



MINNESOTA DEPARTMENT OF HEALTH

In the Matter of the Proposed Adoption of
Amendments to Permanent Rules of the
Department of Health Governing Assisted
Living Home Care Providers, Home Care
and Hospice Services, Minnesota Rules,
Chapter 4668

STATEMENT OF NEED
AND REASONABLENESS

September, 1998

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I. INTRODUCTION

Minnesota Rules, Chapter 4668, establish licensure standards for home care services and hospice services. Those rules set forth operational requirements considered necessary to assure, to the extent possible, the health, safety, well-being and appropriate treatment of persons who receive home care and hospice services. There are five existing classes of home care licenses. The proposed revisions establish a sixth class of home care license, called "assisted living home care provider," to comply with the statutory requirements found in Laws of Minnesota 1997, Chapter 113, and in Minnesota Statutes, Chapter 144D, the Housing with Services Registration Act.

A notice titled "Comments Sought on Planned Amendment to Rules Governing Home Care and Hospice Licensure" was published in the *State Register*, 20 S.R. 2476, on May 6, 1996. The purpose of this notice was to inform interested parties that the Minnesota Department of Health was beginning the rulemaking process and to request information and opinions concerning the regulation of home care and hospice services. The notice included the statement that:

"The Department is considering rule amendments that will: decrease the supervisory requirements for home health aides; develop regulations compatible with the Elderly Housing with Services Act (Minnesota Statutes Chapter 144D) including training and supervisory requirements; revise standards for medication management including provisions on the centralized storage of medications; and amend other parts of the rule identified as in need of change during the comment period."

This rulemaking proceeding is the first proceeding under that notice. Future rulemaking proceedings under the 5/6/96 *State Register* notice are planned to address revisions to the existing rule language, legislative mandates for changes, and reformatting the rule chapter.

A rule advisory committee was established in late spring of 1996 to provide assistance to the department in developing revisions to the existing rule language that would better reflect the intent of legislation passed since the promulgation of the existing home care and hospice licensure rules. Additional meetings were held with representatives of trade associations that would be affected by the revisions to the existing home care and hospice licensure rules. That rule advisory committee and other interested persons were notified of meetings to develop language to implement Laws of Minnesota 1997, Chapter 113. Many of the members and others attended meetings and provided comments on draft language.

Upon request, this Statement of Need and Reasonableness can be made available in an alternative format, such as large print, Braille, or cassette tape. To make a request, contact:

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II. DEPARTMENT'S STATUTORY AUTHORITY

The Department's statutory authority to adopt the rules is set forth in Minnesota Statutes, section 144A.45, (Supp. 1988), which provides:

144A.45 Regulation of Home Care Services.

Subdivision 1. **Rules.** The commissioner shall adopt rules for the regulation of home care providers pursuant to sections 144A.43 to 144A.48. The rules shall include the following:

(a) provisions to assure, to the extent possible, the health, safety and well-being, and appropriate treatment of persons who receive home care services;

(b) requirements that home care providers furnish the commissioner with specified information necessary to implement sections 144A.43 to 144A.48;

(c) standards of training of home care provider personnel, which may vary according to the nature of the services provided or the health status of the consumer;

(d) standards for medication management which may vary according to the nature of the services provided, the setting in which the services are provided or the status of the consumer. Medication management includes the central storage, handling, distribution, and administration of medications;

(e) standards for supervision of home care services requiring supervision by a registered nurse or other appropriate health care professional which must occur on site at least every 62 days, or more frequently if indicated by a clinical assessment, and in accordance with sections 148.171 to 148.285 and rules adopted thereunder;

(f) standards for client evaluation or assessment which may vary according to the nature of the services provided or the status of the consumer;

(g) requirements for the involvement of a consumer's physician, the documentation of physicians' orders, if required, and the consumer's treatment plan, and the maintenance of accurate, current clinical records;

(h) the establishment of different classes of licenses for different types of providers and different standards and requirements for different kinds of home care services; and

(i) operating procedures required to implement the home care bill of rights.
HIST: 1987 c 378 s 5; 1989 c 282 art 2 s 25; 1991 c 286 s 8; 1997 c 113 s 2, 3;
1998 c 254 a 1 s 30, 31

Under this statute, the Department has the necessary statutory authority to adopt the proposed rules. This rulemaking process is being done to bring the rules into compliance with those statutory mandates, as well as to update the rules to reflect current standards of practice.

III. RELATED STATUTES

The 1997 Legislature amended the home care licensing laws and the Housing with Services Registration Act. The home care licensing laws were amended by the creation of a new home care licensure class. These proposed rules have been developed in response to the statutory changes enacted during the 1996, 1997, and 1998 legislative sessions.

Laws of Minnesota 1997, Chapter 113, codified at Minnesota Statutes, section 144A.4605, directs the creation of a new class of home care license. Laws of Minnesota 1998, Chapter 407 amends that section, which is included below, to clarify that a housing with services establishment that is required to obtain a home care license must obtain an assisted living home care license, a Class A license, or a class E license, depending on the situation and the provider's choice. The statutory text reads as follows:

144A.4605 Assisted Living Home Care Provider.

Subdivision 1. **Definitions.** For purposes of this section, the term "assisted living home care provider" means a home care provider who provides nursing services, delegated nursing services, other services performed by unlicensed personnel or central storage of medications solely for residents of one or more housing with services establishments registered under chapter 144D.

Subd. 2. **Assisted living home care license established.** A home care provider license category entitled assisted living home care provider is hereby established. A home care provider may obtain an assisted living license if the program meets the following requirements:

(a) nursing services, delegated nursing services, other services performed by unlicensed personnel, or central storage of medications under the assisted living license are provided solely for residents of one or more housing with services establishments registered under chapter 144D;

(b) unlicensed personnel perform home health aide and home care aide tasks identified in Minnesota Rules, part 4668.0100, subparts 1 and 2, and part 4668.0110, subpart 1. Qualifications to perform these tasks shall be established in accordance with subdivision 3;

(c) periodic supervision of unlicensed personnel is provided as required by law;

(d) notwithstanding Minnesota Rules, part 4668.0160, subpart 6, item D, client records shall include:

(1) a weekly summary of the client's status and home care services provided;

(2) documentation each time medications are administered to a client; and

(3) documentation on the day of occurrence of any significant change in the client's status or any significant incident, such as a fall or refusal to take medications.

All entries must be signed by the staff providing the services and entered into the record no later than two weeks after the end of the service day, except as specified in clauses (2) and (3);

(e) medication and treatment orders, if any, are included in the client record and are renewed at least every 12 months, or more frequently when indicated by a clinical assessment

(f) the central storage of medications in a housing with services establishment registered under chapter 144D is managed under a system that is established by a registered nurse and addresses the control of medications, handling of medications, medication containers, medication records, and disposition of medications; and

(g) in other respects meets the requirements established by rules adopted under sections 144A.45 to 144A.48.

Subd. 3. Training or competency evaluations required. (a) Unlicensed personnel must:

(1) satisfy the training or competency requirements established by rule under sections 144A.45 to 144A.48; or

(2) be trained or determined competent by a registered nurse in each task identified under Minnesota Rules, part 4668.0100, subparts 1 and 2, when offered to clients in a housing with services establishment as described in paragraphs (b) to (e).

(b) Training for tasks identified under Minnesota Rules, part 4668.0100, subparts 1 and 2, shall use a curriculum which meets the requirements set forth in Minnesota Rules, part 4668.0130.

(c) Competency evaluations for tasks identified under Minnesota Rules, part 4668.0100, subparts 1 and 2, must be completed and documented by a registered nurse.

(d) Unlicensed personnel performing tasks identified under Minnesota Rules, part 4668.0100, subparts 1 and 2, shall be trained or demonstrate competency in the following topics:

(1) an overview of sections 144A.43 to 144A.49 and rules adopted thereunder;

(2) recognition and handling of emergencies and use of emergency services;

(3) reporting the maltreatment of vulnerable minors or adults under sections 626.556 and 626.557;

(4) home care bill of rights;

(5) handling of clients' complaints and reporting of complaints to the office of health facility complaints;

(6) services of the ombudsman for older Minnesotans;

(7) observation, reporting, and documentation of client status and of the care or services provided;

(8) basic infection control;

- (9) maintenance of a clean, safe, and healthy environment;
- (10) communication skills;
- (11) basic elements of body functioning and changes in body function that must be reported to an appropriate health care professional; and
- (12) physical, emotional, and developmental needs of clients, and ways to work with clients who have problems in these areas, including respect for the client, the client's property, and the client's family.

(e) Unlicensed personnel who administer medications must comply with rules relating to the administration of medications in Minnesota Rules, part 4668.0100, subpart 2, except that unlicensed personnel need not comply with the requirements of Minnesota Rules, part 4668.0100, subpart 5.

Subd. 4. License required. (a) A housing with services establishment registered under chapter 144D that is required to obtain a home care license must obtain an assisted living home care license according to this section or a class A or class E license according to rule. A housing with services establishment that obtains a class E license under this subdivision remains subject to the payment limitations in sections 256B.0913, subdivision 5, paragraph (h), and 256B.0915, subdivision 3, paragraph (g).

(b) A board and lodging establishment registered for special services as of December 31, 1996, and also registered as a housing with services establishment under chapter 144D, must deliver home care services according to sections 144A.43 to 144A.49 and may apply for a waiver from requirements under Minnesota Rules, parts 4668.0002 to 4668.0240, to operate a licensed agency under the standards of section 157.17. Such waivers as may be granted by the department will expire upon promulgation of home care rules implementing section 144A.4605.

(c) An adult foster care provider licensed by the department of human services and registered under chapter 144D may continue to provide health-related services under its foster care license until the promulgation of home care rules implementing this section.

Subd. 5. License fees. The license fees for assisted living home care providers shall be as follows:

- (1) \$125 annually for those providers serving a monthly average of 15 or fewer clients, and for assisted living providers of all sizes during the first year of operation;
- (2) \$200 annually for those providers serving a monthly average of 16 to 30 clients;
- (3) \$375 annually for those providers serving a monthly average of 31 to 50 clients; and
- (4) \$625 annually for those providers serving a monthly average of 50 or more clients.

Subd. 6. Waiver. Upon request of the home care provider, the commissioner may waive the provisions of this section relating to registered nurse duties.

HIST: 1997 c 113 s 6; 1Sp1997 c 5 s 2; 1998 c 407 a 2 s 82

Minnesota Statutes, Chapter 144D Housing With Services also directly relates to this rulemaking proceeding, as follows:

144D.01 DEFINITIONS.

Subdivision 1. **Scope.** As used in sections 144D.01 to 144D.06, the following terms have the meanings given them.

Subd. 2. **Adult.** "Adult" means a natural person who has attained the age of 18 years.

Subd. 3. **Commissioner.** "Commissioner" means the commissioner of health or the commissioner's designee.

Subd. 4. **Housing with services establishment or establishment.** "Housing with services establishment" or "establishment" means an establishment providing sleeping accommodations to one or more adult residents, at least 80 percent of which are 55 years of age or older, and offering or providing, for a fee, one or more regularly scheduled health-related services or two or more regularly scheduled supportive services, whether offered or provided directly by the establishment or by another entity arranged for by the establishment.

Housing with services establishment does not include:

- (1) a nursing home licensed under chapter 144A;
- (2) a hospital, boarding care home, or supervised living facility licensed under sections 144.50 to 144.56;
- (3) a board and lodging establishment licensed under chapter 157 and Minnesota Rules, parts 9520.0500 to 9520.0670, 9525.0215 to 9525.0355, 9525.0500 to 9525.0660, or 9530.4100 to 9530.4450, or under chapter 245B;
- (4) a board and lodging establishment which serves as a shelter for battered women or other similar purpose;
- (5) a family adult foster care home licensed by the department of human services;
- (6) private homes in which the residents are related by kinship, law, or affinity with the providers of services;
- (7) residential settings for persons with mental retardation or related conditions in which the services are licensed under Minnesota Rules, parts 9525.2100 to 9525.2140, or applicable successor rules or laws;
- (8) a home-sharing arrangement such as when an elderly or disabled person or single-parent family makes lodging in a private residence available to another person in exchange for services or rent, or both;
- (9) a duly organized condominium, cooperative, common interest community, or owners' association of the foregoing where at least 80 percent of the units that comprise the condominium, cooperative, or common interest community are occupied by individuals who are the owners, members, or shareholders of the units; or
- (10) services for persons with developmental disabilities that are provided under a license according to Minnesota Rules, parts 9525.2000 to 9525.2140 in effect until January 1, 1998, or under chapter 245B.

Subd. 5. **Supportive services.** "Supportive services" means help with personal laundry, handling or assisting with personal funds of residents, or arranging for medical

services, health-related services, social services, or transportation to medical or social services appointments. Arranging for services does not include making referrals, assisting a resident in contacting a service provider of the resident's choice, or contacting a service provider in an emergency.

Subd. 6. **Health-related services.** "Health-related services" include professional nursing services, home health aide tasks, and home care aide tasks identified in Minnesota Rules, parts 4668.0100, subparts 1 and 2; and 4668.0110, subpart 1; or the central storage of medication for residents.

Subd. 7. **Family adult foster care home.** "Family adult foster care home" means an adult foster care home that is licensed by the department of human services, that is the primary residence of the license holder, and in which the license holder is the primary caregiver.

HIST: 1995 c 207 art 9 s 29; 1997 c 107 s 1; 1997 c 113 s 7-10; 3Sp1997 c 3 s 6

144D.02 REGISTRATION REQUIRED.

No entity may establish, operate, conduct, or maintain an elderly housing with services establishment in this state without registering and operating as required in sections 144D.01 to 144D.06.

HIST: 1995 c 207 art 9 s 30

144D.03 REGISTRATION.

Subdivision 1. **Registration procedures.** The commissioner shall establish forms and procedures for annual registration of housing with services establishments. The commissioner shall charge an annual registration fee of \$35. No fee shall be refunded. A registered establishment shall notify the commissioner within 30 days of the date it is no longer required to be registered under this chapter or of any change in the business name or address of the establishment, the name or mailing address of the owner or owners, or the name or mailing address of the managing agent. There shall be no fee for submission of the notice.

Subd. 2. **Registration information.** The establishment shall provide the following information to the commissioner in order to be registered:

- (1) the business name, street address, and mailing address of the establishment;
- (2) the name and mailing address of the owner or owners of the establishment and, if the owner or owners are not natural persons, identification of the type of business entity of the owner or owners, and the names and addresses of the officers and members of the governing body, or comparable persons for partnerships, limited liability corporations, or other types of business organizations of the owner or owners;
- (3) the name and mailing address of the managing agent, whether through management agreement or lease agreement, of the establishment, if different from the owner or owners, and the name of the on-site manager, if any;

(4) verification that the establishment has entered into an elderly housing with services contract, as required in section 144D.04, with each resident or resident's representative;

(5) the name and address of at least one natural person who shall be responsible for dealing with the commissioner on all matters provided for in sections 144D.01 to 144D.06, and on whom personal service of all notices and orders shall be made, and who shall be authorized to accept service on behalf of the owner or owners and the managing agent, if any; and

(6) the signature of the authorized representative of the owner or owners or, if the owner or owners are not natural persons, signatures of at least two authorized representatives of each owner, one of which shall be an officer of the owner.

Personal service on the person identified under clause (5) by the owner or owners in the registration shall be considered service on the owner or owners, and it shall not be a defense to any action that personal service was not made on each individual or entity. The designation of one or more individuals under this subdivision shall not affect the legal responsibility of the owner or owners under sections 144D.01 to 144D.06.

HIST: 1995 c 207 art 9 s 31; 1997 c 113 s 11

144D.04 ELDERLY HOUSING WITH SERVICES CONTRACTS.

Subdivision 1. **Contract required.** No elderly housing with services establishment may operate in this state unless a written elderly housing with services contract, as defined in subdivision 2, is executed between the establishment and each resident or resident's representative and unless the establishment operates in accordance with the terms of the contract. The resident or the resident's representative shall be given a complete copy of the contract and all supporting documents and attachments and any changes whenever changes are made.

Subd. 2. **Contents of contract.** An elderly housing with services contract, which need not be entitled as such to comply with this section, shall include at least the following elements in itself or through supporting documents or attachments:

(1) name, street address, and mailing address of the establishment;

(2) the name and mailing address of the owner or owners of the establishment and, if the owner or owners is not a natural person, identification of the type of business entity of the owner or owners;

(3) the name and mailing address of the managing agent, through management agreement or lease agreement, of the establishment, if different from the owner or owners;

(4) the name and address of at least one natural person who is authorized to accept service on behalf of the owner or owners and managing agent;

(5) statement describing the registration and licensure status of the establishment and any provider providing health-related or supportive services under an arrangement with the establishment;

(6) term of the contract;

(7) description of the services to be provided to the resident in the base rate to be paid by resident;

(8) description of any additional services available for an additional fee from the establishment directly or through arrangements with the establishment;

(9) fee schedules outlining the cost of any additional services;

- (10) description of the process through which the contract may be modified, amended, or terminated;
- (11) description of the establishment's complaint resolution process available to residents;
- (12) the resident's designated representative, if any;
- (13) the establishment's referral procedures if the contract is terminated;
- (14) criteria used by the establishment to determine who may continue to reside in the elderly housing with services establishment;
- (15) billing and payment procedures and requirements;
- (16) statement regarding the ability of residents to receive services from service providers with whom the establishment does not have an arrangement; and
- (17) statement regarding the availability of public funds for payment for residence or services in the establishment.

Subd. 3. **Contracts in permanent files.** Elderly housing with services contracts and related documents executed by each resident or resident's representative shall be maintained by the establishment in files from the date of execution until three years after the contract is terminated. The contracts shall be made available for on-site inspection by the commissioner upon request at any time.

HIST: 1995 c 207 art 9 s 32

144D.05 AUTHORITY OF COMMISSIONER.

The commissioner shall, upon receipt of information which may indicate the failure of the elderly housing with services establishment, a resident, a resident's representative, or a service provider to comply with a legal requirement to which one or more of them may be subject, make appropriate referrals to other governmental agencies and entities having jurisdiction over the subject matter. The commissioner may also make referrals to any public or private agency the commissioner considers available for appropriate assistance to those involved.

