DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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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 nutritional and dietary 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 vitamins and/or minerals should be documented at F332 and counted towards the 5 percent error rate but would not be considered to be a significant medication error 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.

Discussion

Nutritional or dietary supplements are not explicitly defined in the State Operations Manual (SOM), Appendix PP. We are providing the following guidance regarding these types of 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.)"[1]

- "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."[2]

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 document any potential adverse consequences between medications, nutritional supplements, and dietary supplements that a resident is receiving.

Medication errors involving vitamins and/or minerals should be documented at F332 and counted towards the 5 percent error rate. Medication errors involving vitamins and minerals would not be considered to be a significant medication error unless the criteria at F333 were met. An example of a significant medication error related to vitamin administration could be: failure to administer Vitamin K for a resident with complications related to warfarin which was prescribed by a physician. The CMS Long-Term Care Facility Resident Assessment Instrument User's Manual provides guidance to code medications administered in the past seven days which includes the administration of vitamins.[3]

For questions on this memorandum, please contact Linda O'Hara at 410-786-8347 or via email at linda.ohara@cms.hhs.gov).

[1] Pharmacy Times, 71(1): p. 28, 31-32. 2005.
[2] CMS Long-Term Care Facility Resident Assessment Instrument User's Manual Version 2.0. "Section O. Medications," 2002, p 3-177.
[3] Ibid., p. 3-177,

Effective Date: Immediately. The State Agency should disseminate this information within 30 days of the date of this memorandum.

Training: The materials should be distributed immediately to all State Agencies and training coordinators.

/s/
Thomas E. Hamilton

cc: Survey and Certification Regional Office Management