



STATE OF WASHINGTON
DEPARTMENT OF SOCIAL AND HEALTH SERVICES
Aging and Long-Term Support Administration
PO Box 45600, Olympia, Washington 98504-5600

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CLARIFYING INFORMATION REGARDING STORAGE AND
MANAGEMENT OF CONTROLLED MEDICATIONS

Dear Nursing Facility/Home Administrator:

The purpose of this letter is to provide clarifying information and to alert you of the controlled medication storage requirement and reconciliation requirement in the nursing home setting. Additionally, this letter advises you of inconsistent language between the Medication Storage and Labeling Long Term Care Survey Pathway and the guidance found in Appendix PP at F761.

The Center for Medicare and Medicaid Services (CMS) released updated rules for nursing homes in [Appendix PP](#) of the State Operating Manual (SOM) on 11/28/17. The new rules and guidance included expanded and/or revised guidance for Pharmacy Services (F755) and Storage and Labeling of Drugs and Biologicals (F761). In particular, Residential Care Services (RCS) has received questions about storage and reconciliation of controlled medications (medications which fall under US Drug Enforcement Agency (DEA) Schedules II—V).

Controlled Medication Storage: F761 requires the facility must provide, “separately locked, permanently affixed compartments for storage of controlled drugs listed in Schedule II of the Comprehensive Drug Abuse Prevention and Control Act of 1976 and other drugs subject to abuse, except when the facility uses single unit package drug distribution systems in which the quantity stored is minimal and a missing dose can be readily detected.” The guidance in F761 further clarifies, “Schedule II-V medications must be maintained in separately locked, permanently affixed compartments,” and makes some exceptions for controlled medication storage in a single unit package medication distribution system.

The wording of the rule about medication storage has not changed, but the guidance to maintain Schedule **IV-V** medications separate from non-scheduled drugs is new. This guidance exceeds the state rules that govern controlled medication storage in nursing homes ([WAC 246-865](#)). Please consult with your facility pharmacist and/or use this link from [DEA](#) to determine which medications in your facility might require different storage.

Controlled Medication Reconciliation: F755 in Appendix PP of the SOM states “The facility must employ or obtain the services of a licensed pharmacist who... (b)(2) Establishes a system of records of receipt and disposition of all controlled drugs in sufficient detail to enable an accurate reconciliation; and, (b)(3) Determines that drug records are in order and that an account of all controlled drugs is maintained and periodically reconciled.”

Providers and surveyors have asked about the meaning of “periodic” reconciliation. The pharmacy services regulations do not specifically address the frequency of counting or reconciling controlled medications. Guidance at F755 states, “Because diversion can occur at any time, periodic reconciliation should accommodate actual facility experience, such that if there is any evidence or even suspicion that diversion may be occurring, then that may dictate conducting the periodic reconciliation as frequently as daily. State or other federal requirements may specify the frequency of reconciliation.”

Washington Administrative Code (WAC) 246-865-060, in (6)(d) specifies, “At least once each 24 hours, the amount of all Schedule II controlled substances stored in the facility shall be counted by at least two persons who are legally authorized to administer drugs. A similar count shall be made of all Schedule III controlled substances at least weekly. Records of counts shall be entered in the Schedule II and III controlled substances book(s).” Section (6)(h) allows a nursing home to vary from the standard in (6)(d), “if they are using a unit dose drug distribution system and if that system provides for the accurate accounting, by the nursing home and the supplying pharmacy, of the receipt and disposition of all Schedule II and III controlled substances.”

WAC 246-865-060 also requires facilities to have a pharmaceutical committee that develops written policies and procedures for distribution, control and use of medications. Facilities may want to use this committee as a means to evaluate their unique “facility experience” in determining a reconciliation schedule that adequately protects and accounts for controlled medications while meeting the specific state requirements.

Medication Storage Pathway: CMS-20089 (02/2017) Medication Storage and Labeling (to view, click [LTC Survey Pathways](#)), a pathway published by CMS for use by surveyors during the recertification survey, contains a checklist on the upper part of the form. Through observation, surveyors try to affirm items on the checklist.

The second item on the checklist, “Schedule II controlled medications (excluding single-unit packaging in minimal quantities that can readily be detected if missing) were maintained within a separately locked permanently affixed compartment,” is not congruent with the scope of the guidance in F761. The guidance states, “Schedule II-V medications must be maintained in separately locked, permanently affixed compartments.”

CMS recognizes there is inconsistency in the language and plans to update CMS-20089 in a future revision. When evaluating storage of controlled medications, CMS directs surveyors to follow the language in the current guidance at F761 in Appendix PP.

Thank you for your continued commitment to resident health and safety. If you have any questions, please contact your RCS Field Manager.

Sincerely,



Candace Goehring, Director
Residential Care Services

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