The commissioner shall have standing to bring an action for injunctive relief in the district court in the district in which an establishment is located to compel the elderly housing with services establishment to meet the requirements of this chapter or other requirements of the state or of any county or local governmental unit to which the establishment is otherwise subject. Proceedings for securing an injunction may be brought by the commissioner through the attorney general or through the appropriate county attorney. The sanctions in this section do not restrict the availability of other sanctions.

HIST: 1995 c 207 art 9 s 33

144D.06 OTHER LAWS.

A housing with services establishment shall obtain and maintain all other licenses, permits, registrations, or other governmental approvals required of it in addition to registration under this chapter. A housing with services establishment is subject to the provisions of sections 504.01 to 504.28 and 566.01 to 566.175.

HIST: 1995 c 207 art 9 s 34; 1996 c 305 art 1 s 36; 1997 c 113 s 13

144D.07 RESTRAINTS.

Residents must be free from any physical or chemical restraints imposed for purposes of discipline or convenience.

HIST: 1997 c 113 s 12

IV. NEED FOR THE RULES

Minnesota Statutes, chapter 14, the Administrative Procedures Act, requires the Department to explain the facts establishing the need for the rules as proposed. "Need" means that a problem exists which requires administrative attention.

Minnesota Statutes, section 144A.45, subdivision 1, as shown above, describes the topics that must be included in the administrative rules for home care and hospice licensure. These rules are necessary to provide minimum assurance of protection of the health, safety, and well-being of and appropriate treatment for the consumers of home care services. These minimum standards include training of the persons providing the services, supervision or monitoring by a registered nurse, documentation of an evaluation or assessment and a treatment plan, medication management, and other areas, as described in that statute shown above.

In general, home care services are medical, nursing, or therapy services delivered to a client in the client's home. Persons providing these services may or may not be licensed or registered professionals; they may be minimally trained persons providing these hands-on cares and services to the clients, in the clients' homes, with delegation from a health care professional but without direct supervision. Many of the clients are vulnerable adults who can easily become dependent on receiving home care services. Occasionally, home care providers have taken advantage of the vulnerabilities of the client and of the lack of supervision of services. Clients often do not complain about the care or treatment they are receiving (or not receiving) because they are afraid they would have to leave their homes and go elsewhere to get the services they require. Rules are needed to provide a basic level of protection of clients, by an assurance of minimum standards for the services provided, minimum training requirements for persons providing those services, a service agreement that spells out what services the client needs and how the provider intends to ensure that the client receives those services, and the other minimum requirements that are included in these rules.

There have been discussions over the last several years regarding the type of system or model of regulations that Minnesota should have for "assisted living." Initially, the Legislature created the "residential care home" licensure class in statute. Providers, provider organizations, consumers, consumer organizations, and regulators met over a few years' time and tried to develop rules that would implement that as a health facility license. However, they were unable to find consensus for rule development on several issues, many in the physical plant arena.

The next suggestion was that regulatory policy should “separate the housing piece from the services piece” - keep the regulations for the building itself separate from the regulations for the services offered or provided. In theory, it would not matter where services are provided, nor what services they are, as long as the client receives the services they need and want, and if there are existing regulations for those services, then the services comply with those regulations. Minnesota already had regulations for group housing settings in Minnesota Statutes, Chapter 157 and Minnesota Rules, Chapter 4625 (boarding and lodging); for smaller settings (4 or fewer, or 5 or fewer if all clients are elderly), there are the Adult Foster Care regulations in Minnesota Statutes, Chapter 245A, and Minnesota Rules, Chapter 9555. There are regulations for health-related services provided at a person’s home in Minnesota Statutes, Chapter 144A and in Minnesota Rules, Chapter 4668 (the home care regulations).

Minnesota Statutes, Chapter 144D, the Housing With Services Registration Act, was created to provide some level of consumer protection for older persons that are purchasing a housing setting and services from the same entity, or from related entities. Basically, the act requires a written agreement between the consumer and the provider that discloses what services the housing setting will provide, for what cost, where and how to complain about services, and other consumer information. The act, through that written agreement, seeks to provide a link between the housing setting provided and the supportive services or health-related services provided, and letting consumers know what they are purchasing.

The assisted living industry, nationwide, is debating the basic philosophy of “assisted living” - what that means, what it includes, how it should be regulated, how to pay for it, and so on. There are two major models that are often mentioned - the medical model and the social model. The medical model could be described as a housing setting where health-related services are provided by licensed health care professionals (doctors, nurses, therapists, etc.) with assistance by unlicensed personnel that report to the health care professionals. The social model, sometimes called the hospitality model, tends to be more a housing setting where supportive services are offered or provided (laundry, transportation, activities). An assisted living company representative has stated, “If you look at this as a medical model, then there are going to be expectations from all sides that the facility is responsible for everything, whereas under a social model, people understand that we are here to fill gaps, not to take over.”¹

The statutory language for the new assisted living home care provider category is somewhat different from the general home care licensing statute. For example, an assisted living home care provider is limited to providing only certain home care services, only to residents of a registered housing with services establishment. An assisted living home care provider only needs to provide one or more services allowed in Minnesota Statutes, section 144A.4605, to be licensed. Moreover, an assisted living home care provider does not need to provide all the assisted living home care services included in Minnesota Statutes, section 144A.4605; providers

¹ Mauro Hernandez, Public Policy Director, Assisted Living Concepts, “Assisted Living Business Week”, Volume 1, Number 2, 1997.

may choose which services they will provide, and must ensure that those services are provided by persons trained and competent to provide those services.

The home care licensing rules must be revised to reflect statutory changes that have occurred over the last few years, including the passage of Minnesota Statutes, Chapter 144D Elderly Housing with Services Registration Act, the 1997 revisions to that Act, and the 1997 and 1998 revisions to Minnesota Statutes, sections 144A.43 to 144A.49. It is necessary to revise the rules so they are not in conflict with these statutes and to implement those revised statutes. The 1997 amendments to the home care statute are fairly specific regarding rulemaking and the content of administrative rules, specifically for assisted living home care providers. Because the legislation is so specific, the department needs to create a new class of home care license and needs to place the rules specific to that new class in a separate location from rules for the other classes of home care license. Since the department had already begun reformatting the rules to make the entire rule chapter easier to follow, understand, and comply with, new rules related to the new license class require very little change in the proposed rule format.

The housing with services model (board and lodging plus supportive services, and sometimes plus home care) is Minnesota's current approach to what is commonly known as "assisted living." In a paper sponsored by the American Association for Retired Persons, Dr. Keren Brown Wilson describes the philosophy of assisted living as:

"Assisted living's philosophy is to provide physically and cognitively impaired older persons the personal and health-related services that they require to age in place in a homelike environment that maximizes their dignity, privacy, independence, and autonomy. Assisted living maximizes dignity, privacy, and independence by providing a range of personal and health-related services (including supervision and assistance with scheduled and unscheduled needs on a 24-hour basis) designed to accommodate and support the needs and preferences of individual tenants in private residential units. To meet the goal of tenant autonomy, assisted living emphasizes individuals' rights to make decisions about their own care and to take responsibility for certain risks that may result from those decisions, consistent with the individual's capacity to make decisions and the provider's exercise of prudent risk management through negotiated risk agreements. Autonomy is reflected in opportunities for self-governance, protection of individual rights, the exercise of autonomy within the context of bounded choice, and the negotiated levels of risk agreed to by the individual (or his/her designated representative) and management."²

². "Assisted Living: Reconceptualizing Regulation to Meet Consumers' Needs and Preferences", Keren Brown Wilson, Ph.D., for the American Association of Retired Persons, 1996; <http://stanley.feldberg.brandeis.edu/~sciegaj/asstlvng/AARPAL.html>

The home care rules need to be augmented to reflect current standards of practice in the home care and assisted living industries, and what home care consumers want and need. For example, the existing home care rules do not address central storage of medications in a housing setting. The new home care license class created by the 1997 legislature, the "assisted living home care provider" class, is allowed by statute to centrally store medications. To assure protections for the clients, the rules must be revised to require that medications are stored appropriately (safely, securely, and at the proper temperature), the client receives his or her medication as it was prescribed, that medications are not taken by nor administered to someone other than the person for whom they were prescribed, and all administrations of medications are properly documented.

V. REASONABLENESS OF THE RULES

Minnesota Statutes, Chapter 14, requires the Department to explain the facts establishing the reasonableness of the proposed rules. "Reasonableness" means that there is a rational basis for the Department's proposed action. The reasonableness of the proposed rules is explained in this section.

A. Reasonableness of the Rules as a Whole

This Statement of Need and Reasonableness is prepared to comply with the requirements of Minnesota Statutes, sections 14.131 and 14.23, in the Administrative Procedures Act. Specific requirements of the Administrative Procedures Act will be addressed below, with the applicable section of that act provided in italics.

These proposed rules create a new home care license class, the assisted living home care provider class. The home care and hospice law requires that providers be licensed and that the services they provide meet minimum standards to protect the health, safety, and well-being of their clients. It is reasonable to establish standards for licensure in rule to comply with statutes providing for the public health, safety, and well-being. It is reasonable to establish standards for the training and competency of home care personnel to assure there are minimal protections for the clients receiving home care or hospice services. It is reasonable to provide minimum standards in rule so that home care providers or potential home care providers have a single, complete source of information on what are considered home care services under state regulations, and on what is expected of persons or organizations that provide these services to consumers who purchase these services.

Minnesota Rules, Chapter 4668 currently describes five classes of home care licensure. Some of the existing rule parts apply to all five licensure classes and will also apply to the new assisted living home care provider class. Some of the existing rule parts apply to only one or two of the classes. Some rule parts have subparts that apply to all five classes and subparts that apply to only one or two of the classes. The existing format of the rule chapter, while keeping the length of the chapter at a minimum, has caused extensive confusion and apprehension among

home care providers, consumers, and regulators. To someone new to the industry, receiving a 68-page document (the length of the current handout of statutes and rules) and being told that you need to read and implement its contents can be overwhelming.

Licensees and applicants frequently call the Department saying things such as, "I don't want to read all that. Just tell me what I need to do." This attitude indicates that those rules are not user-friendly. If the intended users of the rules are not reading them or comprehending them, then those rules cannot assure a minimum level of protection of the health, safety, and well being of the clients. Home care providers must be able to read the licensure rules and understand them, and then organize their business and provide services in compliance with those rules.

Reorganization and simplification is achieved in these proposed rules, although additional reorganization will be part of a future rulemaking project. The rules that apply to all license classes are at, and will remain at, the beginning of the rule chapter. Part 4668.0012, subpart 4 will be revised to list rule parts that are applicable to each license class, including the new assisted living home care provider class. In the future, each of the license classes will have its own section of the rule chapter, which will contain those rule parts that specifically apply only to that license class. For example, the rules specific to the Class A Home Care Agency license class will be located together, probably in rule parts 4668.0300 to 4668.0395; the rules specific to the assisted living home care provider class will all be located together, in rule parts 4668.0800 to 4668.0895. There will continue to be rule parts that apply to all license classes; these will continue to be located at the beginning of the rule chapter. The location of the assisted living home care provider class rules within Chapter 4668 may be confusing at this time, but will make better sense to rule users when the chapter reformatting is completed.

1. Classes of Persons Affected By the Rule

(1) a description of the classes of persons who probably will be affected by the proposed rule, including classes that will bear the costs of the proposed rule and classes that will benefit from the proposed rule;

The classes of persons who will be affected by this proposed rule are housing with services providers that provide or offer one or more health-related service, housing with services clients, and indirectly their family members and friends; also other home care licensees, administrators, and staff, state agency surveyors and other staff, ombudsmen, other advocates for home care clients, and other interested persons.

Many businesses in Minnesota that provide housing and some sort of services to older persons refer to themselves as "assisted living." To date, the department has not enforced the meaning of that term, as it is defined in the current home care regulations. As a result, the term "assisted living" is being used for a variety of situations and thus has no single meaning. Connotations of the term do not always match up with what is provided, and consumers may not always understand exactly what they can expect to receive. For example, a number of housing

with services providers say that "24 hour nursing care" is available in their establishments. Although consumers may expect there is a nurse on site 24 hours a day, in many situations this means that there is a nurse on call 24 hours a day. "Assisted living" is a relatively new industry as compared with hospitals and nursing homes. Consumers need to become more educated on what is required in regulation and to ask questions about what a provider promises to provide.

Among those who would bear the costs of these rules would be those home care clients or their family members or other responsible persons that pay for their home care services, and the Medicaid program for licensees that are Medicaid certified providers or for clients that receive services through a Medicaid waiver program, and state taxpayers. Long term care insurance policies are not very common yet, and it is unknown how many would pay for home care services in a housing with services establishment. Generally such policies are intended to cover costs of a nursing home stay.

The proposed rules are not expected to impose additional costs on licensees because many of these proposed rules revise existing rules that the providers must already comply with, either in whole or as part of a waiver package from the current Class A licensure requirements. For existing and new licensees, the cost of compliance with state laws and rules for home care are among the costs of doing business in that field in this state. The laws and rules are in place to provide minimal standards for the protection of the clients as well as to provide some basic education for providers regarding the appropriate services for this type of licensure.

Existing licensees who choose to change to the assisted living home care provider license class may experience decreased costs, because generally, the proposed rules are more flexible and less prescriptive than those for other home care licensees. In some areas, the proposed rules for this license class include alternative methods to reach to the desired outcomes, so a provider can tailor its operations to the business. Another reason for possible decreased costs to licensees is the license fee structure established in Minnesota Statutes, section 144A.4605. This statute establishes a method to compute the license fees for the assisted living home care provider, which is significantly different from the statute and rules (Chapter 4669) that establish the license fees for other classes of home care licenses. Minnesota Statutes, section 144A.4605, subdivision 5, reads:

144A.4605, subdivision 5. License fees. The license fees for assisted living home care providers shall be as follows:

(1) \$125 annually for those providers serving a monthly average of 15 or fewer clients, and for assisted living providers of all sizes during the first year of operation;

(2) \$200 annually for those providers serving a monthly average of 16 to 30 clients;

(3) \$375 annually for those providers serving a monthly average of 31 to 50 clients; and

(4) \$625 annually for those providers serving a monthly average of 50 or more clients.

Classes that would benefit financially or economically from these rules are the registered housing with services establishments that provide one or more health-related service and so are required either to be licensed as home care provider or to contract with a licensed home care provider for those health-related services. The Housing with Services Registration Act became effective August 1, 1996. A registered housing with services establishment that provides health related services was required to provide those services through a home care license beginning January 1, 1997. Because these proposed rules were not in place when section 144A.4605 became effective, the Department created waiver "packages" to existing rules available to the entities that fit the category of "assisted living home care provider" (places that are registered as a housing with services establishment that provide one or more health-related service). These entities could benefit financially or economically from these rules because the proposed rules are specifically designed for the registered housing with services establishments and are thus compatible with the registration requirements. The proposed rules include the minimum standards for topics described in the statute authorizing the Department to promulgate these rules. The proposed rules include options for staff training which could save both staff time and dollars, as compared with the training requirements for other home care license classes.

2. Probable Agency Costs

(2) the probable costs to the agency and to any other agency of the implementation and enforcement of the proposed rule and any anticipated effect on state revenues;

The Department likely will incur additional costs to the department to implement the proposed rules because there likely will be more home care licensees because of the promulgation of these rules. The 1997 Legislature set the license fees for this class in statute, based on the monthly average number of clients served by the licensee. This method of fee setting is unlike the method that has existed in rule for other home care license classes (Minnesota Rules, Chapter 4669), which is based on the amount of home care revenues of the licensee. Based on preliminary estimates, the license fees as set in statute are not likely to be adequate to cover the staff time and resources necessary to provide technical consultation to applicants, licensees, and consumers, and conduct meaningful visits with providers to assure compliance with the regulations. The department must monitor the revenue from licensing fees and the costs of administering the program over the next few years.

There are no probable additional costs to any other agency for the implementation and enforcement of the proposed rule, nor is there any anticipated increase to state revenue because the licensing program is supposed to be self-supporting through the licensing fees.

3. Less Costly or Intrusive Methods

(3) a determination of whether there are less costly methods or less intrusive methods for achieving the purpose of the proposed rule;

The purpose of the proposed rules is to assure the health, safety, and well-being, and appropriate treatment of all persons who receive home care services. These proposed rules for the assisted living home care provider class were developed as a less costly, less intrusive, less "regulatory" method to establish minimal standards for residential settings that provide health-related services, as compared with the traditional Class A home care license rules, which were not developed for residential settings.

There was a significant amount of comments and suggestions from the public during the development of these proposed rules. This input confirmed that ensuring quality and appropriate cares for the consumers of assisted living home care provider services was more important than developing less costly or intrusive methods of regulation for those providers.

Much of the proposed rules is based directly on legislative mandates over the last three years that were agreed upon by the major provider organizations. These provider organizations represent their constituents, and so can reasonably be expected to support rule language that would be beneficial to their constituents as well as being the least intrusive regulations appropriate for this industry. Some people believe there should be little or no government regulation of business; however, there is a long history of public interest in the establishment and maintenance of minimum standards for the protection of the health and safety of health care consumers.

The proposed rules establish parameters for the provision of assisted living home care services; licensees are free to determine what is provided. A licensee may choose to provide only a few health-related services (as they are defined in the rule) or may choose to provide the full range of possible services. Other licensees may choose to provide a limited service package so that clients would need to get additional services through another home care licensee (generally a Class A home care agency). A more limited service package could mean that staff training requirements are easier to manage, and management and coordination of services require less time and effort. By reserving these decisions to licensees rather than prescribing them in rule, the Department has developed a "least intrusive" method of regulation.

4. Alternatives to a Rule

(4) a description of any alternative methods for achieving the purpose of the proposed rule that were seriously considered by the agency and the reasons why they were rejected in favor of the proposed rule;

One alternative method for achieving the purpose of the proposed rules would be to ask the Legislature to enact more detailed laws regarding home care and hospice services, including precise identification of the services commonly referred to as "assisted living." This alternative to the proposed rules would rely on laws and statutes to achieve the purpose of these proposed rules. This alternative method of achieving the purpose of the proposed rules was rejected because that level of regulatory detail is generally not included in statute. The amount of detail necessary to assure adequate levels of protection, given the wide range of variables in the nature of services provided and the health status of consumers, appropriately belongs in administrative rule and not in statute. In fact, the statute directs the department to develop rules for the "assisted living home care provider" license class, enumerates some of the topics to be addressed in those rules, and states that those rules should "in other respects meets the requirements established by rules adopted under sections 144A.45 to 144A.48." These proposed rules are intended to comply with that statute by developing rule language specific to assisted living home care providers where appropriate, and consistent with existing home care rules where appropriate.

