

Center for Medicaid and State Operations/Survey and Certification Group

Ref: S&C-06-29
(Revised: 9-20-06)

DATE: September 20, 2006

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: **Nursing Homes** - Issuance of Revised Surveyor Guidance for Unnecessary Medications (F329) and the entire Pharmacy Services section at §483.60 (collapsing current regulatory language into three tags (F425, F428, and F431) in Appendix PP, State Operations Manual, as well as medication related revisions in Appendix P Task 5 and Sub-Tasks 5A, 5C, and 5E: **REVISED**

NOTE: An advance copy of the Interpretive guidance for F329 (unnecessary drugs) was originally issued on 9-15-06. The copy released on 9-15-06 contains erroneous information. The corrected version is attached to this communication. **Please delete the previous version.**

The following dosages have been changed in the Table 1 listing of medications:

- Clorazepate was inadvertently listed as 5 mg and has been revised to read Clorazepate 15 mg.
- Diazepam was inadvertently listed as 1.5 mg and has been revised to read Diazepam 5 mg.
- Clonazepam was inadvertently listed as 7.5 mg and has been revised to read Clonazepam 1.5 mg.

The original letter with corrections noted above follows:

Letter Summary

- Revised guidance for long-term care surveyors regarding Unnecessary Drugs, Pharmacy Services, Drug Regimen Review, and Labeling and Storage of Drugs and Biologicals will be effective December 18, 2006.
- ASPEN System changes in preparation for these revisions will be effective at the same time.
- An advance copy of the guidance and training materials is attached.
- This training packet is to be utilized in assuring that all surveyors who survey nursing homes are trained in the revised guidance by the implementation date.

Revised surveyor guidance for surveying Unnecessary Drugs, Pharmacy Services, Drug Regimen Review, and Labeling and Storage of Drugs and Biologicals and is scheduled to become effective December 18, 2006. At that time, a final copy of the new guidance will be available at <http://www.cms.hhs.gov/Transmittals/> and ultimately incorporated into Appendix PP of the State Operations Manual. (Note: System changes will be effective the same date.)

We have entirely revised interpretive guidelines for F329, Unnecessary Medications, including clarifications of several aspects of medication management and a new medication table that Page includes medications that are problematic to the nursing home population. We have provided an Investigative Protocol that also covers both Medication and Medication Regimen Review issues. and severity guidance for F329.

For Pharmacy Services at §483.60, we have combined regulatory guidance presently at Tags F425-431 into three remaining tags, F425 Pharmacy Services, F428 Drug Regimen Review, and F431 Labeling and Storage of Drugs and Biologicals. The new guidance speaks to the provision of pharmaceutical services for the entire distribution system, from ordering and acquisition to administration and disposal of medications to assure a safe system for each resident. We have also provided severity guidance for each of these F Tags.

Due to these changes to surveyor guidance in Appendix PP, we have made corresponding changes to certain survey tasks as follows:

- Task 5 – text added that describes the assessment of pharmaceutical services;
- Sub-Task 5A – text revised to state that each surveyor completing a medication pass observation will review drug storage on their assigned units;
- Sub-Task 5C – text added to guide the surveyor to use the investigative protocol for F329 for each Resident Review, deleted adverse drug reactions section of 5C, part G3; and
- Sub-Task 5E. – complete revision of text and renaming of 5E as Medication Pass and Pharmacy Services.

We are providing an advance copy of the revised guidance for Appendix P and PP. Also attached to this memorandum are training materials for the revised F Tags and the survey process changes. This training packet is to be utilized in assuring that all surveyors who survey nursing homes are trained in this new guidance by the implementation date. The training materials have been presented and discussed in teleconference with the CMS Regional Offices. We encourage training to be conducted in person with group discussion to optimize learning. However, if this is not feasible to meet the needs of your surveyors, it is acceptable to use other methods. The training materials may also be used to communicate with provider groups and other stakeholders. RO training coordinators will document the completion of training on this new guidance for all RO and State nursing home surveyors within their region.

We will be providing additional training for F329, Unnecessary Medications in two two-day train-the-trainer sessions in Baltimore in November, 2006. Attendees of these sessions will be responsible for training surveyors on F329. In addition we will broadcast a satellite presentation on F329 on December 15, 2006 at 1:00 p.m. EST.

For questions on this memorandum, please contact Beverly Cullen at 410-786-6784 or via email at Beverly.Cullen@cms.hhs.gov.

Effective Date: 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 (G-5)

Enclosures:

- Advance Interpretive Guidance for Tags F329(REV), F425, F428 and F431;
- Advance Appendix P changes;
- Training Powerpoints; and
- Training Instructor Guide