug product and the elapsed time since the last "shake." The surveyor should
use common sense in determining the adequacy of the shaking of the
medication. Some drugs, for example dilantin, are more critical to achieve
correct dosage delivery than others.

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Adequate fluids



With NSAIDs the surveyor should count fluids consumed during meals or snacks as fluids taken with the medications as long as they have consumed within a reasonable time of taking the medication (e.g. within approximately 30min).

Adequate fluids

Duk iakanves (e.g., iviciamuch, Flocian, Seruian, Konsyl, Chrucch),

Nonsteroidal Anti-Inflammatory Drugs (NSAIDs) should be administered with adequate fluid. Adequate fluid is not defined by the manufacturer but is usually four to eight ounces. The surveyor should 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). If the resident refuses to take adequate fluid, the facility should not be 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. It is important that the surveyor not apply this rule to residents who are fluid restricted; and

Potassium supplements (solid

^{*} CMS SOM 08/07

Something to Remember Adequate Fluids

If the patient is on a fluid restrictions then adequate fluid consideration does NOT apply

Something to Remember Adequate Fluids

If the resident refuses to take adequate fluid and the facility made a good faith effort and provided assistance, the facility **should** not be at fault.

NOTE

• If the person administering the drug follows all the procedures and there is failure to administer the medication because the resident is uncooperative this "SHOULD" not be called a medication error.

* CMS SOM 12/06

Timing Errors

If a drug is ordered before meals (AC) and administered after meals (PC).

Always count this as a medication error.



The same applies if a drug is ordered after meals (PC) and administered before meals (PC).

^{*} CMS SOM 12/06

Timing Errors

Is it always a medication error if a medication is administered over 60 minutes later than ordered?

NO not always

Count a wrong time error if;

The drug is administered 60 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 residents health and safety.

* CMS SOM 12/06

Count a wrong time error if;

Determining Medication Errors

Timing Errors -- If a drug is ordered before meals (AC) and administered after meals (PC), always count this as a medication error. Likewise, if a drug is ordered PC and is given AC, count as a medication error. Count a wrong time error if the drug is administered 60 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 drug with a long half-life (e.g., digoxin) as a wrong time error when it is 15 minutes late is improper because this drug 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).

^{*} CMS SOM 08/07

- Half-Life The time required for ½ of the medications to be eliminated from the system under normal circumstances.
- It is recognized that it takes 5 half-lives to totally remove a drug.
- In many cases reduced renal function will prolong the elimination even more

Commonly seen drugs with long half-lives
Lisinopril – Prinivil – 12hr – 60hrs(2.5 days)*1
Ramipril – Altace – 13-17hrs – 65hrs(2.7days)
Fosinopril – Monopril -12hrs -60hrs(2.5days)
Digoxin – Lanoxin – 30hrs – 150hrs(6.25days) *2

^{*1} Fact and Comparisons

^{*2} Clinical Pharmacology

True or False

Is it always a medication error if the nurses administers digoxin and lisinopril at 10:25AM when the medication pass is scheduled for 9:00AM?

False

It would be dependent of the patient's condition and ultimately cause the resident discomfort or jeopardize the residents health and safety.

* CMS SOM 12/06

True or False

The latest recapitulation of drug orders is sufficient for determining whether a valid order exists provided the prescriber has signed the "recap".

TRUE

administers the first dose in a +-times-a-day dosing senedure.

Prescriber's Orders — he latest recapitulation of drug 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 drug.

Procedures §483.25(m)

Medication Error Detection Methodology -- Use an observation technique to determine medication errors. The survey team should observe the administration of drugs, on several different drug "passes," when necessary. Record what is observed; and

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^{*} CMS SOM 08/07

General Information

Initially observe the administration at least **20-25** medications, observing as many staff administering medication as possible to facilitate a review of the facilities entire medication distribution system.

Sub-Task 5E, Section C. 1. Medication Pass

General Information

After the medication pass, compare your observations with the prescriber's orders.

If no errors are found after reconciliation of the pass with the prescriber's orders, the medication pass observation is complete.

If one or more errors are found, observe the administration of another **20-25** medications.

Sub-Task 5E, Section C. 1. Medication Pass

What is a significant medication error?

- An error that causes the resident discomfort or jeopardizes his or her health and safety.
- There are three general guidelines
 - Resident Condition-fluid pill to a dehydrated resident
 - Drug Category- (NTI) coumadin, dilantin, etc
 - Frequency of error

• Examples of significant errors

- Nitrol patch or oint omitted once
- Coumadin administered without an order
- 0.25mg Digoxin administered when 0.125mg ordered
- Wrong volume of Dilantin Suspension

Time to Pass

 Unless a time is specified you have 60 minutes before and after with a scheduled medication pass.

Exception would be if a drug is ordered before or after a meal. Then the time is more critical.

Inhalers

- Shake the container <u>WELL</u>
- Position the inhaler in front or in the residents mouth.
- If more than ONE puff is required wait <u>ONE</u>
 (1) minute between the puffs.
- In <u>many</u> cases have the resident swish water in mouth after – DO NOT SWALLOW!

Eye Drops

- Make sure the eye drop, not the dropper, makes full contact with the conjunctival sac
- If more than one drop is required WAIT 3-5 minutes between drops

* CMS SOM 12/06

Medications administered via G-Tube

- Check the placement of the tube
- Flush the tube with at least <u>30ml</u> of water before and after medications. Not COLD water.

* CMS SOM 12/06

OTCs

- Make sure you have the right product !!
- Multivitamin and multivitamin with Iron are not the same.
- Calcium with Vit-D –watch the strengths

Adequate Fluids with Medications Examples:

- Bulk Laxatives Metamucil / Citrucel
- NSAIDS 4-8oz with Ibuprofen / naproxen
- Potassium supplements with or after a meal with a full glass of water or fruit juice

Drugs taken with Food or Antacids
Example:

NSAIDS

Common NSAIDS
Ibuprofen / naproxen

Other medication errors

- Failure to "Shake Well"
- Insulin suspensions must be rolled not shaken
- Crushing medications that should not be crushed.
- Providing adequate fluids with medications
- Drugs that require food or antacids

Other Points to Remember

Date Openings

When you open an Insulin or multi use container, date the container

Wash Hands

When in doubt, wash your hands and any time you touch a resident.

Med Cart

Unless in is in your direct control or sight it must be locked

What can the facility to improve the facility error rate?

OTC Formulary

This greatly impacts the number of items a nurse must choose from and directly reduce the odds of an error.

Patient Specific Packaging

Usually at a small expense the pharmacy will supply all medications patient specific and will improve the relationship with the MAR/TAR.

Incorporate a policy and procedure to remove discontinued medications immediately when the order is stopped and turn them into nursing management.

Incorporate a policy and procedure to ensure meds are received in a timely fashion and report any not available to nursing management.

Routine Med-Pass observations

Competent Testing of all staff that passes medications

Color code each medication time pass on the MAR

It is an OPEN BOOK TEST!

The answers are right before you on the *MAR*.

What four letter word will help you always get it right?

READ