A second alternative method of achieving the purpose of the proposed rules would be to allow multiple and varied waivers to the existing rules. The department developed a set of waivers in late 1996 to enable entities providing health-related services (as defined in the home care rules) in registered housing with services establishments to obtain Class A home care licenses without meeting all the requirements of that license. These waivers were developed based on the assisted living home care provider language that was, at that time, in a bill before the legislature, which was enacted in 1997 as chapter 113. These pre-set waivers, which allow licensees extra time to come into compliance with the existing rules or to provide alternative methods of compliance with the intent of the rules, are available until the promulgation and adoption of the assisted living home care provider licensure rules. This waiver "package," along with the ability for licensees to request waivers from other rule parts, has been an effective and efficient method to satisfy the statutory changes while the Department completes the necessary rule promulgation process as delineated in the Administrative Procedures Act and its implementing rules.

A second set of waivers was developed in the spring of 1997 to accommodate another subset of entities affected by Chapter 144D, those that have been licensed as a board and lodging establishment and registered to provide "special services" (B&LSS) under Minnesota Statutes, section 157.17. This "special services" registration has been part of the process of establishing some sort of minimum standards for housing establishments that are providing services above and beyond what their boarding and lodging license requirements address. B&LSS establishments that meet the definition of a "housing with services establishment" (i.e., provide sleeping accommodations, 80% of the clients are age 55 or older, and provide supportive or health-related services) must now register as a Housing with Services (HWS) provider under Chapter 144D. An establishment must register either as a B&LSS or as a HWS. If the "special services" the establishment had been providing are health-related services as defined in the home care rule, then those services must now be provided through a home care license. If the establishment meets the requirements for a housing with services registration, then it must be registered as housing with services and it cannot be registered as a "special services" provider.

The second set of waivers to has provided alternatives for B&LSSs by continuing to allow the level of staff training and the types of services allowed under Minnesota Statutes, section 157.17. As with the first waiver set, this waiver package, along with the general waiver possibilities in the current rule, has allowed potential licensees a lot of flexibility and relative ease in completing the initial licensing process, while allowing time for them to become familiar with and comply with all the home care licensing regulations.

Granting waivers to the existing rules has been rejected as an acceptable long term alternative to achieving the purpose of these proposed rules. It is not good public policy to allow such a wide variety of methods of compliance because there is then no way to assure consistent interpretation and provision of services. Moreover, this approach makes it difficult for consumers to know what they can expect from any one home care provider. It is better public policy to establish standards for a variety of levels of services to be provided, or "classes" as they are called in these rules, so that providers can make clearer, better informed choices of how to be licensed based on the services to be provided, and so that consumers have more reasonable expectations of the range of services they can receive from a specific provider within a class of providers.

5. Probable Costs of Compliance

(5) the probable costs of complying with the proposed rule; and

The Department does not foresee additional costs to any other agency for the implementation and enforcement of the proposed rule. There is no anticipated effect on state revenue.

The existing rules regulating home care and hospice providers provide an enforcement process. There could be additional costs to the Department if there is a large increase in the number of applications for new home care licenses. The additional costs would include staff travel expenses related to surveys, telephone consultation for questions about the regulations as well as completing the application packet, the completion of the actual paperwork, and issuing of the license.

The probable costs to licensees for complying with the rules are minimal because much of the current rule language and current waiver language has been maintained in these proposed rules. Where there are differences in the proposed rules from existing rules, those differences often reflect the current standards of practice in the home care industry or in the assisted living industry, which most licensed providers already are doing, so the costs should be minimal.

One group that will incur costs of complying with the rules are unlicensed entities that are providing home care services and have not been doing the things that the licensure rules require (e.g., documentation, evaluation and development of a service plan, and staff training). These entities should have been licensed because they are providing home care or hospice services, according to Minnesota Statutes, section 144A.43, subdivision 4. However, because they have

also been providing a housing setting, the existing statutes and rules have not clearly applied to these entities. The 1997 statutory changes and these proposed rules should eliminate that confusion and provide clarity to providers, consumers, and regulators as to what the home care licensure expectations are.

Minnesota is not alone in imposing a somewhat complicated regulatory system for housing establishment that provide health related services. For many states, the regulation of housing with services settings is still a relatively new development, in part because the industry has not had a strong presence in those states. Many of the eastern states, on the other hand, have regulations for assisted living settings because the industry has had a greater influence there for a longer time period.

The regulatory process for “assisted living” in Minnesota is as follows:

- ▶ Housing settings that have needed a license will continue to need:

a food, beverage, and lodging license for the building, kitchen, and food safety under Minnesota Statutes, Chapter 157

OR

a food and beverage license for the kitchen and food safety under Minnesota Statutes, Chapter 157

OR

an adult foster care license under Minnesota Rules, Parts 9555.5105 to 9555.6265 (also known as Rule 203).

- ▶ Housing settings that offer sleeping accommodations, where 80% or more of the residents are age 55 or older and where two or more supportive services or one or more health-related services are offered or provided, must be registered as a housing with services establishment under Minnesota Statutes, Chapter 144D.
- ▶ Registered housing with services establishments that offer or provide health-related services must provide those services through a home care license under Minnesota Statutes, Chapter 144A and Minnesota Rules Chapter 4668, either obtaining a home care license or contracting for those services with a licensed home care provider.

Local ordinances may also apply, such as zoning, building and fire safety, or additional food safety and sanitation requirements. Applicants are encouraged to contact their local environmental health department and their local (city and/or county) fire safety representatives.

Some registered housing with services establishments do not have or need a food and beverage, lodging, or adult foster care license. Many of these are apartment buildings where some supportive services are available, either through the apartment building's management or another entity under contract to the building management. The residents rent their apartments from the owners, and may contract for additional services which are not included in the rental cost.

The department is attempting to coordinate the relicensure and re-registration processes as much as possible. For example, all establishments that have had to register as a housing with services establishment under Chapter 144D will need to re-register annually, on August 1 of each year.

6. Differences from Existing Federal Regulations

(6) an assessment of any differences between the proposed rule and existing federal regulations and a specific analysis of the need for and reasonableness of each difference.

Licensed Class A home care providers wishing to participate in the federal Medicare or Medicaid programs must comply with the federal regulations known as "Requirements for Participation." Only the state Class A licensure standards approximate the federal regulations for certification as a home health agency. The statutes authorizing MDH to promulgate these "assisted living home care provider" rules do not provide the level of expectation, regulation, and documentation that would satisfy the current federal conditions of participation to enable the assisted living home care provider licensees to qualify for participation as certified home health agencies through the federally-funded programs. It should be noted that some clients may be eligible for Medicare home health benefits for certain services (which must be provided by a certified home health agency) or for a Medicaid waiver program which is administered through the county.

Many home care providers do not provide the level of services that are required to qualify as Medicare eligible home care services, whether by choice or by the nature of their business, the services they provide, and the clientele they serve. It is necessary to have a set of state licensure standards that are complete enough to assure, at minimum, the health, safety, and well-being, and appropriate treatment of home care clients, and to not rely on federal regulatory standards for those assurances since the federal standards do not apply in all instances. Those federal standards are significantly more stringent than what is necessary to require for the majority of entities that would be providing "assisted living home care," as defined in Minnesota Statutes, section 144A.4605. There are many services that are included in what Minnesota statutes and rules call "home care services" that are not included in what the Medicare program considers reimbursable services under the home care benefit. Yet, many of the services are needed by the clients to remain in their own homes or to delay moving to a nursing home. It is reasonable for the department to develop and maintain administrative rules to address some of these services.

B. Reasonableness of Individual Rules

This section addresses the reasonableness of specific parts of the proposed rules in Minnesota Rules, Chapter 4668.

Part 4668.0002 APPLICABILITY, AUTHORITY, AND SCOPE.

Part 4668.0002 provides the statutory authority for the promulgation of administrative rules for the licensing of home care providers and hospice programs. It is necessary and reasonable to revise this rule part in two places by correcting the reference to the end point of the relevant statutes. Minnesota Statutes, section 144A.49 was repealed by the 1997 Legislature, so the new end point of the applicable statutes authorizing this rule chapter is now Minnesota Statutes, section 144A.48.

The 1997 Legislature also added a section authorizing a new home care licensing class, that of the assisted living home care provider. This rule promulgation project implements that new section so it is necessary and reasonable to include a cite to that authorizing statute in this rule part.

Part 4668.0003 DEFINITIONS, Subpart 1 Scope.

Part 4668.0003, subpart 1 establishes the scope of the applicability of the definitions listed in other subparts of this part. It is necessary that the scope section encompass the entire rule chapter. The revision includes what will be the new final rule part in the chapter, which will be part 4668.0870. This language is reasonable because it provides the extent of the applicable rules for home care and hospice licensure, including the definitions of terms used in those rule parts.

Part 4668.0003 DEFINITIONS, Subpart 2a Assistance with self-administration of medication.

Part 4668.0003, subpart 2a provides a definition of the term "assistance with self-administration of medication" for this rule chapter. The existing home care licensing rules set forth requirements for unlicensed personnel who administer medications after receiving appropriate training and being delegated the task of medication administration by a registered nurse. The Nurse Practice Act (Minnesota Statutes, sections 148.171 to 148.285) defines medication administration as a nursing task. Since many home care providers, including housing with services establishments, provide assistance with self-administration of medications or medication administration, it is necessary and reasonable to clarify in rule what those terms mean to provide an educational tool to providers, consumers, and regulators.

Over the years there has been much discussion on what constitutes "administering medication." The department has recognized that a variety of tasks comprise medication administration, and there are a variety of reasons why a home care client might need someone to provide assistance with medication administration. Some clients are assessed and found to need help opening their medication containers, some need to be reminded to take their medication, and some clients need to have their medication given to them. In all three examples, there is participation by someone other than the client in the client's medication administration. However, there are significant differences in level of participation by another person, the level of participation by a client, and in the methods of administration.

In November 1995, the Minnesota Home Care Association wrote a letter to the Elderly Housing With Services Home Care Subcommittee to suggest a method to clarify the meaning of "medication administration" in the home care licensing rules. The suggestion included specifying the distinction between medication assistance, including passive assistance and active assistance, and medication administration, and outlined varying levels of education for the different types or amounts of assistance required. The suggestion was made in the form of an outline, which follows:

Medication Assistance

Passive Assistance: Verbal reminder

*Active Assistance: Bringing the medications to the client
Opening a dispenser that was set up by an RN
Emptying the contents from the dispenser set up by the RN into the client's hand, assisting the client as needed
Providing liquids or nutrition to accompany medication*

Medication assistance may be done by a home health aide or home care aide.

Medication Administration

*Teaching
Interpreting labels
Dispensing
Reading labels
Analyzing medication interactions and/or client response to medications*

Medication administration may be done by a home health aide (not a home care aide), under the delegation and supervision of a registered nurse per the current licensure rule requirements.

This outline was the basis for the development of new rule language addressing providing assistance with medications and administering medications. However, the outline was revised by using terms that are commonly used. For example, the term "medication reminder" is used in

these assisted living home care provider rules rather than "passive assistance," and "assistance with self-administration of medication" is used in rule rather than "active assistance with medication" because those terms are commonly used and commonly understood. It is reasonable to use terms that are in common usage rather than creating additional jargon so that the meaning and intent of the rule language can be easily understood by affected persons.

This rule language is necessary to reflect differences in the amount or type of provider involvement in the act of clients getting their medication, because the Legislature directed the Department to set standards to protect the health and safety of the clients. Many of the complaints received by the Office of Health Facility Complaints and many of the violations identified during licensing surveys relate to assistance with medications. There is clear need for clarification of expectations and additional provider education on this issue.

Part 4668.0003, subpart 2a, subpart 21a, and subpart 21b are proposed to distinguish between what is meant in the home care licensing rules regarding assistance with medication and medication administration. Subpart 2a defines "assistance with self-administration of medication" using the distinctions provided by the Minnesota Home Care Association in 1995, to apply where the licensee or staff of the licensee perform a physical action to enable the client to self-administer his or her own medication. It is necessary and reasonable to include this definition in the home care licensing rules because this definition clarifies those situations where there is actual physical involvement by a person to assist the client to self-administer his or her medications.

Items A and B: It is necessary and reasonable to include checking the client's medication record and preparing the medication for administration as part of the act of medication administration to protect the health and safety of clients receiving medication administration. These are standard parts of medication administration curriculum across the country, and are also commonly included in state nurse practice acts as integral parts of the act of medication administration.

Item C: The Nurse Practice Act allows professional nurses to delegate the administration of medications as a delegated medical function to nursing personnel (Minnesota Statutes, section 148.171, subdivision 1, clause 3). "Unlicensed nursing personnel" includes nursing-assistants who have received training as specified later in these proposed rules. The delegating professional nurse is ultimately responsible for delegating medication administration duties to persons who can perform them safely and competently.

Item D: The Department believes that it is necessary for the documentation of medication administration to be done AFTER it is administered. Because the medication record is a legal document, it is necessary to record each medication as soon as possible after the medication is given. Documentation prior to administration even if done immediately prior to the administration would indicate that a resident received a medication when that is not actually true. It is necessary for documentation of medications to occur immediately after they are administered to avoid any potential for a duplicate dose to be given. Recording medications

prior to administration is unethical and can create a potential for needing to alter a legal document. The current standard of practice is to document medications, treatments and observations after they have occurred.^{3,4,5,6}

In 1987, a nursing home requested a waiver for current part 4655.7700, subpart 9, which was denied. A hearing was subsequently held at which the Administrative Law Judge (ALJ) also recommended denial of the waiver. The ALJ stated that there were increased occasions for nursing errors when pre-charting is done and that complying with the current rule would not place a burden on the facility. Refer to the Matter of St. Anthony Eldercare on Main, OAH Docket #9-0900-1695-2, Findings of Fact, Conclusions and Order, November 6, 1990.^{7,8}

It is just as important, if not more so, to document when medications are not administered as ordered. This can have a definite impact on the client's health, so it is necessary and reasonable to include language in the definition of "medication administration" to clarify that information is something that needs to be documented.

Item E: It is necessary and reasonable to include a requirement for reporting pertinent information to the nurse within the definition of "medication administration" because medication administration includes observing the client for adverse effects, positive effects; and change in condition, as well as other activities.

Part 4668.0003 DEFINITIONS, Subpart 2b Assisted living home care provider.

It is necessary to define "assisted living home care provider" because the term is used throughout this chapter to refer to a particular category of home care provider and its meaning is ambiguous without a definition. It is reasonable to adopt the definition set forth in Minnesota Statutes, section 144A.4605 because this chapter implements Minnesota Statutes, sections 144A.43 to 144A.48.

³ Minnesota Board of Technical Colleges, "Medication Administration for Unlicensed Personnel Curriculum," Minnesota Technical College System, Dec. 1993.

⁴ Taylor, C., Lillis, C., LeMone, P., "Fundamentals of Nursing: The Art and Science of Nursing Care, 2nd Edition," J.B. Lippincott Company, 1993:1252.

⁵ Loeb, S., editor, "Nursing Procedures," Springhouse Corp., 1992:214.

⁶ Talaska Fischbach, F., "Documenting Care: Communication, the Nursing Process and Documentation Standards," F.A.Davis Company, 1991:471-476.

⁷ "In the Matter of St. Anthony Eldercare on Main; Findings of Fact, Conclusions and Order," Minnesota Department of Health, Nov. 6, 1990.

⁸ Reha, P., "In the Matter of St. Anthony Eldercare on Main; Findings of Fact, Conclusions and Recommendations," HLTH-88-001-PR, 9-0900-1695-2, State of Minnesota Office of Administrative Hearings.

Part 4668.0003 DEFINITIONS, Subpart 2c Assisted living home care service.

It is necessary to define "assisted living home care service" because the term is used throughout this chapter in defining "assisted living home care provider." The term is defined by listing the services that are included in the statute authorizing this license class (Minnesota Statutes, section 144A.4605). The definition is reasonable because it is the same as the statute, and will avoid any confusion or conflict between the statute and the rule. The term "assisted living" by itself is not defined in statute or rule in Minnesota, and has come to mean so many things that it has no real regulatory meaning.

Part 4668.0003, DEFINITIONS, Subpart 3 Assisted living services.

Part 4668.0003, subpart 3 defines "assisted living services", as services provided by a Class E home care licensee. The addition of the new "assisted living home care provider" category has created confusion over what the term "assisted living services" means and how it applies to "assisted living home care providers." Because of that confusion, it is necessary to revise the definition of "assisted living services" to include the term "as provided under a Class E home care license" to be more specific in that definition.

There are some similarities between the Class E home care license and the new assisted living home care provider license, but there are also differences that are significant enough to warrant keeping both licenses at this time.

An assisted living home care provider can only provide assisted living home care services to residents of housing with services establishments registered under Minnesota Statutes, Chapter 144D. The statute allows for a wide range of services that may be provided by an assisted living home care provider.

A Class E licensee may provide individualized home care aide tasks or home management tasks to clients of a residential center in their living units. Home care aide tasks are listed in the current part 4668.0110, and home management tasks are addressed in part 4668.0120. A "residential center" is defined in part 4668.0003, subpart 35, as "a building or complex of buildings in which clients rent or own distinct living units."

It is reasonable to clarify this definition of "assisted living services" because there has been confusion over the applicability of this term; the revised language is reasonable because it retains the current definition while clarifying the applicability. MDH will monitor the implementation of this new home care licensure class, and how its implementation affects the numbers of licensed Class E home care licensees. It may be that the existing Class E licensees would prefer this new license class, so the Class E license class could become obsolete, or it may be that there is sufficient value in the distinctions between the two classes that the Class E license should remain as a home care licensing option.

Part 4668.0003 DEFINITIONS, Subpart 16 Hospital.

Part 4668.0003, subpart 16 provides a definition of the term "hospital." The Office of the Revisor of Statutes recommends that rule language should list applicable rule chapters before applicable statutes. The revision to the definition of the term "hospital" is necessary and reasonable to comply with rule drafting standards established by the Office of the Revisor of Statutes.

Part 4668.0003 DEFINITIONS, Subpart 17a Legend drug.

