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**4658.1300 MEDICATIONS AND PHARMACY SERVICES; DEFINITIONS.**

Subpart 1. **Controlled substances.** "Controlled substances" has the meaning given in Minnesota Statutes, section [152.01](#), subdivision 4.

Subp. 2. **Schedule II drugs.** "Schedule II drugs" means drugs with a high potential for abuse that have established medical uses as defined in Minnesota Statutes, section [152.02](#), subdivision 3.

Subp. 3. **Pharmacy services.** "Pharmacy services" means services to ensure the accurate acquiring, receiving, and administering of all drugs to meet the needs of each resident.

Subp. 4. **Drug regimen.** "Drug regimen" means all prescribed and over-the-counter medications a resident is taking.

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**4658.1305 PHARMACIST SERVICE CONSULTATION.**

A nursing home must employ or obtain the services of a pharmacist currently licensed by the Board of Pharmacy who:

A. provides consultation on all aspects of the provision of pharmacy services in the nursing home;

B. establishes a system of records of receipt and disposition of all controlled drugs in sufficient detail to enable an accurate reconciliation; and

C. determines that drug records are accurately maintained and that an account of all controlled drugs is maintained.

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**4658.1310 DRUG REGIMEN REVIEW.**

A. The drug regimen of each resident must be reviewed at least monthly by a pharmacist currently licensed by the Board of Pharmacy. This review must be done in accordance with Appendix N of the State Operations Manual, Surveyor Procedures for Pharmaceutical Service Requirements in Long-Term Care, published by the Department of Health and Human Services, Health Care Financing Administration, April 1992. This standard is incorporated by reference. It is available through the Minitex interlibrary loan system. It is not subject to frequent change.

B. The pharmacist must report any irregularities to the director of nursing services and the attending physician, and these reports must be acted upon by the time of the next physician visit, or sooner, if indicated by the pharmacist. For purposes of this part, "acted upon" means the acceptance or rejection of the report and the signing or initialing by the director of nursing services and the attending physician.

C. If the attending physician does not concur with the pharmacist's recommendation, or does not provide adequate justification, and the pharmacist believes the resident's quality of life is being adversely affected, the pharmacist must refer the matter to the medical director for review if the

medical director is not the attending physician. If the medical director determines that the attending physician does not have adequate justification for the order and if the attending physician does not change the order, the matter must be referred for review to the quality assessment and assurance committee required by part [4658.0070](#). If the attending physician is the medical director, the consulting pharmacist must refer the matter directly to the quality assessment and assurance committee.

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**4658.1315 UNNECESSARY DRUG USAGE.**

Subpart 1. **General.** A resident's drug regimen must be free from unnecessary drugs. An unnecessary drug is any drug when used:

A. in excessive dose, including duplicate drug therapy;

- B. for excessive duration;
- C. without adequate indications for its use; or
- D. in the presence of adverse consequences which indicate the dose should be reduced or discontinued.

In addition to the drug regimen review required in part [4658.1310](#), the nursing home must comply with provisions in the Interpretive Guidelines for Code of Federal Regulations, title 42, section [483.25](#)(1)(1) found in Appendix P of the State Operations Manual, Guidance to Surveyors for Long-Term Care Facilities, published by the Department of Health and Human Services, Health Care Financing Administration, April 1992. This standard is incorporated by reference. It is available through the Minitex interlibrary loan system and the State Law Library. It is not subject to frequent change.

Subp. 2. **Monitoring.** A nursing home must monitor each resident's drug regimen for unnecessary drug usage, based on the nursing home's policies and procedures, and the pharmacist must report any irregularity to the resident's attending physician. If the attending physician does not concur with the nursing home's recommendation, or does not provide adequate justification, and the pharmacist believes the resident's

quality of life is being adversely affected, the pharmacist must refer the matter to the medical director for review if the medical director is not the attending physician. If the medical director determines that the attending physician does not have adequate justification for the order and if the attending physician does not change the order, the matter must be referred for review to the Quality Assurance and Assessment (QAA) committee required by part [4658.0070](#). If the attending physician is the medical director, the consulting pharmacist shall refer the matter directly to the QAA.

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**4658.1320 MEDICATION ERRORS.**

A nursing home must ensure that:

A. Its medication error rate is less than five percent as described in the Interpretive Guidelines for Code of Federal Regulations, title 42, section [483.25\(m\)](#), found in

Appendix P of the State Operations Manual, Guidance to Surveyors for Long-Term Care Facilities, which is incorporated by reference in part [4658.1315](#). For purposes of this part, a medication error means:

(1) a discrepancy between what was prescribed and what medications are actually administered to residents in the nursing home; or

(2) the administration of expired medications.

