

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.
- The updated guidance is currently available on the CMS Web site at [SOM Appendix P](#) and [SOM Appendix PP](#)

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.

The guidance is now available on the CMS Website at [SOM Appendix P](#) and [SOM Appendix PP](#). 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 or for training materials, 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

Enclosures:

CMS Manual System

Pub. 100-07 State Operations Provider Certification

Department of Health &
Human Services (DHHS)
Centers for Medicare &
Medicaid Services (CMS)

Transmittal

Date:

SUBJECT: Revisions to Appendix P and PP

I. SUMMARY OF CHANGES: Revised Task 5 and Sub-Tasks 5A, 5C, and 5E of Appendix P. Appendix PP has the following revisions: The regulatory text at Tags F329, F330, and F331 has been combined into Tag F329, the regulatory text at Tags F425, F426, and F427 has been combined into Tag F425, the regulatory text at Tags F428, F429, and F430 has been combined into Tag F428. Finally, the regulatory text at Tags F431 and F432 has been combined into Tag 431. In addition, the entire interpretive guidelines for all of the combined tags have been revised as well.

NEW/REVISED MATERIAL - EFFECTIVE DATE*: Upon Issuance
IMPLEMENTATION DATE: January 2007

Disclaimer for manual changes only: The revision date and transmittal number apply to the red italicized material only. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual not updated.)
(R = REVISED, N = NEW, D = DELETED) – (Only One Per Row.)

| R/N/D | CHAPTER/SECTION/SUBSECTION/TITLE |
|--------------|--|
| R | Appendix P/ Index |
| R | Appendix P/Task 5/Information Gathering |
| R | Appendix P/Task 5/Subtask 5A/General Observations of the Facility |
| R | Appendix P/Task 5/Subtask 5C/Resident Review |
| R | Appendix P/Task 5/Subtask 5E/Medication Pass and Pharmacy Services |
| R | Appendix PP/§483.25(l)/F329/Unnecessary Drugs |
| D | Appendix PP/§483.60(c)(2)/F330/Anti-psychotic Drugs |
| D | Appendix PP/§483.60(d)/F331/Anti-psychotic Drugs |
| R | Appendix PP/§483.60/F425/Pharmacy Services |
| D | Appendix PP/§483.60(a)/F426 Procedures |
| D | Appendix PP/§483.60(b)/F427/Service Consultation |
| R | Appendix PP/§483.60(c)/F428/Drug Regimen Review |
| D | Appendix PP/§483.60(c)(2)/F429/Drug Regimen Review |
| D | Appendix PP/§483.60(c)(2)/F430/Drug Regimen Review |
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|---|---|
| R | Appendix PP/§483.60(d)/F431/Labeling of Drugs and Biologicals |
| D | Appendix PP/§483.60(e)/F432/Storage of Drugs and Biologicals |

III. FUNDING: Medicare contractors shall implement these instructions within their current operating budgets.

IV. ATTACHMENTS:

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|----------|--------------------------------------|
| | Business Requirements |
| x | Manual Instruction |
| | Confidential Requirements |
| | One-Time Notification |
| | Recurring Update Notification |

***Unless otherwise specified, the effective date is the date of service.**