It is necessary to define "legend drug" because part 4668.0865 distinguishes between legend drugs and other types of drugs for the purpose of central storage of medication. Part 4668.0003, subpart 17a provides a definition of the term "legend drug" by referencing the applicable definition included in the Minnesota Board of Pharmacy statutes. Minnesota Statutes, section 151.01, subdivision 17 states:

Subd. 17. Legend drug. "Legend drug" means a drug which is required by federal law to bear the following statement, "Caution: Federal law prohibits dispensing without prescription."

This definition of the term "legend drug" is necessary to clarify the term used in this rule chapter. The definition itself and the cite to the statutory definition are reasonable because they provide consistency within state statutes and rules, and with the applicable federal laws regarding prescription medications.

Part 4668.0003 DEFINITIONS, Subpart 18 Licensee.

Part 4668.0003, subpart 18 provides a definition of the term "licensee" for this rule chapter. It is necessary and reasonable to revise the cited end point of the applicable statutes because the 1997 Legislature repealed Minnesota Statutes, section 144A.49. Section 144A.48 is the new end point of the home care provider and hospice program licensing statutes. Because these proposed rules would add more rule parts to the chapter, it is necessary and reasonable to revise the definition to include all applicable rule parts, including those in the new section for the assisted living home care provider, parts 4668.0800 to 4668.0895.

The language in the definition is also reformatted somewhat. Based on standards established by the Office of the Revisor of Statutes, the cited rule parts are listed prior to the cited statutes in rule language.

Part 4668.0003 DEFINITIONS, Subpart 21a Medication Administration.

Part 4668.0003, subpart 21a defines "medication administration" based on the suggestions from the Minnesota Home Care Association in late 1995, as discussed above under part 4668.0003, subpart 2a. It is necessary to include this definition and to clarify the differences

between “assistance with medication” and “medication administration” as safety measures for clients and educational purposes for providers and consumers. “Assistance with medication” means the client is self-administering his or her medication, while “medication administration” means the licensee or staff of the licensee is administering the client’s medication. There can be significant differences between those two methods, depending on the client’s needs and abilities. It is reasonable to clarify this definition in these rules in order that the rule parts that address medications can also be clarified.

Part 4668.0003 DEFINITIONS, Subpart 21b Medication reminder.

It is necessary to define “medication reminder” because the term is used in this chapter in defining services to be performed by unlicensed personnel. In this rule chapter, “medication reminder” means providing a verbal or written reminder to a client to take medication. This means that the licensee somehow conveys the message to the client to take his or her medication, and the client is able to get the medication container, open the medication container, and take the medication on his or her own, without any physical assistance from the licensee or staff of the licensee. This definition is necessary and reasonable to clarify the varying levels of assistance with medications that providers are providing (see the discussion under part 4668.0003, subparts 2a and 21a above). Along with the varying levels of assistance are varying levels of client abilities and needs, so it is reasonable to require varying levels of safety measures for those home care clients and to allow various methods to meet those needs.

Part 4668.0003 DEFINITIONS, Subpart 26a Oral hygiene.

It is necessary to define “oral hygiene” because the term is used in this chapter in defining services to be performed by unlicensed personnel. This term has been defined within the rule, and it is reasonable to relocate the definition to this rule part to be consistent in the format of the rule, and to make the rule chapter more user-friendly.

Part 4668.0003 DEFINITIONS, Subpart 26b Over-the-counter drug.

It is necessary to define “over-the-counter drug” because part 4668.0865 distinguishes between over-the-counter drugs and other drugs for the purpose of central storage of medications. In effect, an “over-the-counter drug” is one that may be sold without a prescription, in accordance with federal law. The authorizing statute requires the assisted living home care provider rules to address the administration and storage of medications which have not previously been addressed in the home care licensing rules. It is reasonable to provide definitions of terms used to ensure that the rules will be understandable and consistent with other applicable regulations.

Part 4668.0003 DEFINITIONS, Subpart 35 Residential center.

Part 4668.0003, subpart 35 defines "residential center," which is used to define "assisted living services" in part 4668.0003, subpart 3. It is necessary to revise this subpart to clarify the differences between a Class E licensee and an assisted living home care provider licensee.

It is necessary to revise the meaning of the term "assisted living services" to clarify that the term means those services provided by a Class E licensee to residents of a residential center, in their individual living units. It is reasonable to make the revision here to the term "residential center" to clarify that a residential center is a building or a complex of buildings that are contiguous or adjacent. The revision is necessary to clarify, in other rule parts, that a Class E licensee may provide services to one residential center. An assisted living home care provider may provide services to the residents of one or more registered housing with services establishments (in which the residents may or may not have individual living units).

Part 4668.0003 DEFINITIONS, Subpart 41 Survey.

Part 4668.0003, subpart 41 defines the term "survey" as it is used throughout this rule chapter. The Office of the Revisor of Statutes recommends listing the applicable rule chapters before the applicable statutes in rule language. The revision to the definition of the term "hospital" is necessary and reasonable to comply with those rule drafting standards established by the Office of the Revisor of Statutes. The revision is reasonable because the reorganization of the words does not alter the definition of the term.

Part 4668.0008 SERVICES INCLUDED IN AND EXCLUDED FROM LICENSURE, Subpart 3 Contract services.

Part 4668.0008, subpart 3 is revised by correcting the citation to the home care and hospice statutes. It is necessary and reasonable to revise the cited end point of the applicable statutes since the 1997 Legislature repealed Minnesota Statutes, section 144A.49. Section 144A.48 is the new end point of the home care provider and hospice program licensing statutes, so it is necessary and reasonable to cite that statute as the end point of this set of licensing rules.

Part 4668.0012 LICENSURE, Subpart 1 License issued.

It is necessary to revise Part 4668.0012, subpart 1 to reflect the correct scope of statutes relevant to home care and hospice licensure. The 1997 Legislature repealed Minnesota Statutes, section 144A.49, so it is reasonable to revise that language to make it match the statute.

Part 4668.0012 LICENSURE, Subpart 2 Multiple units.

Part 4668.0012, subpart 2 is revised to clarify the licensure requirements for multiple units of a provider, including the requirement that multiple units must share the same management. This requirement is necessary to distinguish between units which may share a

license and those that require separate licenses because they effectively operate independently of one another. It is not appropriate to enforce licensure requirements on a provider that is in reality not in charge of nor in a position to control what happens at another site. On the other hand, there should be more than one licensee where the person in charge of operations is not the same in both locations.

Language in this subpart about the distance between the main office and a unit of that main office is being repealed, because distance is not necessarily the determining factor in whether or not the main office can adequately share supervision and administration of services with a unit, nor whether the main office does not have the same management as a unit. The repeal of that language is reasonable because it eliminates something that is not an essential component of the decision of whether one or more licenses are required.

It is reasonable and necessary to restructure the language in what is now the second sentence in the subpart to have it be more straight-forward and easier to understand. The intent and applicability has not been changed by this sentence restructuring.

Part 4668.0012 LICENSURE, Subpart 3 Classes of licenses.

It is necessary to revise this subpart to reflect the addition to Minnesota Statutes, Chapter 144A of the assisted living home care provider license class and the ability for a provider to now hold more than one class of home care license.

Item A: This item is revised by replacing the term "shall" with the term "must" according to rulewriting instructions from the Office of the Revisor of Statutes. This revision is reasonable because it uses language that is used in everyday speech and writing, making the rules easier to understand. Item A is further revised by adding subitem 6, which is the new home care license class authorized by the 1997 changes to the home care licensing statute. The applicable statute is cited in this subitem, similarly to the way the statute authorizing rules for hospice services is included in subitem 4. This revision is necessary and reasonable to specify that the assisted living home care provider license is a separate license class and to clearly state where the statutory requirements for that license class are located.

Item B: It is necessary to revise item B to reflect 1997 statutory changes. Before the 1997 changes, only a provider of hospice services could have more than one class of home care license. That provision was needed to allow a hospice to provide the kinds and levels of services that a Class A home care provider could provide, to be eligible for Medicare certification of the home care business, and to also comply with those additional requirements for hospice found in the Class D licensure rules. In 1997, the statute was changed to read:

144A.46 LICENSURE.

Subdivision 1. **License required.** (a) A home care provider may not operate in the state without a current license issued by the commissioner of health. A home care provider may hold a separate license for each class of home care licensure.

It is reasonable to include this revision here to reflect the current statute and new ability of providers to have more than one class of home care license. For example, some providers may seek a Class A license so they can provide Medicare-eligible services to persons in a housing with services setting and in the community, and may also seek an assisted living home care provider license to provide services that would not qualify for Medicare reimbursement to avoid additional documentation required under the Medicare Conditions of Participation.

Part 4668.0012 LICENSURE, Subpart 4 Applicability of rules to classes.

Part 4668.0012, subpart 4 has been revised to include the new assisted living home care provider license class and to clarify which rule parts apply to each of the license classes. This revision is reasonable and necessary in light of complaints that the chapter is too confusing because readers must skip forwards and backwards to find all the parts applicable to a specific license class. By including all applicable rule parts in each of the items A through F, we are intending to provide clarity and ease in use, as well as being consistent in the way the new license class is added to this list.

A future rulemaking effort will reformat Minnesota Rules, Chapter 4668. Those rule parts that are applicable to all licensees would then remain in the initial sections of the rule chapter. Each license class would then have its own distinct section of applicable rules, similar to the way the new assisted living home care provider license class rules are detailed in parts 4668.0800 to 4668.0870. This reformatting effort is in response to comments and complaints from consumers, providers, and regulators who find the current format difficult to follow.

Part 4668.0012 LICENSURE, Subpart 5 New license.

Part 4668.0012, subpart 5 is revised to reflect the correct scope of statutes relevant to home care and hospice licensure. The 1997 Legislature repealed Minnesota Statutes, section 144A.49, so it is necessary and reasonable to make the revisions to be consistent between statute and rule language, so providers, consumers, and regulators can more readily understand the state regulations and how they interconnect.

The Office of the Revisor of Statutes now recommends listing applicable rule chapters before applicable statutes in rule language. The revisions to this subpart that reflect that recommendation are necessary and reasonable to comply with those rule drafting standards established by the Office of the Revisor of Statutes.

Part 4668.0012 LICENSURE, Subpart 6 License application.

It is necessary to revise part 4668.0012, subpart 6 to accurately describe the procedures to follow to apply for a home care license. Item A of this subpart contains a list of information that must be provided as part of the license application process.

Item A, Subitem 5: The 1997 Legislature repealed Minnesota Rules, part 4668.0020, so it is necessary to revise other parts of Chapter 4668 that have cited that rule part. The repeal of part 4668.0020 was included in an Act that changed statutes having to do with background studies of health care facility and provider employees. The proposed revisions to part 4668.0012, subpart 6, item A, subitem 5 contains a reference to Minnesota Statutes, section 144A.46, subdivision 5, which authorizes those background studies.

Item A, Subitem 6: The reference in subitem 5 obviates the need for subitem 6. It is reasonable to delete the language in that current subitem, since the intent of it is now included in the proposed revised subitem 5. The following subitems will be renumbered as necessary to reflect the deletion of the language in the current subitem 6.

Item A, Subitem 10: Because of the deletion of the language in the current subitem 6, what has been subitem 10 will become subitem 9. It is necessary and reasonable to include a reference to the statute that contains the list of services that may be provided under an assisted living home care provider license because the list of services found in Minnesota Statutes, section 144A.4605 is somewhat different from the list of home care services found in Minnesota Statutes, section 144A.43, subdivision 3. It is reasonable to include both of those statutes in this subitem to provide applicants with accurate cites and reasonable licensing requirements.

Part 4668.0012 LICENSURE, Subpart 7 Agent.

Part 4668.0012, subpart 7 requires that there be someone designated as the agent of the licensee who is authorized to transact any licensing business with the commissioner of health, and upon whom all notices and orders will be served. Both Items A and B contain references to the home care licensing statutes. Minnesota Statutes, section 144A.49 was repealed in 1997, so part 4668.0012, subpart 7, items A and B will be revised by replacing "144A.49" with "144A.48" where it occurs, which is reasonable to eliminate an inconsistency between current statute and rule.

The Office of the Revisor of Statutes recommends listing applicable rule chapters before applicable statutes in rule language. The revisions to the rule language in subpart 7, subitems A, B, and C are necessary and reasonable to comply with rule drafting standards established by the Office of the Revisor of Statutes.

Part 4668.0012 LICENSURE, Subpart 8 Notification of changes in information.

Part 4668.0012, subpart 8 refers to the services that must be reported to the commissioner under subpart 6 of this part. Subpart 6 was revised, so it is necessary and reasonable to revise subpart 8 to accurately cite the applicable rule language and subitem, based on the new numbering of the rule text due to revisions.

Part 4668.0012 LICENSURE, Subpart 10 Prelicensing survey.

Part 4668.0012, subpart 10 authorizes the department to investigate a home care license applicant's compliance with the home care licensing statutes and with Minnesota Rules, Chapter 4668. It is necessary to revise this subpart to reflect repeal of section 144A.49 by replacing "144A.49" with "144A.48" where it occurs. This revision is reasonable because it corrects an inconsistency between current statute and rule.

The Office of the Revisor of Statutes recommends listing applicable rule chapters before applicable statutes in rule language. The revision to this rule language, moving the cite to the rule chapter ahead of the cite to the statute, is necessary and reasonable to comply with rule drafting standards established by the Office of the Revisor of Statutes.

Part 4668.0012 LICENSURE, Subpart 11 Denial of license.

Part 4668.0012, subpart 11 lists circumstances under which an application for a home care license must be denied.

Items B and E: Items B and E contain references to the home care licensing statutes. These items are revised by replacing "144A.49" with "144A.48" where it occurs because Minnesota Statutes, section 144A.49 was repealed in 1997. This revision is reasonable because it corrects an inconsistency between current statute and rule.

The Office of the Revisor of Statutes recommends listing applicable rule chapters before applicable statutes in rule language. The revision to the rule language in items B and E, moving the cite to the rule chapter ahead of the cite to the statute, is necessary and reasonable to comply with rule drafting standards established by the Office of the Revisor of Statutes.

Items C and D: Items C and D contain references to part 4668.0020, which was repealed by Laws of Minnesota 1997, Chapter 248. That law contains revisions to the background study requirements. It is necessary and reasonable to revise item C of this subpart to cite the correct statute that governs disqualification of persons from providing home care services. It is necessary and reasonable to revise item D of this subpart to cite the statute that would allow for a disqualification to be set aside, which would be allowed under the statutory changes made by the 1997 Legislature. These revisions to this rule language would reflect current statutory language, making it easier for applicants to learn the application requirements.

Part 4668.0012 LICENSURE, Subpart 13 License renewals.

Part 4668.0012, subpart 13 provides procedures for renewing a home care license. Item C contains a reference to the home care licensing statutes. This reference is revised by replacing "144A.49" with "144A.48" where it occurs because Minnesota Statutes, section 144A.49 was repealed in 1997. This revision is reasonable because it corrects an inconsistency between current statute and rule.

Part 4668.0012 LICENSURE, Subpart 14 Conditional license.

Part 4668.0012, subpart 14 authorizes the department to issue a conditional license to a provider that is not in full compliance with the home care licensing statutes and rules. This subpart contains a reference to the home care licensing statutes, including section 144A.49 which was repealed in 1997. This subpart will be revised by replacing "144A.49" with "144A.48" which is a reasonable revision because it corrects an inconsistency between current statute and rule.

Part 4668.0012 LICENSURE, Subpart 15 Suspension, revocation, or denial of renewal of license.

Item A: Part 4668.0012, subpart 15 lists grounds to deny renewal of a license, or suspend, revoke, or make conditions on a license. Subitem A contains a reference to the home care licensing statutes. Minnesota Statutes, section 144A.49 was repealed in 1997. It is necessary and reasonable to revise the rule language here in subitem A to reflect the accurate end point of the home care licensing statutes.

Items H and I: Subitems H and I contain references to the home care licensing statutes. Minnesota Statutes, section 144A.49 was repealed in 1997; section 144A.48 is now the final section in the home care licensing statutes. It is necessary and reasonable to revise the rule language here in subitems H and I to reflect the accurate end point of the home care licensing statutes.

The Office of the Revisor of Statutes recommends listing applicable rule chapters before applicable statutes in rule language. The revision to this rule language, moving the cite to the rule chapter ahead of the cite to the statute, is necessary and reasonable to comply with rule drafting standards established by the Office of the Revisor of Statutes.

Item J: Part 4668.0012, subpart 15, item J includes a cite to part 4668.0020, which was repealed by the Legislature in 1997 as part of the revision of the background study requirements for many health care professionals and providers. It is necessary and reasonable to revise the language here to cite the correct statute addressing background studies.

Item K: Part 4668.0012, subpart 15, item K cites the location of the existing schedule of fines for violations of rule parts in this chapter. With the addition of the new license class, it is necessary to include here a cite to the new rule part that addresses fines for violations of parts 4668.0800 to 4668.0870.

Part 4668.0017 HEARINGS, Subpart 1 Hearing rights:

Part 4668.0017, subpart 1 is revised by adding a cite to part 4668.0800, subpart 9, which contains language on assessing fines for noncompliance with rule parts 4668.0800 to 4668.0865 (the section of rules that apply only to assisted living home care provider licenses). This revision

is reasonable because the current rule part 4668.0016, subpart 1 cites the current rule part containing fining levels for noncompliance with existing rules (4668.0230), and the new rule part 4668.0800, subpart 6, needs to be cited here to assure a connection to the hearing rights provided in the existing enforcement procedures for this chapter.

Part 4668.0040 COMPLAINT PROCEDURE, Subpart 1 Complaint procedure.

The existing language of subpart 1 is revised by deleting the listing of the applicable classes and replacing that listing with the word “a licensee” to clearly state that this requirement applies to all applicable licensees regardless of whether it is a Class A, B, D, E, or assisted living home care provider licensee. This is reasonable because the proposed language is consistent with effective rulewriting and makes the rule easier to understand. This revision does not change the effect of the rule language.

This subpart is also revised by replacing the term “shall” with the term “must” according to rulewriting instructions from the Office of the Revisor of Statutes. This revision is reasonable because it uses language that is used in everyday speech and writing, making the rules easier to understand.

Part 4668.0040 COMPLAINT PROCEDURE, Subpart 3

Subpart 3 is revised for clarity and not to change the effect of the rule. Rather than stating “No licensee shall...”, the wording will be changed to “A licensee must not ...” to use clearer, less confusing, more accurate language in the rule. This change is reasonable because it makes the rule more user-friendly and easier to understand, and presented in positive language rather than prohibitive language.