B. It is free of any significant medication error. A significant medication error is:

(1) an error which causes the resident discomfort or jeopardizes the resident's health or safety; or

(2) medication from a category that usually requires the medication in the resident's blood to be titrated to a specific blood level and a single medication error could alter that level and precipitate a reoccurrence of symptoms or toxicity.

C. All medications are administered as prescribed. An incident report or medication error report must be filed for any medication error that occurs. Any significant medication

errors or resident reactions must be reported to the physician or the physician's designee and the resident or the resident's legal guardian or designated representative and an explanation must be made in the resident's clinical record.

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**4658.1325 ADMINISTRATION OF MEDICATIONS.**

Subpart 1. **Pharmacy services.** A nursing home must arrange for the provision of pharmacy services.

Subp. 2. **Staff designated to administer medications.** A nurse or unlicensed nursing personnel, as described in part [4658.1360](#), must be designated as responsible for the administration of medications during each work period.

Subp. 3. **List of staff to administer medications.** A list of staff authorized to administer medications must be available at each nursing station.



Subp. 4. **Self-administration.** A resident may self-administer medications if the comprehensive resident assessment and comprehensive plan of care as required in parts [4658.0400](#) and [4658.0405](#) indicate this practice is safe and there is a written order from the attending physician.

Subp. 5. **Medications administered by injection.** Medications for injection may be given only by a physician, physician's assistant, registered nurse, nurse practitioner, or licensed practical nurse, or may be self-administered by a resident in accordance with subpart 4.

Subp. 6. **Medications added to food.** Adding medication to a resident's food must be prescribed by the resident's physician and the resident, or the resident's legal guardian or designated representative, must consent to having medication added to food. This subpart does not apply to adding medication to food if the sole purpose is for resident ease in swallowing.

Subp. 7. **Administration requirements.** The administration of medications must include the complete procedure of checking the resident's record, transferring individual doses of the medication from the resident's prescription container, and distributing the medication to the resident.

Subp. 8. **Documentation of administration.** The name, date, time, quantity of dosage, and method of administration of all medications, and the signature of the nurse or authorized person who administered and observed the same must be recorded in the resident's clinical record. Documentation of the administration must take place following the administration of the medication. If administration of the medication was not completed as prescribed, the documentation must include the reason the administration was not completed, and the follow-up that was provided, such as notification of a registered nurse or the resident's attending physician.

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**4658.1330 WRITTEN AUTHORIZATION FOR ADMINISTERING DRUGS.**

All medications, including those brought into a nursing home by a resident, must be administered only in accordance with a written order signed by a health care practitioner licensed to prescribe in Minnesota except that order may be given by

telephone provided that the order is done according to part [4658.0455](#).

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**4658.1335 STOCK MEDICATIONS.**

Subpart 1. **Stock supply medications.** Only medications obtainable without prescription may be retained in general stock supply and must be kept in the original labeled container.

Subp. 2. **Emergency medication supply.** A nursing home may have an emergency medication supply which must be approved by the QAA committee. The contents, maintenance, and use of the emergency medication supply must comply with part [6800.6700](#).

Subp. 3. **Prohibitions.** No prescription drug supply for one resident may be used or saved for the use of another resident in the nursing home.

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**4658.1340 MEDICINE CABINET AND PREPARATION AREA.**

Subpart 1. **Storage of drugs.** A nursing home must store all drugs in locked compartments under proper temperature controls, and permit only authorized nursing personnel to have access to the keys.

Subp. 2. **Storage of Schedule II drugs.** A nursing home must provide separately locked compartments, permanently affixed to the physical plant or medication cart for storage of controlled drugs listed in Minnesota Statutes, section [152.02](#), subdivision 3.

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### **4658.1345 LABELING OF DRUGS.**

Drugs used in the nursing home must be labeled in accordance with part [6800.6300](#).

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### **4658.1350 DISPOSITION OF MEDICATIONS.**

Subpart 1. **Drugs given to discharged residents.** Current medications, except controlled substances listed in Minnesota Statutes, section [152.02](#), subdivision 3, belonging to a resident must be given to the resident, or the resident's legal guardian or designated representative, when discharged or transferred and must be recorded on the clinical record.