4668.0040 COMPLAINT PROCEDURE, Subpart 4 Scope.

It is necessary to revise this part by adding a new subpart 4, which describes the rule part’s scope to enhance understanding the applicability of complaint procedure requirements. The existing language, which has been found in subpart 1, lists four license classes that the existing language in this rule part applies to. It is clearer and less cumbersome, especially with the creation of a sixth license class, to replace that language with the statement that “this part applies to all licensees except Class C licensees” in a new subpart 4. This is reasonable because it makes the rule language and applicability of this part easier to understand for consumers, licensees, and regulators.

4668.0050 ACCEPTANCE, RETENTION, AND DISCHARGE OF CLIENTS, Subpart 1 Acceptance of clients.

Part 4668.0050, subpart 1, requires that the licensee has sufficient staffing to adequately provide the agreed-upon services to the licensee’s clients. This rule part applies to all licensees.

This subpart is revised by adding a cite to the rule part requiring service plans for clients of assisted living home care provider licensees. This revision is necessary to ensure that assisted living home care provider licensees follow this same requirement in part 4668.0050 regarding sufficient staffing that all other licensees must follow. The revision is reasonable because the service plan serves for assisted living home care providers the same purpose as the service agreement for other categories of home care licensees.

**Part 4668.0075 ORIENTATION TO HOME CARE REQUIREMENTS, Subpart 2
Content, Item A.**

Part 4668.0075, subpart 2, item A is revised by relocating the cite to the rule chapter ahead of the cite to the statute, which is necessary and reasonable to comply with standards for rulewriting developed by the Office of the Revisor of Statutes. This item would also be revised by correcting the cite to the statutes. Minnesota Statutes, section 144A.49 was repealed in 1997; section 144A.48 is now the final section in the home care licensing statutes. It is necessary and reasonable to revise the rule language here to reflect the accurate end point of the home care licensing statutes.

Part 4668.0220 SURVEYS AND INVESTIGATIONS, Subpart 3 Biennial surveys.

This subpart identifies licensee that may be put on a biennial (vs. annual) survey schedule. It is necessary and reasonable to revise this subpart to reflect that section 144A.49 of the home care licensing statutes was repealed in 1997.

Part 4668.0220 SURVEYS AND INVESTIGATIONS, Subpart 4 Complaint investigations.

Part 4668.0220, subpart 4 requires the commissioner to investigate complaints that licensees may be or may have violated a rule or statutory requirement. It is necessary and reasonable to revise this subpart to reflect that section 144A.49 was repealed in 1997.

Part 4668.0230 FINES FOR UNCORRECTED VIOLATIONS, Subpart 1 Authority.

Part 4668.0230, subpart 1 cites the two statutes authorizing the commissioner to impose fines for uncorrected home care violations. A revision is being made to put those cited statutes in numerical order. This revision is necessary and reasonable to comply with guidelines from the Office of the Revisor of Statutes to organize cites in numerical order.

Part 4668.0230 FINES FOR UNCORRECTED VIOLATIONS, Subpart 5 Schedule of fines for violations of rules.

Part 4668.0230, subpart 5 informs licensees of the law which requires the imposition of fines for uncorrected violations of home care rule provisions. Because of the revisions to the existing rules, including the addition of new rule parts and the repeal of other rule parts, it is necessary and reasonable that subpart 5 be re-ordered.

Items G through N: In these proposed rules, the current part 4668.0230, subpart 5, items G, H, I, J, K, L, M, and N would be deleted because they include the fines for violations of part 4668.0020, which was repealed by the 1997 Legislature. The subsequent items are then re-lettered to account for the deletion of those seven listed subparts.

Parts 4668.0800 to 4668.0895 address the new “Assisted Living Home Care Provider” home care license class.

Part 4668.0800 ASSISTED LIVING HOME CARE PROVIDER, Subpart 1 Scope of license.

Part 4668.0800, subpart 1 describes the scope for the assisted living home care provider license class by listing the services stated in section 144A.4605 that may be provided by an assisted living home care provider licensee. This language is reasonable because it provides a clear statement in the rule chapter as to what services may be provided by this class of licensee to residents of housing with services establishments.

Part 4668.0800 ASSISTED LIVING HOME CARE PROVIDER, Subpart 2 Required services.

It is necessary to define “required services” because Minnesota Statutes, section 144A.43 requires that “at least one home care service must be provided directly” for the entity to qualify for licensure. Other services may be provided by contractors to the licensee. It is reasonable to specify the services that are addressed under an assisted living home care provider license, of which at least one must be provided directly by the licensee, to clarify that requirement for providers, consumers, and regulators. It is reasonable and necessary to make this requirement very clear in the rule language because this is a new licensure category as well as a fairly new industry.

Part 4668.0800 ASSISTED LIVING HOME CARE PROVIDER, Subpart 3 Fulfillment of services.

Part 4668.0800, subpart 3 is similar to the requirements of the current part 4668.0060, subpart 3 regarding fulfillment of all services required by the client’s service plan. Minnesota Statutes, section 144A.44, subdivision 1, clauses (2) and (16) guarantee clients:

“(2) the right to receive care and services according to a suitable and up-to-date plan, and subject to accepted medical or nursing standards, to take an active part in creating and changing the plan and evaluating care and services;

(16) the right to reasonable, advance notice of changes in services or charges.”

To ensure these rights, it is necessary to require licensees to provide services as set forth in clients' service plans, unless alternative arrangements are made under part 4668.0815, subparts 5 and 6. This proposed subpart is reasonable because the service plan is a binding contract between the licensee and the client and may not be breached or compromised without the consent of the client. This requirement is necessary to provide a standard for the provision of services as agreed on in that service plan.

Part 4668.0800 ASSISTED LIVING HOME CARE PROVIDER, Subpart 4 Referrals.

Part 4668.0800, subpart 4 is similar to the current part 4668.0180, subpart 8, and requires action by the licensee when the licensee reasonably believes the client needs another medical or health service. As with other subparts in this rule part, this requirement is necessary to assure the health, safety, and appropriate treatment of clients, and is reasonable because it complies with Minnesota Statutes, section 144A.4605, subdivision 2(g).

Part 4668.0800 ASSISTED LIVING HOME CARE PROVIDER, Subpart 5 Availability of contact person.

Part 4668.0800, subpart 5 is similar to current part 4668.0060, subpart 6, and requires a licensee to have a contact person available for consultation to unlicensed personnel whenever the unlicensed person is providing assisted living home care provider services. This is necessary to comply with Minnesota Statutes, section 144A.4605, subdivision 2(g) and to assure the health, safety, and well-being of assisted living home care provider clients. It is possible that an unlicensed person may be the only staff on duty at the housing with services establishment; that person must be able to contact a responsible person with questions or concerns about a client or for assistance in an emergency. The rule is reasonable because it allows the licensee flexibility in the means of direct communication between the contact person and the unlicensed personnel. The rule is reasonable because it does not dictate professional requirements for the contact person. The decision as to whether the contact should be a licensed health professional is left to the licensee. That decision will need to be based on 1) the needs of the clients living in that housing with services establishment, 2) the skills, training, and delegated authority of the unlicensed persons performing assisted living home care services, and 3) what services are being provided by an unlicensed person at any given time.

Part 4668.0800 ASSISTED LIVING HOME CARE PROVIDER, Subpart 6 Violations of rules.

Part 4668.0800, subpart 6 is similar to current language in part 4668.0230, subpart 5, which provides the fining schedule for the current home care rule language. This is necessary and reasonable to comply with Minnesota Statutes, section 144A.4605, subdivision 2(g) and to create the link between the minimal standards established by statute and rule and the consequences of failing to comply with those minimal standards.

In the current rule, fines for noncompliance are located at what had been the end of Chapter 4668. With the future reformatting of the rule chapter in mind, the fines for noncompliance with rules for this new license class are located in each applicable rule part. The language here at part 4668.0800, subpart 6, states that there are fines established for violations of parts 4668.0800 to 4668.0870, as required by Minnesota Statutes, section 144.563, subdivision 6, which reads:

Subd. 6. Reinspections; fines. If upon reinspection it is found that the licensee of a facility required to be licensed under the provisions of sections 144.50 to 144.58 has not corrected deficiencies specified in the correction order, a notice of noncompliance with a correction order shall be issued stating all deficiencies not corrected. Unless a hearing is requested under subdivision 8, the licensee shall forfeit to the state within 15 days after receipt by the licensee of such notice of noncompliance with a correction order up to \$1,000 for each deficiency not corrected. For each subsequent reinspection, the licensee may be fined an additional amount for each deficiency which has not been corrected. All forfeitures shall be paid into the general fund. The commissioner of health shall promulgate by rule a schedule of fines applicable for each type of uncorrected deficiency.

Part 4668.0800 ASSISTED LIVING HOME CARE PROVIDER, Subpart 7 Failure to correct deficiency.

Part 4668.0800, subpart 7 is the same as language in the current part 4668.0240. This is necessary and reasonable to comply with Minnesota Statutes, section 144A.4605, subdivision 2(g), as shown above. Including this subpart in the licensing rules for the assisted living home care provider class is necessary and reasonable to describe the consequences for noncompliance with those standards that are in place to protect consumers of home care services.

Part 4668.0800 ASSISTED LIVING HOME CARE PROVIDER, Subpart 8 Schedule of fines.

Part 4668.0800, subpart 8 provides the fines for noncompliance with other subparts of part 4668.0800. This subpart is necessary and reasonable to provide a direct link between the licensure requirements and the consequences of noncompliance with those requirements, which have been established in accordance with state statute to provide protections to consumers of home care services. This subpart is included to comply with the requirements in Minnesota Statutes, section 144.653, subdivision 6, as shown above. The amounts of the fines are consistent with the schedule of fines established for the entire home care rule chapter. As discussed in the Statement of Need and Reasonableness for the promulgation of Chapters 4668 and 4669, the underlying premise behind a system of fines is to ensure that there is an efficient mechanism to promote compliance with statutes and rules, and that the licensee operates in accordance with these statutes and rules. The system of fines relates the amount of the fine to the impact on the client resulting from noncompliance with the statute or rule. In other words, it looks at how noncompliance jeopardizes the health, safety, and well-being, and the appropriate treatment of clients.

Item A: The fine for part 4668.0800, subpart 3 is set at \$350. The \$350 penalty assessment has been assigned to those rules that are related to the direct provision of services to clients. This subpart requires the fulfillment of services required by the client's service plan. It is reasonable to impose a \$350 fine for noncompliance with subpart 3 because it relates to the direct provision of services.

Item B: The fine for part 4668.0800, subpart 4 is set at \$200. The \$200 penalty assessment has been assigned to those rules for which noncompliance could impact on the health or safety of clients. Subpart 4 requires the licensee to take action when it is believed the client needs a referral for other medical or health services. It is reasonable to impose a \$200 fine for noncompliance with this subpart because it could impact on the health or safety of a client.

Item C: The fine for part 4668.0800, subpart 5 is \$300. The \$300 penalty assessment has been assigned to those rules that are necessary to assure that the service is properly provided. This subpart requires the availability of a contact person when an unlicensed person is providing assisted living home care provider services. It is reasonable to impose a \$300 fine for noncompliance with subpart 5 because having a contact person is necessary to assure that services are properly provided and to assure the health, safety, and well-being of the client.

Part 4668.0805 ORIENTATION TO HOME CARE REQUIREMENTS, Subpart 1 Orientation.

Part 4668.0805, subpart 1 requires that every applicant and every person providing direct care, supervision of direct care, or management of services, must complete an orientation to the state home care requirements. This language is almost identical to that found in the current part 4668.0075, subpart 1. It is necessary and reasonable to replicate that language from 4668.0075 for this license class so that assisted living home care provider licensees and their employees are familiar with their legal rights and obligations and those of their clients. The language is reasonable to assure that persons involved in providing services have been provided with some basic information on home care requirements prior to providing home care services. Orientation training is a reasonable means of conveying this information in an efficient and effective method, in a short period of time with relatively little administrative burden.

Part 4668.0805 ORIENTATION TO HOME CARE REQUIREMENTS, Subpart 2 Content.

Part 4668.0805, subpart 2 provides the content of the orientation to home care requirements. The language is identical to that in the current part 4668.0075, and is replicated here as part of the reformatting of Chapter 4668. To ensure that all orientations properly instruct these persons on the relevant laws, rules, regulations, and other basic information that providers need to know, it is necessary to define the topics that are to be covered in each orientation.

Item A: Item A is reasonable because licensees, employees, and staff are bound by and need to be aware of the home care licensing statute and this chapter.

Item B: Item B is reasonable because providers need to react quickly in emergency situation to protect the health, safety, and well-being of clients. They must either deal with emergencies on their own or know how and in what circumstances to contact a community emergency service if the situation demands skills beyond their capabilities.

Item C: Item C is reasonable because home care providers are required to report the maltreatment of vulnerable minors and adults pursuant to this chapter and Minnesota Statutes, sections 626.556 and 626.557, and they need to be aware of the relevant statutory provisions.

Item D: Item D is reasonable because Minnesota Statutes, section 144A.44 guarantees certain rights to home care clients.

Item E: Minnesota Statutes, section 144A.44, subdivision 1, clause (16), and Minnesota Statutes, section 144A.44, subdivision 2, grant clients the right to make complaints about home care services to providers and to the Office of Health Facility Complaints. The existence of such rights requires that licensees establish procedures for receiving and processing complaints. It is reasonable to require that providers be instructed on the complaint procedure prior to initiating home care services to ensure that they deal appropriately with complaints when they arise.

Item F: Item F is reasonable in light of the role of the Ombudsman for Older Minnesotans, which includes:

256.9742 Duties and powers of the office.

Subdivision 1. Duties. The ombudsman's program shall:

- (1) gather information and evaluate any act, practice, policy, procedure, or administrative action of a long-term care facility, acute care facility, home care service provider, or government agency that may adversely affect the health, safety, welfare, or rights of any client;
- (2) mediate or advocate on behalf of clients;
- (3) monitor the development and implementation of federal, state, or local laws, rules, regulations, and policies affecting the rights and benefits of clients;
- (4) comment on and recommend to public and private agencies regarding laws, rules, regulations, and policies affecting clients;
- (5) inform public agencies about the problems of clients;
- (6) provide for training of volunteers and promote the development of citizen participation in the work of the office;
- (7) conduct public forums to obtain information about and publicize issues affecting clients;
- (8) provide public education regarding the health, safety, welfare, and rights of clients; and
- (9) collect and analyze data relating to complaints, conditions, and services.

Subdivision 3 of that statute requires home care providers to provide all recipients, including those in housing with services under chapter 144D, with the address and telephone number of the Ombudsman's office. Because of the potential for significant involvement by the Ombudsman in the operations of assisted living home care providers, it is reasonable to require that orientations include a discussion of the Ombudsman's role in home care.

Part 4668.0805 ORIENTATION TO HOME CARE REQUIREMENTS, Subpart 3 Sources of orientation.

Part 4668.0805, subpart 3 permits assisted living home care providers to provide orientation training themselves or from some other source, and requires the commissioner of MDH to provide an orientation curriculum and materials. The language in this part is almost identical to that in the existing part 4668.0075, subpart 3. This subpart is necessary and reasonable to provide information to applicants and licensees about the provision of the required orientation. The department is interested in educating providers, not in dictating how or where this education should take place. It is reasonable to require the department to make an orientation curriculum and materials available to the public to standardize the training among providers and ensure that all topics are adequately and appropriately addressed. Along with additional guides for the teacher and the student, the curriculum for orientation is available through the Minnesota's Bookstore.

Part 4668.0805 ORIENTATION TO HOME CARE REQUIREMENTS, Subpart 4 Verification and documentation.

Part 4668.0805, subpart 4 requires licensees to retain evidence that appropriate persons have completed the required orientation training. This language is identical to that found in the current part 4668.0075, subpart 4. It is necessary and reasonable to replicate language that applies to all licensees in the rule section that applies to assisted living home care providers to ensure compliance with consistent requirements for the various licensure classes that all persons have completed an orientation to home care requirements.

Part 4668.0805 ORIENTATION TO HOME CARE REQUIREMENTS, Subpart 5 Transferability.

Part 4668.0805, subpart 5 allows licensees to accept orientation verification from other providers to avoid providers having to complete orientation more than once. This language is identical to that found in the current part 4668.0075, subpart 5. It is necessary and reasonable to replicate that language here to provide for consistent requirements for the various licensure classes. The language is reasonable because to do otherwise would create an unnecessarily duplicative training requirement and impose an unacceptable burden on licensees.

Part 4668.0805 ORIENTATION TO HOME CARE REQUIREMENTS, Subpart 6
Schedule of fines.

Part 4668.0805, subpart 6 provides the fines for noncompliance with the other subparts in this rule part. This subpart is necessary to comply with the requirements in Minnesota Statutes, section 144.653, subdivision 6, as shown above. The amounts of the fines are reasonable because they are consistent with the schedule of fines established for the entire home care rule chapter. See part 4668.0230, subpart 5, above for a discussion on the fining schedule established for Minnesota Rules, Chapter 4668.

Item A: The fine for noncompliance with part 4668.0805, subpart 1, is \$300. The \$300 penalty assessment has been assigned to those rules that are necessary to assure that the service is properly provided. It is reasonable to impose the \$300 fine to violations of Subpart 2 because lack of orientation could result in services not being properly provided.

Item B: The fine for noncompliance with part 4668.0805, subpart 2 is \$100. The \$100 fine is assigned to violations of rules which only indirectly affect the health, safety, or well-being of clients, and to violations involving regulatory compliance issues. Subpart 2 provides the content of the orientation to home care requirements. The \$100 fine is reasonable for violations of part 4668.0805, subpart 2 because noncompliance with that subpart only indirectly affects the health, safety, or well-being of clients. The statutes, rules, and safety information listed as orientation content in that subpart will still apply to the home care licensee regardless of whether or not persons have been oriented to it, and licensees are still liable for compliance with those regulations.

Item C: The fine for noncompliance with part 4668.0805, subpart 4 is \$50. The minimum fine of \$50 is assigned to those rules that do not directly jeopardize the health, safety, or well-being of clients. Subpart 4 requires the licensee to retain evidence that persons have completed the required orientation. While that documentation is important to have, a violation of this subpart does not directly jeopardize the health, safety, and well-being of clients, so the \$50 fine is reasonable.

Part 4668.0810 CLIENT RECORDS, Subpart 1 Maintenance of client record.

Part 4668.0810, subpart 1 requires that a client record be maintained for each client. The language proposed here is based on the current part 4668.0160, subparts 1 and 2, and has been expanded to include the requirement that the record be maintained at the housing with services establishment where the services are provided. There is extensive legislative support for a requirement for client records to be maintained by an assisted living home care provider. The Home Care Bill of Rights, Minnesota Statutes, section 144A.44, subdivision 1, item (12), guarantees client access to records and information about care. Minnesota Statutes, section 144A.45, subdivision 1(g), directs the Department to develop administrative rules requiring the involvement of a consumer's physician, the documentation of physicians' orders, if required, and the consumer's treatment plan, and the maintenance of accurate, current clinical records."

Minnesota Statutes, section 144A.4605, subdivision 2, item (d), provides additional requirements for client records unique to the assisted living home care provider licensees.

Minnesota Statutes, section 144A.4605, subdivision 1, allows an assisted living home care provider to provide services for residents of one or more housing with services establishments registered under Chapter 144D. A resident of a housing with services establishment may or may not be a client of an assisted living home care provider providing services at that housing with services establishment. There may be more than one assisted living home care provider licensee providing services at a housing with services establishment and there may be other classes of home care licensees providing services to clients at that same housing with services establishment. It is possible, therefore, that a client will be receiving services from more than one home care licensee, for example, from an assisted living home care provider licensee and from a Class A home care agency. It is reasonable to require that records for an assisted living home care client be maintained at the housing with services establishment where the services are provided. This will facilitate the transfer of information to other providers and practitioners, provide for continuity of care, enable providers to evaluate the appropriateness and effectiveness of client services at that housing with services establishment, and provide documentation for survey and compliance purposes. In most cases, the location where the services are provided is the housing with services establishment where the client resides.

Part 4668.0810 CLIENT RECORDS, Subpart 2 Security.

Part 4668.0810, subpart 2 is based on the language in part 4668.0160, subpart 2. It is necessary and reasonable to replicate that language here to ensure that assisted living home care client records are properly developed and maintained. It is necessary to require that licensees establish criteria for the release of client information based on Minnesota Statutes, section 144A.44, subdivision 1, clause (11), which guarantees clients the "right to have personal, financial, and medical information kept private, and to be advised of the provider's policies and procedures regarding disclosure of such information." Moreover, Minnesota Statutes, section 144A.44, subdivision 1, clause (12), grants clients "the right to be allowed access to records and written information from records in accordance with section 144.335." This subpart is reasonable in light of the strong public policy to keep health and related information inaccessible to all but the subject of the information. Because of the organizational differences among the providers, however, it is reasonable to allow them the flexibility to establish their own procedures for the security of client records, consistent with law and this chapter.

Part 4668.0810 CLIENT RECORDS, Subpart 3 Retention.

Part 4668.0810, subpart 3 is identical to part 4668.0160, subpart 3. It is necessary and reasonable to replicate that language here to provide consistency in regulation (a "level playing field") among the various home care licensure classes.

Part 4668.0810 CLIENT RECORDS, Subpart 4 Transfer of client.

Part 4668.0810, subpart 4 is identical to part 4668.0160, subpart 4. It is necessary and reasonable to replicate that language here to provide a "level playing field" among the various home care licensure classes.

Part 4668.0810 CLIENT RECORDS, Subpart 5 Form of entries.

Part 4668.0810, subpart 5 provides detail on the form and frequency of entries to the client record. The language in the first sentence is necessary to comply with Minnesota Statutes, section 144A.4605, subdivision 2, clause (d), which states:

"notwithstanding Minnesota Rules, part 4668.0160, subpart 6, item D, client records shall include:

- (1) a weekly summary of the client's status and home care services provided;
- (2) documentation each time medications are administered to a client; and
- (3) documentation on the day of occurrence of any significant change in the client's status or any significant incident, such as a fall or refusal to take medications.

All entries must be signed by the staff providing the services and entered into the record no later than two weeks after the end of the service day, except as specified in clauses (2) and (3)."

Item A: This language is the same as in part 4668.0160, subpart 5. It is necessary and reasonable to replicate it here to provide consistent regulations between the various licensure classes.

Item B: The language in the proposed item B is based on part 4668.0160, subpart 5, but has been expanded to clarify expectations of electronic information storage. It is necessary to require that systems to electronically store client information be capable of producing a paper copy for: 1) sharing that information between providers of services and 2) purposes of the survey and compliance process. The language used is reasonable because it is based on current standards of practice in the health information management field.

Part 4668.0810 CLIENT RECORDS, Subpart 6 Content of client record.

Part 4668.0810, subpart 6 is based on language in part 4668.0160, subpart 6. Minnesota Statutes, section 144A.45, subdivision 1, paragraph (g) requires that providers maintain "accurate, current clinical records." This subpart is necessary and reasonable to implement this requirement and the requirements of Minnesota Statutes, section 144A.4605, subdivision 1, paragraphs (d) and (e), which state:

“(d) notwithstanding Minnesota Rules, part 4668.0160, subpart 6, item D, client records shall include:

- (1) a weekly summary of the client’s status and home care services provided;
- (2) documentation each time medications are administered to a client; and
- (3) documentation on the day of occurrence of any significant change in the client’s status or any significant incident, such as a fall or refusal to take medications.

All entries must be signed by the staff providing the services and entered into the record no later than two weeks after the end of the service day, except as specified in clauses (2) and (3);

(e) medication and treatment orders, if any, are included in the client record and are renewed at least every 12 months, or more frequently when indicated by a clinical assessment.”

Part 4668.0810 CLIENT RECORDS, Subpart 7 Confidentiality.

Part 4668.0810, subpart 7 is the same as part 4668.0160, subpart 7. It is necessary to replicate that language here for the assisted living home care provider licensure rules to ensure consistency in regulations between the various licensure classes. It is reasonable to include a requirement for keeping information gathered about a client confidential based on the factors discussed under part 4668.0810, subpart 2 above.

Part 4668.0810 CLIENT RECORDS, Subpart 8 Schedule of fines.

Part 4668.0810, subpart 8 provides the penalties for noncompliance with the other subparts of this part. This subpart is necessary to comply with the requirements in Minnesota Statutes, section 144.653, subdivision 6, as shown above. The amounts of the fines are reasonable because they are consistent with the schedule of fines established for the entire home care rule chapter. See part 4668.0230, subpart 5, above for a discussion on the fining schedule established for Minnesota Rules, Chapter 4668.

Item A: The fine for noncompliance with part 4668.0810, subpart 1, is \$100, the same as for part 4668.0160, subpart 1. The \$100 fine is assigned to violations of rules which only indirectly affect the health, safety, or well-being of clients, and to violations involving regulatory compliance issues. The client record required by this subpart is necessary to show that an evaluation has been performed for each client, and that a service plan has been developed and implemented. It is reasonable to impose a \$100 fine because the client record, although necessary to show documentation, only indirectly affects the health, safety, or well-being of clients.

Item B: The fine for noncompliance with part 4668.0810, subpart 2 is \$100, the same fine amount as for the existing part 4668.0160, subpart 2. Maintaining written procedures for the security of client records only indirectly affects clients, so the \$100 fine is reasonable for noncompliance with this subpart.

Item C: The fine for noncompliance with part 4668.0810, subpart 3 is \$50, the same as for part 4668.0160, subpart 3. The minimum fine of \$50 is assigned to those rules that do not directly jeopardize the health, safety, treatment, comfort or well-being of clients. This subpart addresses the retention of the client record, which does not directly affect clients, so the \$50 fine level is reasonable for this subpart.

Item D: The fine for noncompliance with part 4668.0810, subpart 4 is \$100, the same as for part 4668.0160, subpart 4. The \$100 fine is reasonable for this subpart because failure to forward a copy of the client's record, upon request, to another health care practitioner or provider would indirectly affect the health, safety, or well-being of clients.

Item E: The fine for noncompliance with part 4668.0810, subpart 5 is \$50. This minimal penalty is reasonable because the form of the entries in the client record does not directly affect the health, safety, and well-being of the clients.

Item F: The fine for noncompliance with part 4668.0810, subpart 6 is \$100, the same as for part 4668.0160, subpart 6. Noncompliance with the content requirements for the client record can indirectly affect the health, safety, and well-being of clients, so the \$100 penalty is reasonable for this subpart.

Item G: The fine for noncompliance with part 4668.0810, subpart 7 is \$350, the same as for part 4668.0160, subpart 7. The \$350 penalty assessment has been assigned to those rules which relate to the direct provision of services to clients. Subpart 7 requires keeping the client record confidential. The \$350 penalty is appropriate because this subpart relates to the direct provision of services and the protection of client privacy.

Part 4668.0815 EVALUATION AND SERVICE PLAN, Subpart 1 Evaluation; documentation.

Part 4668.0815, subpart 1 requires the completion of an individualized evaluation and service plan for each client, in accordance with accepted standards of practice for professional nursing. This subpart is based on part 4668.0140, subpart 1 and also implements language in Minnesota Statutes, section 144A.44, subdivision 1, the Home Care Bill of Rights, and section 144A.45, subdivision 1, which authorizes MDH to adopt rules for home care licensees, including "standards for client evaluation or assessment which may vary according to the nature of the services provided or the status of the consumer."

Conducting an evaluation or an assessment is the responsibility of a professional nurse, as defined in Minnesota's Nurse Practice Act, and as a part of current standards of practice in the nursing and home care industries. It is necessary to have appropriate knowledge of the client's condition, service needs, preferences, and goals upon which to develop a plan for providing services to that client. It is necessary and reasonable to require that this assessment be completed by a registered nurse because Minnesota Statutes, section 148.171, clause (3) defines the practice of professional nursing as:

(3) The practice of professional nursing means the performance for compensation or personal profit of the professional interpersonal service of: (a) providing a nursing assessment of the actual or potential health needs of individuals, families, or communities; (b) providing nursing care supportive to or restorative of life by functions such as skilled ministrations of nursing care, supervising and teaching nursing personnel, health teaching and counseling, case finding, and referral to other health resources; and (c) evaluating these actions.

The language proposed in part 4668.0815, subpart 1 is reasonable to protect the health and safety of clients and complies with statutory requirements for home care.

During the development of these proposed rules, discussions about “assessments” and “evaluations” demonstrated significant confusion and misunderstanding over what those terms mean and who can perform them. Some commenters felt that the term “service agreement”, used in the current home care licensing rules, had connotations of being burdensome because of its complexity and the need for frequent updating. The service agreement has been the written contract or agreement between the client or the client’s responsible person (i.e., the consumer) and the provider regarding what home care services the client needs and wants, and what the provider can and will provide for that client. It was recommended to the Department that the rule for assisted living home care providers use some other term for the documentation of the discussion and initial agreement between the client and the assisted living home care provider. The term “evaluation” was decided on because it had connotations of a simpler, less detailed review of the client’s condition than the term “assessment.” The term “assessment” is also included in statute as a responsibility of a registered professional nurse, so comments received during draft development indicated that term should not be used for an initial review that would not necessarily indicate the need for professional nursing services.

The evaluation to be performed under the proposed part 4668.0815 is required as a home care license requirement. By the time this evaluation is being completed for a client, a determination has already been made that the client needs home care services, regardless of who has made that determination. This subpart does not require that a registered nurse or other health care professional make that decision. Making the determination that a person needs home care services is NOT a home care service, and does not have to be made by a home care licensee. It can be made by anyone, including the receptionist or social services person or any other staff member at a housing with services establishment, the client, or the client’s family or friend. Minnesota Rules, part 4668.0008, subpart 4 reads:

Subp. 4. Coordination of providers of home care services. The coordination of home care services is not itself a home care service. Coordination of home care services means one or more of the following:

A. Determination whether a client needs home care services, what services are needed, and whether existing services need to continue or be modified.

- B. Referral of clients to home care providers.
- C. Administration of payments for home care services.

Not all residents in a registered housing with services establishment will need health-related services as defined in the home care licensing statutes. Some residents may not need home care services when they initially move in, but over time or because of a change in their condition, may need more services, including health-related services. At that time, a determination is made by the housing with services establishment formally or informally (often in conjunction with the client or the client's family), as to whether the client will need or would like services, and if so, whether those services are health-related. It is not necessary that the initial determination of a need for health-related services be conducted by a nurse. If the determination is made that the resident needs home care services, then the resident should have an evaluation. This is an evaluation of the need for assisted living home care provider services, which the Minnesota Legislature has determined are home care services under state laws.

Once the determination that the client needs home care services is made, it is necessary that the evaluation of the client's needs and the development of the service plan be completed by a registered nurse because registered nurses are trained to conduct those tasks, and it is a reasonable and appropriate use of health care professional time and expertise. It is reasonable to require a registered nurse to complete an evaluation of these home care service needs and to develop a plan for the provision of the appropriate services, in the same manner that a registered nurse would complete an assessment of home care service needs if the client lived on their own. A registered nurse is the appropriate health professional to conduct an evaluation or assessment of that client's home care needs, regardless of where a client lives.

Not every assisted living home care provider service automatically needs to be performed by a nurse. It is reasonable to require a registered nurse to determine which services must be done by a registered nurse, which may be delegated, and which do not need delegation by a registered nurse, because that is, by law, what a registered nurse does. The Minnesota Board of Nursing has commented on what is delegation:

"However, only the professional nurse has the direct statutory authority to delegate to others, and the nursing assistant may carry out only those nursing acts or functions which have been delegated by a professional nurse. ...The decision of whether or not to delegate to other nursing personnel rests with the professional nurse. Both the status of the patient/client and the knowledge and skill of the person receiving the delegation (delegatee) must be considered. The delegator has the responsibility to make a proper act of delegation by giving clear, specific directions to a person who can perform safely and competently. And the delegatee has the responsibility of carrying out the delegated act or function correctly. Good communication between the giver and the recipient is necessary so that any ambiguity in instruction or lack of ability can be addressed. Although delegation is a technique that facilitates the provision of nursing care, it carries with it legal as well as professional accountability."⁹

⁹ "For Your Information", Minnesota Board of Nursing, Volume 2, Number 2, May 1986.

It is reasonable to also leave the language in this subpart as nonspecific as possible regarding how to conduct the evaluation, what to evaluate, and so on, to allow licensees the flexibility to develop their own process or method or tools to best meet the needs of their business and of their clients. With that flexibility in regulation, licensees have the opportunity to be more creative in how that evaluation occurs.

During the development of the proposed rule language, many people provided comments and suggestions on the nature and scope of an assessment or evaluation of a housing with services resident/assisted living home care client's needs. Guidance was sought from Minnesota Statutes, section 256B.0627 which enumerates home care services covered under the Medical Assistance program. The following language was included in an early draft of proposed rules, but subsequently was rejected because of comments received. The list includes existing rule language plus suggestions provided by providers and consumers on evaluation, making sound nursing judgments, and ensuring appropriate care. The language is included here in the Statement of Need and Reasonableness only as an educational tool, and to illustrate the intent of the statute and rule requirements.

Assessment. The assessment required by subpart 1 must include, but is not limited to:

- A. clean and safe environment;
- B. communication needs including, vision, hearing, speech and language;
- C. bathing, dressing, and personal hygiene needs;
- D. nutrition and fluid needs including special diets or restrictions;
- E. mobility needs including transferring and positioning;
- F. elimination and toileting needs;
- G. mental health needs, including behaviors that may require staff intervention such as drug therapy or other measures that may limit the person's ability to move about their home or community environment;
- H. social support service needs;
- I. physical health needs;
- J. medications, whether prescription or over-the-counter;
- K. central medication storage needs or preferences;
- L. client's need for passive assistance with medication, active assistance with medication, or medication administration;
- M. supervision needs;
- N. vulnerability assessment in accordance with Minnesota's vulnerable adults act, Minnesota Statutes, section 626.557; and
- O. any other areas necessary to the provision of care for each individual client.

Plan of Care. A. The plan of care required by subpart 1 must be developed by a registered nurse with active participation and agreement of the client or the client's responsible person.

B. The plan of care must be based on the most current assessment and reflect individualized needs, interventions, and objectives that have realistic and

measurable outcomes, and must address the frequency of registered nurse supervision for the tasks or services to be provided.

This subpart requires that the service plan includes a signature or other authentication. Over the years since promulgation of the original home care rules, the department has received comments and questions on the language in part 4668.0140, subpart 1 which requires that the "...licensee shall enter into a written service agreement with the client or the client's responsible person..." Although the original Statement of Need and Reasonableness adequately addresses the need for a signature or other authentication by the client indicating agreement with the service agreement, the rule language does not explicitly address that need. The language in proposed part 4668.0815, subpart 1, specifically addresses the need for a signature or other authentication by both parties to the service plan.

Part 4668.0815 EVALUATION AND SERVICE PLAN, Subpart 2 Re-evaluation.

Part 4668.0815, subpart 2 requires a re-evaluation of the client's needs at least annually or when there is a change in the client's condition that may require a change in services. It is necessary to require a re-evaluation of a client's needs periodically to ascertain whether the services being provided continue to benefit the client's health, safety, and well-being. It is reasonable to compare the client's current condition to the client's condition at the initial or most recent evaluation to compare current data with baseline data and determine where changes have occurred. If the data indicates changes in client condition, the services being provided can be changed as appropriate to best meet client needs and preferences, thereby protecting their health and safety.

As with subpart 1, it is necessary and reasonable that a registered nurse review and revise the client's service plan to protect the health and safety of clients because under the Minnesota Nurse Practice Act, those are responsibilities of a professional nurse. It is reasonable that these rules are in compliance with that statute.

Part 4668.0815 EVALUATION AND SERVICE PLAN, Subpart 3 Modifications.

Part 4668.0815, subpart 3 requires that modifications to the service plan be agreed to by the client or the client's responsible person before starting the change in services described by the modification. This language is based on part 4668.0140, subpart 1, and implements several provisions in Minnesota Statutes, section 144A.44, the Home Care Bill of Rights. This subpart is necessary because people have a right to know what they are purchasing and what services they will receive, and they have a right to refuse treatments if they so choose.

The service plan is the written documentation of the understanding between the licensee and the client regarding the services that the client needs or chooses to receive, which will be provided by the licensee. For some clients, the service plan will not be modified very often, because that client's condition is stable or the client does not want or need additional services.