Subp. 2. **Destruction of medications.**

A. Unused portions of controlled substances remaining in the nursing home after death or discharge of a resident for whom they were prescribed, or any controlled substance discontinued permanently must be destroyed in a manner recommended by the Board of Pharmacy or the consultant pharmacist. The board or the pharmacist must furnish the necessary instructions and forms, a copy of which must be kept on file in the nursing home for two years.

B. Unused portions of other prescription drugs remaining in the nursing home after the death or discharge of the resident for whom they were prescribed or any prescriptions discontinued permanently, must be destroyed according to part [6800.6500](#), subpart 3, or must be returned to the pharmacy according to part [6800.2700](#), subpart 2. A notation of the destruction listing the date, quantity, name of medication, prescription number, signature of the person destroying the drugs, and signature of the witness to the destruction must be recorded on the clinical record.

Subp. 3. **Loss or spillage.** When a loss or spillage of a prescribed Schedule II drug occurs, an explanatory notation must be made in a Schedule II record. The notation must be signed by the person responsible for the loss or spillage and by one witness who must also observe the destruction of any remaining contaminated drug by flushing into the sewer system or wiping up

the spill.

Subp. 4. **Returned to pharmacy.** Drugs and prescribed medications used in nursing homes may be returned to the dispensing pharmacy according to part [6800.2700](#), subpart 2.

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**4658.1355 MEDICATION REFERENCE BOOK.**

A nursing home must maintain at least one current medication reference book. For the purposes of this part, "current" means material published within the previous two years.

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**4658.1360 ADMINISTRATION OF MEDICATIONS BY UNLICENSED PERSONNEL.**

Subpart 1. **Authorization.** The director of nursing services may delegate medication administration to unlicensed personnel according to Minnesota Statutes, sections [148.171](#), subdivision 15, and [148.262](#), subdivision 7.

Subp. 2. **Training.** Unlicensed nursing personnel who administer medications in a nursing home must:

A. have completed a nursing assistant training program approved by the department; and

B. have completed a standardized medication administration training program for unlicensed personnel in nursing homes which is offered through a Minnesota postsecondary educational institution that includes, at a minimum, instruction on the following:

(1) the complete procedure of checking the resident's medication record;

(2) preparation of the medication for administration;



(3) administration of the medication to the resident;

(4) assisting residents with self-administration as necessary;

(5) documentation after administration of the date, time, dosage, and method of administration of all medications, or the reason for not administering the medication as ordered, and the signature of the nurse or authorized person who administered and observed the same; and

(6) the type of information regarding medication administration reportable to a nurse.

Subp. 3. **Documentation of training course.** A nursing home must keep written documentation verifying completion of the required course by all unlicensed nursing personnel administering medications.

Subp. 4. **Medication administration.** A person who completes the required training course, and has been delegated the responsibility, may administer medication, whether oral, suppository, eye drops, ear drops, inhalant, or topical, if:

A. the medications are regularly scheduled; and

B. in the case of pro re nata (PRN) medications, the administration of the medication is authorized by a nurse or reported to a nurse within a time period that is specified by nursing home policy prior to the administration.

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**4658.1365 PENALTIES FOR MEDICATIONS AND PHARMACY SERVICES RULE VIOLATIONS.**

Penalty assessments will be assessed for violations of parts [4658.1300](#) to [4658.1360](#) and are as follows:

- A. part [4658.1305](#), \$300;
- B. part [4658.1310](#), \$300;
- C. part [4658.1315](#), \$300;

- D. part [4658.1320](#), \$500;
  
- E. part [4658.1325](#), subpart 1, \$500;
  
- F. part [4658.1325](#), subpart 2, \$300;
  
- G. part [4658.1325](#), subpart 3, \$50;
  
- H. part [4658.1325](#), subpart 4, \$250;
  
- I. part [4658.1325](#), subpart 5, \$500;
  
- J. part [4658.1325](#), subpart 6, \$250;
  
- K. part [4658.1325](#), subpart 7, \$350;
  
- L. part [4658.1325](#), subpart 8, \$300;
  
- M. part [4658.1330](#), \$350;
  
- N. part [4658.1335](#), \$300;
  
- O. part [4658.1340](#), \$300;
  
- P. part [4658.1345](#), \$300;

Q. part [4658.1350](#), \$300;

R. part [4658.1355](#), \$100;

S. part [4658.1360](#), subpart 1, \$350;

T. part [4658.1360](#), subpart 2, \$300;

U. part [4658.1360](#), subpart 3, \$50; and

V. part [4658.1360](#), subpart 4, \$350.

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