Another client's service plan may change frequently, depending on that client's condition and needs and what services the assisted living home care licensee is to provide for that client.

It is reasonable to require that the modification of the service plan be agreed to by the client prior to modifying the services provided because the client is the purchaser of those services and so has a right to have a say in what is being purchased. The Home Care Bill of Rights clearly delineates these rights in the following subdivisions:

144A.44 HOME CARE BILL OF RIGHTS.

(2) the right to receive care and services according to a suitable and up-to-date plan, and subject to accepted medical or nursing standards, to take an active part in creating and changing the plan and evaluating care and services;

(3) the right to be told in advance of receiving care about the services that will be provided, the disciplines that will furnish care, the frequency of visits proposed to be furnished, other choices that are available, and the consequences of these choices including the consequences of refusing these services;

(4) the right to be told in advance of any change in the plan of care and to take an active part in any change;

(5) the right to refuse services or treatment;

Modifications may be entered into the client records up to two weeks after the modification is initiated. It is necessary to instruct providers on maintaining these records so that the information is readily available in an emergency or when services to be provided to a client need to be verified. This language is reasonable because it allows the assisted living home care provider adequate time to complete documentation of the services to be provided, based on an agreement between the client and the licensee, with minimal disruption of service provision.

Part 4668.0815 EVALUATION AND SERVICE PLAN, Subpart 4 Contents of service plan.

The language in part 4668.0815, subpart 4 (the same as part 4668.0140, subpart 2) is necessary and reasonable to describe what minimally must be in the service plan to implement language in the Home Care Bill of Rights and to assure consistent, sufficient information to protect clients' health, safety, and well-being. It is reasonable to leave the language in this subpart as nonspecific as possible to allow licensees the flexibility to develop their own process, method, or tools to best meet the needs of their business and their clients. With that flexibility in regulation, providers and consumers have more opportunities for negotiation on the services addressed in the individualized service plan and provided to the consumer. It is reasonable to be more flexible in rule to recognize the varying levels of needs of the clients while supporting their ability to age in place with adequate support and freedom of choice, and to recognize that providers may want to limit the services that home care licensee is willing or able to provide.

Item A: Minnesota Statutes, section 144A.44, subdivision 1, clause (3), grants clients "the right to be told in advance of receiving care about the services that will be provided, the disciplines that will furnish care, the frequency of visits proposed to be furnished, other choices that are available, and the consequences of these choices including the consequences of refusing

these services.” It is reasonable to require that the service plan contain a statement describing both the service agreed to and the frequency with which it will be provided because the right to be told about “services that are being provided” infers the right to be told when or how often these services will be provided.

Item B: Minnesota Statutes, section 144A.44, subdivision 1, clause (13), grants clients “the right to be served by people who are properly trained and competent to perform their duties.” It is reasonable to require that service plans identify the persons or category of persons who will be providing services to enable clients to ascertain the level of provider expertise and to put clients at ease by providing a physical identity to persons who will be providing them with a service.

Item C: Certain paraprofessional tasks addressed by this section of the chapter require supervision by registered nurses or monitoring by licensed practical nurses under the direction of registered nurses, to be consistent with requirements of the Nurse Practice Act. This supervision or monitoring ensures that services are properly performed and appropriate to clients’ conditions and needs and enables nurses to affect changes in these services as warranted. It is reasonable to require that the frequency of these supervisory visits be clearly set forth in the service agreement to inform clients of the licensee’s obligation to supervise or monitor these tasks and encourage licensee compliance with any supervisory or monitoring requirements. Supervision should be appropriate to the level of services provided. Certain services provided by unlicensed persons employed by the licensee to assisted living home care provider clients may not require supervision nor monitoring by a nurse, because they are not specifically delegated nursing tasks, but they will still require supervision by the licensee to ensure that those services are properly performed and appropriate to client’s conditions and needs.

Item D: Minnesota Statutes, section 144A.44, subdivision 1, clause (8), grants clients “the right to know what the charges are for services, no matter who will be paying the bill.” A fundamental element of any commercial agreement is the price. It therefore is reasonable to require that the method for determining charges be clearly set forth in the service agreement, such as costs per visit, per service, per hour, or a flat fee, or other method, and that the rate for services be clearly set forth.

Item E: This item is necessary to implement the statutory rights granted to home care clients by Minnesota Statutes, section 144A.44, subdivision 1, clauses (2), (3), (4), and (5).

Subitem (1): This subitem is necessary to provide for and clarify the “procedure” for keeping scheduled appointments for nonessential and essential services or the alternative arrangements referred to in subparts 5 and 6. It is reasonable to require that the licensee, the client and responsible person outline the action they will take if scheduled services are unable to be provided to clarify each party’s rights and responsibilities, eliminate confusion, and promote and provide for the continuity of services.

Subitem (2): Minnesota Statutes, section 144A.44, subdivision 1, clause (19) grants clients "the right to know how to contact an individual associated with the provider who is responsible for handling problems..." This subitem is necessary to implement this statutory right. It is reasonable because it enables clients or responsible persons to contact licensees with service problems, concerns, or questions as they occur, before they escalate to proportions that jeopardize clients' interests or hamper their care. Part 4668.0800, subpart 5 requires that there be a person the client can contact with questions, concerns or complaints.

Subitem (3): Minnesota Statutes, section 144A.44, subdivision 1, authorizes the commissioner to adopt rules for the regulation of home care providers that ensure "to the extent possible, the health, safety and well-being, and appropriate treatment of persons who receive home care services." This subitem is reasonable because it instructs the licensee on the procedure to follow when a sudden change in condition threatens a client's health, safety, or well-being. This "change" might necessitate or warrant the intervention of an emergency medical service, a physician, or a member of the clergy.

Subitem (4): Minnesota Statutes, section 144A.44, subdivision 1, grants clients significant rights, such as the right to take an active part in creating and changing the service plan, the right to be told about the services that are being provided or suggested, the right to refuse services or treatment, and the right to reasonable notice of changes in services or charges. To enable clients to partake equally of these rights, it is necessary to provide licensees with the means of contacting the "responsible person" of clients who are incapacitated or unable to comprehend or communicate with licensees on their own. This allows responsible persons to indirectly exercise the rights not capable of being directly exercised by clients.

Subitem (5): The Adult Health Care Decisions Act, Minnesota Statutes, Chapter 145B, gives individuals the right to declare their preferences or instructions about health care, including when emergency medical services are not to be summoned or administered. This subitem is necessary and reasonable because it informs clients of their rights under both this statute and the home care bill of rights to refuse services or treatment. By establishing these preferences and plans in a service plan, all parties are informed of clients' preferences and instructions so that misunderstandings and errors in this area will be minimized.

Part 4668.0815 EVALUATION AND SERVICE PLAN, Subpart 5 Scheduled appointments for nonessential services.

The language in the proposed part 4668.0815, subpart 5 is the same as part 4668.0060, subpart 4. This subpart is necessary to implement Minnesota Statutes, section 144A.4605, subdivision 2(g), which allows a home care provider to obtain an assisted living license if the program meets certain requirements, including meeting "the requirements established by rules adopted under sections 144A.45 to 144A.48."

It is necessary to address in rule what to do when scheduled appointments, even for nonessential services, are not kept to protect the health, safety, and well-being of clients. Under the rights guaranteed by Minnesota Statutes, section 144A.44, subdivision 1, clauses (2), (3), (4), and (16), and the service plan required by subpart 1, it is necessary that licensees provide services as set forth in clients' service plans (see the discussion under part 4668.0800, subpart 3, above). Occasionally, however, unforeseen circumstances arise that make it impractical or impossible for the provider to complete a service. In these instances, it is necessary to establish a procedure to ensure a remedy that protects the client. This subpart is reasonable because providers and consumers alike are concerned with the problems that arise when a provider fails to provide a scheduled home care service. To ensure that services are provided as set forth in the service plan, this rule establishes alternatives with which the licensee must comply to ensure the delivery of both "essential" (see subpart 6 below) and "nonessential" services. These alternatives establish a common performance expectation for licensees and clients and give providers wide latitude without compromising a client's well-being or rights.

Part 4668.0815 EVALUATION AND SERVICE PLAN, Subpart 6 Scheduled appointments for essential services.

The language in the proposed part 4668.0815, subpart 6 is the same as part 4668.0060, subpart 5. This subpart is necessary to implement Minnesota Statutes, section 144A.4605, subdivision 2(g), which allows a home care provider to obtain an assisted living license if the program meets certain requirements, including meeting "the requirements established by rules adopted under sections 144A.45 to 144A.48."

It is necessary that licensees keep all appointments for "essential services" because these services are necessary to ensure and protect the client's health and safety. For example, insulin must be administered to diabetic clients at regular intervals or they will suffer adverse medical reactions. Therefore, if for any reason the licensee is not able to provide an essential service at the scheduled time, it must find another means to have the service provided, either by contracting with another provider, or otherwise ensuring its provision in a means acceptable to the client and consistent with this chapter. This places the burden of supplying and providing services on the party contracting to do so and ensures that the client's health, safety, and well-being are not jeopardized. It is reasonable to require inclusion of this contingency plan in the service plan so it can be implemented when necessary.

Part 4668.0815 EVALUATION AND SERVICE PLAN, Subpart 7 Schedule of fines.

Part 4668.0815, subpart 7 contains the penalties for noncompliance with the other subparts of this part. This subpart is necessary to comply with the requirements in Minnesota Statutes, section 144.653, subdivision 6, as shown above. The amounts of the fines are reasonable because they are consistent with the schedule of fines established for the entire home care rule chapter. See part 4668.0230, subpart 5, above for a discussion on the fining schedule established for Minnesota Rules, Chapter 4668.

Item A: The fine for noncompliance with part 4668.0815, subpart 1 is \$250, the same fine amount as for part 4668.0140, subpart 1. This subpart implements provisions in the Home Care Bill of Rights.

Item B: The fine for noncompliance with part 4668.0815, subpart 2 is \$250. It is reasonable to impose a \$250 fine because this subpart requires the review and revision of the client's evaluation and service plan, which implements the Home Care Bill of Rights.

Item C: The fine for noncompliance with part 4668.0815, subpart 3 is \$250. It is reasonable to impose a \$250 fine because this subpart addresses modifications to the service plan which implements the Home Care Bill of Rights.

Item D: The fine for noncompliance with part 4668.0815, subpart 4 is \$50. Noncompliance with documentation requirements does not necessarily directly jeopardize a client, so the \$50 fine level is appropriate for this subpart.

Item E: The fine for noncompliance with part 4668.0815, subpart 5 is \$350. This subpart directly relates to the direct provision of services, so the \$350 fine level is reasonable.

Item F: The fine for noncompliance with part 4668.0815, subpart 6 is \$500. The maximum penalty assessment of \$500 is assigned to those rules and statutes for which noncompliance would present an imminent risk of harm to the health, treatment, comfort, safety, or well-being of clients, and for violations interfering with the regulatory process. Not keeping appointments for essential services presents an imminent risk of harm to a client, so the \$500 fine level is appropriate for part 4668.0815, subpart 6.

Part 4668.0820 NURSING SERVICES, Subpart 1 Scope.

Part 4668.0820, subpart 1 limits application of this rule part to assisted living home care provider licensees that provide nursing services. It is necessary to include this subpart because not all assisted living home care providers will choose to provide nursing services. This subpart is reasonable because it acknowledges provider flexibility to choose whether or not to provide nursing services while providing this part as an educational tool to providers and consumers.

Part 4668.0820 NURSING SERVICES, Subpart 2 Compliance with Nurse Practice Act.

Part 4668.0820, subpart 2 requires that nursing services provided by an assisted living home care licensee comply with Minnesota's Nurse Practice Act and rules adopted under that Act. This same requirement is found in part 4668.0180, subpart 5 and applies to those Class A home care licensees that provide nursing services. This subpart is necessary to implement Minnesota Statutes, section 144A.4605, subdivision 2(g), which allows a home care provider to obtain an assisted living license if the program meets certain requirements, including meeting "the requirements established by rules adopted under sections 144A.45 to 144A.48."

Part 4668.0825 DELEGATED NURSING SERVICES, Subpart 1 Scope.

Part 4668.0825, subpart 1 limits application of this rule part to assisted living home care provider licensees that provide nursing services delegated to unlicensed personnel. It is necessary to include this subpart because not all assisted living home care providers will choose to provide delegated nursing services. This subpart is reasonable because it acknowledges provider flexibility to choose what services to provide, while providing specificity in the rule language as an educational tool to providers and consumers.

Part 4668.0825 DELEGATED NURSING SERVICES, Subpart 2 Clinical assessment and service plan.

Part 4668.0825, subpart 2 requires a clinical assessment and the development of a service plan by a registered nurse prior to the initiation of delegated nursing services. This subpart is based on the current part 4668.0140, subpart 1, which addresses service agreements. The existing classes of home care licenses are required to develop and maintain a service agreement with each client. Because the nature of an assisted living home care provider's business is different from a traditional home care provider, it is necessary and reasonable that the requirements for a contractual agreement between the provider and the consumer should vary from those requirements for other home care licensees.

Minnesota Statutes, section 144A.44, subdivision 1, clause (2) guarantees clients "the right to receive care and services according to a suitable and up-to-date plan, and ...to take an active part in creating and changing the plan and evaluating care and services." Clause (3) guarantees clients "the right to be told in advance of receiving care about the services that will be provided, the disciplines that will furnish care, the frequency of visits proposed to be furnished, other choices that are available, and the consequences of these choices including the consequences of refusing these services." Clause (4) guarantees clients "the right to be told in advance of any change in the plan of care and to take an active part in any change." Clause (8) guarantees clients "the right to know what the charges are for services..." Moreover, Minnesota Statutes, section 144A.45, subdivision 1(f), authorizes the commissioner to adopt rules for the regulation of home care providers that include "standards for client evaluation or assessment which may vary according to the nature of the services provided or the status of the consumer."

This subpart is necessary to assure the health, safety, and well-being of the client, and to reconcile these home care rules and the Nurse Practice Act and its rules. A clinical assessment is required to be conducted on those clients that are going to begin receiving nursing services or delegated nursing services from an assisted living home care provider. It is reasonable to require that a registered nurse conduct the clinical assessment because those delegated nursing services are provided under that registered nurse's authority and license. It is necessary that the registered nurse assess the client's condition, functional status, and need for nursing services so that a service plan can be developed, by the nurse and the client or the client's responsible person, that describes services that will be provided by the nurse or delegated to unlicensed personnel. It is reasonable to require that the service plan describe the services to be provided by unlicensed

personnel, the frequency of those services, the frequency of supervision of the task, and frequency of supervision of the person providing the service, and that it be incorporated into the service plan developed under part 4668.0815 to ensure continuity of care for the client, and to provide the client (or the client's responsible person) with the opportunity to have input on what they are purchasing as assisted living home care services.

Part 4668.0825 DELEGATED NURSING SERVICES, Subpart 3 Nursing services delegated to unlicensed personnel.

Part 4668.0825, subpart 3 enumerates services that a registered nurse may delegate as tasks to an unlicensed person (i.e., a person without a nursing license) when that unlicensed person has successfully completed the initial training required under Minnesota Statutes, section 144A.4605. This subpart is necessary to implement Minnesota Statutes, section 144A.4605, subdivision 2:

Subd. 2. **Assisted living home care license established.** A home care provider license category entitled assisted living home care provider is hereby established. A home care provider may obtain an assisted living license if the program meets the following requirements:

(b) unlicensed personnel perform home health aide and home care aide tasks identified in Minnesota Rules, part 4668.0100, subparts 1 and 2, and part 4668.0110, subpart 1. Qualifications to perform these tasks shall be established in accordance with subdivision 3;

The language is reasonable because it incorporates existing rule language applicable to this license class as specified in that statute, as well as the central storage of medication, which was added to that statute in 1997. The existing rule language cited in the statute and used in this subpart is found in part 4668.0100, subparts 1 and 2, and in part 4668.0110, subpart 1.

The National Council of State Boards of Nursing has published a document titled, "Delegation: Concepts and Decision Making Process."¹⁰ As stated in that document, the "decision to delegate should be consistent with the nursing process (appropriate assessment, planning, implementation and evaluation)." The document lists the Five Rights of Delegation, which provide a resource to nurses to facilitate decisions about delegation.

¹⁰National Council of State Boards of Nursing, Inc., 1995, 676 N. St. Clair St., Ste. 550, Chicago, Illinois, 60611-2921.

The Five Rights of Delegation include:

- RIGHT TASK - One that is delegable for a specific patient.
- RIGHT CIRCUMSTANCES - Appropriate patient setting, available resources, and other relevant factors considered.
- RIGHT PERSON - Right person is delegating the right task to the right person to be performed on the right person.
- RIGHT DIRECTION / COMMUNICATION - Clear, concise description of the task, including its objectives, limits, and expectations.
- RIGHT SUPERVISION - Appropriate monitoring, evaluation, intervention, as needed, and feedback.

Part 4668.0825 DELEGATED NURSING SERVICES, Subpart 4 Performance of routine procedures.

Part 4668.0825, subpart 4 provides minimum requirements for unlicensed persons performing a delegated nursing procedure which must be assessed by a registered nurse. This subpart is similar to part 4668.0100, subpart 4, and implements provisions of the Home Care Bill of Rights, including Minnesota Statutes, section 144A.44, subdivision 1, clause (13), which guarantees clients the right to “be served by people who are properly trained and competent to perform their duties.”

It is necessary to include this language in rule so the registered nurse, the licensee, and the consumer have standardized expectations by which to determine that an unlicensed person may perform specific delegated tasks for specific clients. The language is reasonable because it is consistent with existing rules and because it provides a method to assure that persons providing services are competent to provide those services, as documented by a registered nurse. The improper performance of delegated nursing services or the failure to recognize possibly adverse reactions can negatively impact on the health and well-being of assisted living home care provider clients. It therefore is necessary to specify the conditions under which non-professional providers may perform these procedures. This subpart is reasonable because it recognizes that the registered nurse is ultimately responsible for services provided, as set forth in the Nurse Practice Act, Minnesota Statutes, section 148.261, subdivision 1, clauses (5) and (7).

Item A: It is reasonable to require a registered nurse to individually instruct providers on the proper method of performing procedures for each client to ensure that clients’ individual conditions are taken into account by the registered nurse, and to prevent providers from substituting their judgment for that of the professional nurse.

Item B: It is reasonable to require that a registered nurse instruct providers in writing as to the proper method of performing a procedure for each client, to ensure the appropriate and consistent performance of each procedure, and to provide a back-up for providers should they need to refresh their memories about a particular procedure.

Item C: It is reasonable to require providers to demonstrate to a registered nurse their competence in performing the prescribed nursing procedures to ensure that these tasks are performed in the manner prescribed. This requirement promotes the health, safety, and well-being of clients by enabling the nurse to evaluate and modify providers' techniques before clients suffer any adverse effects.

Item D: It is reasonable to require that all procedures be documented in clients' records to facilitate the evaluation of and continuity of care for each client and to enable the Department to more readily survey for compliance with the requirements of this chapter.

Item E: It is reasonable to require that the licensee retain documentation completed by the registered nurse regarding the demonstrated competency of a person to facilitate the evaluation of that person, to enable the registered nurse to verify appropriate training and delegation acts, and to enable the Department to more readily survey for compliance with the requirements of this chapter.

Part 4668.0825 DELEGATED NURSING SERVICES, Subpart 5 Schedule of fines.

Part 4668.0825, subpart 5 contains the penalties for noncompliance with the other subparts of this part. This subpart is necessary to comply with the requirements in Minnesota Statutes, section 144.653, subdivision 6, as shown above. The amounts of the fines are reasonable because they are consistent with the schedule of fines established for the entire home care rule chapter. See part 4668.0230, subpart 5, above for a discussion on the fining schedule established for Minnesota Rules, Chapter 4668.

Item A: The fine for noncompliance with part 4668.0825, subpart 2, which requires a clinical assessment and service plan for delegated nursing services is \$250. The \$250 penalty assessment is assigned to those rules and statutes that relate to the protection of the individual rights of clients. The client's right to be involved in the development of a plan of care (Minnesota Statutes, section 144A.44, subdivision 1, clauses 2 and 3) is implemented through this subpart, so the \$250 penalty level is appropriate.

Item B: The fine for noncompliance with part 4668.0825, subpart 3 is \$350. The \$350 penalty assessment has been assigned to those rules which relate to the direct provision of services to clients. It is reasonable to impose a \$350 fine because nursing services delegated to unlicensed persons relates to the direct provision of services to clients.

Item C: The fine for noncompliance with part 4668.0825, subpart 4 is \$350. Subpart 4 addresses the procedures to be followed to assure appropriate delegation by a registered nurse of a specific task or tasks to an unlicensed person, which relates to the direct provision of services to clients. Therefore, the \$350 penalty level is appropriate and reasonable.

**Part 4668.0830 OTHER SERVICES PERFORMED BY UNLICENSED PERSONNEL,
Subpart 1 Scope.**

Part 4668.0830, subpart 1 limits application of this rule part to assisted living home care provider licensees that provides services other than delegated nursing services that are performed by unlicensed personnel. This subpart is necessary since an assisted living home care provider may choose whether or not to provide "other services performed by unlicensed personnel" under the statute authorizing this license class. The subpart is reasonable because it acknowledges that flexibility for providers to choose what services to provide and provides specificity to providers and consumers so it is clear which licensees must comply with this rule part.

**Part 4668.0830 OTHER SERVICES PERFORMED BY UNLICENSED PERSONNEL,
Subpart 2 Other services.**

Part 4668.0830, subpart 2 lists the other services that may be performed as tasks by unlicensed personnel for clients in a registered housing with services establishment. This rule part is necessary to implement Minnesota Statutes, section 144A.4605, subdivision 2(b). The language is reasonable because it complies with that statute and incorporates language based on part 4668.0110.

One of the essential components of the Housing With Services Act, Minnesota Statutes, Chapter 144D, and the "assisted living home care provider" license class in Minnesota Statutes, section 144A.4605, was acknowledgment of the existence of "health-related services" and "supportive services" as services that are typically provided in housing with services establishments or as part of an "assisted living" package available at a housing site. The rule advisory committee considering the types of services an assisted living home care provider might provide that would not necessarily require delegation by a registered nurse. This proved to be a difficult task because the need for registered nursing care or supervision often depends on the client's condition as well as on the service itself. Using the language in the current home care licensing rules cited in Minnesota Statutes, section 144A.4605, a list of "other services performed by unlicensed personnel" that is included here was carved out. However, the responsibility and flexibility to determine which are nursing services or delegated nursing services and which are "other services performed by unlicensed personnel" remains a professional nursing duty. That determination is made by the registered nurse under the requirements for a client evaluation in part 4668.0815 and for a clinical assessment under part 4668.0825, subpart 2. A client may need a service listed in part 4668.0830, subpart 2, which, because of the client's condition, will need it to be provided by a licensed nurse or as a delegated nursing service. These rules will not prohibit that from occurring. Rather, this part is intended to list home care services that do not automatically require a nurse to delegate the authority to perform this service if the licensee chooses to have those services performed by unlicensed personnel.

**Part 4668.0830 OTHER SERVICES PERFORMED BY UNLICENSED PERSONNEL,
Subpart 3 Schedule of fines.**

Part 4668.0830, subpart 3 contains the penalties for noncompliance with the other subparts of this part. This subpart is necessary to comply with the requirements in Minnesota Statutes, section 144.653, subdivision 6, as shown above. See part 4668.0230, subpart 8, above for a discussion on the fining schedule established for Minnesota Rules, Chapter 4668.

The penalty for noncompliance with part 4668.0830, subpart 2 is \$350. The \$350 penalty assessment which is assigned to those rules which relate to the direct provision of services to clients is appropriate.

**Part 4668.0835 QUALIFICATIONS FOR UNLICENSED PERSONNEL WHO PROVIDE
ASSISTED LIVING HOME CARE SERVICES, Subpart 1 Scope.**

Part 4668.0835, subpart 1 limits application of this rule part to licensees that provide assisted living home care services using unlicensed personnel. The language is necessary and reasonable because it acknowledges that assisted living home care provider licensees that do not use unlicensed persons to provide assisted living home care provider services do not need to follow this rule part.

**Part 4668.0835 QUALIFICATIONS FOR UNLICENSED PERSONNEL WHO PROVIDE
ASSISTED LIVING HOME CARE SERVICES, Subpart 2 Qualifications.**

Part 4668.0835, subpart 2 lists the qualifications needed for unlicensed personnel who provide assisted living home care services. This subpart is necessary to implement Minnesota Statutes, section 144A.4605, subdivision 3, which requires that unlicensed personnel either meet the home health aide training requirements in the current rules or meet the training or training and competency evaluation requirements that are outlined in the statute and implemented in this rule part. This subpart is reasonable because it provides options for unlicensed personnel to receive the basic knowledge and skills to be able to perform assisted living home care provider services. These basic knowledge and skills are necessary to ensure the safe, consistent, and appropriate performance of these tasks.

Item A: This item provides a training option for unlicensed personnel that includes training or a competency evaluation on the core training requirements found in Minnesota Statutes, section 144A.4605, subdivision 3(d), plus training and a competency evaluation on each specific assisted living home care service provided by the licensee that the unlicensed person will perform.

Minnesota Statutes, section 144A.4605, subdivision 3 was written in such a way that all unlicensed persons performing assisted living home care provider services are trained or demonstrate competency in at a minimum a core set of requirements (found in subdivision 3(d)). The core training requirements include statutes and rules regulating home care, the Vulnerable

Adults Act, and services of the ombudsman, as well as items basic to the safe and appropriate provision of assisted living home care services. It is necessary to establish a core set of basic training requirements to provide a measurable framework for the instruction of persons performing assisted living home care provider services and to require a competency evaluation to measure their mastery of the core training requirements.

It is reasonable to establish a basic training curriculum to provide a measurable framework for the instruction of unlicensed persons performing assisted living home care services. Using the framework detailed in part 4668.0840, post-secondary schools, providers, and other interested institutions and persons may formulate and offer instructional programs confident in the knowledge that their programs conform to this chapter and the home care statutes. To ensure that these courses are effective, it is reasonable to require that students pass a competency evaluation that measures their mastery of the topics and skills addressed in the course of study.

Persons who have successfully completing the core training and competency evaluation under item A are qualified to be employed by assisted living home care providers only to perform those assisted living home care services for which they have been trained and evaluated, that are delegated by a registered nurse or do not need delegation by a nurse, only to clients of the assisted living home care provider licensee.

Item B: This item provides a second training option for unlicensed persons performing assisted living home care services. Under item B, the unlicensed person is trained or deemed competent in the core training requirements and is deemed competent to provide the services offered by the provider. As with item A, this option is necessary to implement Minnesota Statutes, section 144A.4605, subdivisions 3(a) and 3(d).

The necessity for training or competency evaluation on the core training elements is found in the discussion on item A, above. This item recognizes that persons can gain knowledge and skills in different ways and provides a systematic means for persons to demonstrate that these skills and knowledge are equivalent to those obtained by the completion of a formal training course. The method chosen to measure these skills is a "testing out" procedure, or competency evaluation. This provision is reasonable because it promotes efficiency and fairness by eliminating the need to pay for and undergo a formal training program.

Persons who have successfully completed the core training requirements and the competency evaluation under item B are only qualified to be employed to perform those assisted living home care services they have been competency evaluated on, that are delegated by a registered nurse or do not need delegation by a nurse, only to clients of the assisted living home care provider licensee.

Item C: Item C implements the training option found in Minnesota Statutes, section 144A.4605, subdivision 3(a)(1), which permits unlicensed persons performing assisted living home care provider services to "satisfy the training or competency requirements established by

rule under sections 144A.45 to 144A.48.” Those existing training or competency requirements are implemented by part 4668.0100, subpart 5. The need and reasonableness of those requirements have already been established in the original Statement of Need and Reasonableness for Chapter 4668; many of the reasons are the same as for items A and B of this subpart. Using the framework detailed in part 4668.0100, many post-secondary schools, providers, and other interested institutions and persons have formulated and offer home health aide instructional programs that conform to the requirements established by this chapter and the home care statutes.

Persons who have successfully completed a training and competency evaluation program or a competency evaluation program as provided under part 4668.0100, subpart 5, are deemed to be qualified to perform home health aide tasks, which include assisted living home care services, that are delegated by a registered nurse or do not need delegation by a nurse, to clients of the assisted living home care provider licensee.

Part 4668.0835 QUALIFICATIONS FOR UNLICENSED PERSONNEL WHO PROVIDE ASSISTED LIVING HOME CARE SERVICES, Subpart 3 In-service training and demonstration of competency.

Part 4668.0835, subpart 3 incorporates inservice training and continued competency requirements found in existing home care licensure rules at parts 4668.0100, subpart 6 and 4668.0110, subpart 4, and Minnesota Statutes, section 144A.4605, subdivision 2(g), which require that assisted living home care provider license rules must “in other respects meets the requirements established by rules adopted under sections 144A.45 to 144A.48.” This part is necessary to ensure the continued safe and appropriate provision of assisted living home care services by unlicensed persons.

Item A: Item A is reasonable because it is consistent with current home care rule language for unlicensed personnel performing delegated nursing services, as found in part 4668.0100, subpart 6. Minnesota Statutes, section 144A.4605, subdivision 2, item G, which says that the assisted living home care provider license rules must “in other respects meets the requirements established by rules adopted under sections 144A.45 to 144A.48.” This part is necessary to ensure the continued safe and appropriate provision of assisted living home care services by unlicensed persons. In-service training is a means to upgrade or maintain the level of skill possessed by providers of assisted living home care services after their initial training has been completed. There are no other “continuing education” requirements required for unlicensed persons performing assisted living home care provider services. To instruct these persons on new technology and techniques relating to the performance of paraprofessional tasks and to refresh their skills in the performance of paraprofessional tasks, it is necessary to require these persons to complete periodic in-service training requirements.

Item B: If an unlicensed person has not performed assisted living home care services for 24 consecutive months, that person must again demonstrate to a registered nurse competency in those services found in part 4668.0840, subpart 4, item C. This item is necessary to assure that

unlicensed persons performing delegated assisted living home care services maintain their competency in performing those tasks and keep their skills up to date. This item is reasonable because it is consistent with current home care rule language for unlicensed personnel performing delegated nursing services, as found in part 4668.0100, subpart 6, and Minnesota Statutes, section 144A.4605, subdivision 2(g), which requires that the assisted living home care provider license rules must "in other respects meets the requirements established by rules adopted under sections 144A.45 to 144A.48." This part is necessary to ensure the continued safe and appropriate provision of assisted living home care services by unlicensed persons.

Item C: This item requires the licensee to retain documentation that unlicensed persons performing assisted living home care services satisfy the requirements of this part, and to provide documentation to persons who complete the in-service training. This item is necessary to enable the Department to verify that the in-service training was, in fact, completed in accordance with this chapter. It is reasonable to require licensees to furnish trainees with documentation substantiating completion of this requirement to enable them to transfer to or work with other assisted living home care licensees without having to undergo duplicative in-service training.

Part 4668.0835 QUALIFICATIONS FOR UNLICENSED PERSONNEL WHO PROVIDE ASSISTED LIVING HOME CARE SERVICES, Subpart 4 Documentation.

Part 4668.0935, subpart 4 requires unlicensed personnel to retain documentation of their training, competency evaluation, and in-service participation, and requires licensees to verify that unlicensed persons have met the qualifications and to retain documentation of that verification. This subpart is necessary to provide a method of verification of compliance with the requirements of this rule part. The requirement is reasonable because it is consistent with part 4668.0100, subpart 7 and part 4668.0110, subpart 3.

Item A: It is necessary and reasonable that unlicensed persons performing assisted living home care services document to licensees their completion of training and in-service requirements to enable licensees to demonstrate compliance with the requirements of this subpart.

Item B: Employers are, as a rule, responsible for the actions of their employees. It is reasonable to require that licensees verify that their unlicensed employees have complied with this part's training and in-service requirements. This documentation is necessary to enable the Department to verify the licensee's compliance with these requirements and the requirement that the documentation be maintained in the personnel records facilitates ready access to this information by the Department.

Part 4668.0835 QUALIFICATIONS FOR UNLICENSED PERSONNEL WHO PROVIDE ASSISTED LIVING HOME CARE SERVICES, Subpart 5 Initiation of services by unlicensed personnel.

Part 4668.0835, subpart 5 requires the registered nurse to orient unlicensed persons to each client and each service they will perform for that client. This part is necessary to ensure the continued safe and appropriate provision of assisted living home care services to clients by unlicensed persons, and to implement Minnesota Statutes, section 144A.4605, subdivision 2(g), which requires that assisted living home care provider license rules must "in other respects meets the requirements established by rules adopted under sections 144A.45 to 144A.48.". The requirement is reasonable because it is consistent with existing part 4668.0100, subpart 8.

Unlicensed persons are not sufficiently trained or educated to independently assess a client's condition and needs. It therefore is necessary to require that these unlicensed persons be oriented by a registered nurse to the clients and the services they will be performing. The rule is flexible regarding the method of communication used for orientation - leaving it up to the registered nurse to determine, based on professional judgment and the client's needs, whether that orientation will occur at the housing with services establishment (both the RN and the unlicensed person are physically at the site), verbally (for example, in a telephone conversation), or in writing (by the RN). This subpart is reasonable because it allows nurses to exercise their professional judgment, while requiring that there be some sort of individualized orientation to that client's specific situation and that unlicensed person's skills and knowledge.

Part 4668.0835 QUALIFICATIONS FOR UNLICENSED PERSONNEL WHO PROVIDE ASSISTED LIVING HOME CARE SERVICES, Subpart 6 Schedule of fines.

Part 4668.0835, subpart 6 contains the penalties for noncompliance with the other subparts of this part. This subpart is necessary to comply with the requirements in Minnesota Statutes, section 144.653, subdivision 6, as shown above. The amounts of the fines are reasonable because they are consistent with the schedule of fines established for the entire home care rule chapter. See part 4668.0230, subpart 5, above for a discussion on the fining schedule established for Minnesota Rules, Chapter 4668.

Item A: The penalty for noncompliance with part 4668.0835, subpart 2, is \$300. Part 4668.0835, subpart 2 lists the qualifications for unlicensed personnel who perform assisted living home care services. Those qualifications are necessary to include in rule to assure that the service is properly provided, so the \$300 fine is appropriate.

Item B: The penalty for noncompliance with part 4668.0835, subpart 3, is \$300. Part 4668.0835, subpart 3 requires continued training and documentation for unlicensed personnel, which are necessary to assure proper provision of services, therefore the \$300 fine is appropriate.

Item C: The penalty for noncompliance with part 4668.0835, subpart 4, is \$50. Noncompliance with this subpart does not directly jeopardize clients, so the \$50 penalty level is appropriate.

Item D: The penalty for noncompliance with part 4668.0835, subpart 5, is \$350. The \$350 penalty assessment has been assigned to those rules which relate to the direct provision of services to clients. Subpart 5 requires the registered nurse to orient the unlicensed person to each client and the task to be performed. The \$350 penalty level is appropriate because noncompliance with this subpart relates to the direct provision of services.

Part 4668.0840 TRAINING AND COMPETENCY EVALUATION FOR UNLICENSED PERSONNEL, Subpart 1 Scope.

Part 4668.0840, subpart 1 limits application of this rule part to those licensees that use unlicensed personnel to perform assisted living home care services. This is necessary and reasonable because not all licensees will provide assisted living home care services through unlicensed personnel. If a licensee does not use unlicensed personnel to perform assisted living home care services, that licensee does not need to follow this rule part.

Part 4668.0840 TRAINING AND COMPETENCY EVALUATION FOR UNLICENSED PERSONNEL, Subpart 2 Scope of training course and instructor.

Part 4668.0840, subpart 2 provides the basic elements of a training course for unlicensed personnel. It is necessary to include this subpart to comply with Minnesota Statutes, section 144A.4605, subdivision 3. This subpart is reasonable because it is consistent with that statute and sets forth in clear language the requirements for the training course and instructor. The language is similar to that in part 4668.0130, subpart 1.

Item A: It is reasonable that the training course include each assisted living home care service that the unlicensed person will perform for that licensee and that it be taught by a registered nurse with training or experience in the subjects being taught to ensure that the instructor possesses the level of knowledge and expertise necessary to properly instruct providers of assisted living home care services. This assures the health, safety, and well-being of assisted living home care provider clients by requiring that providers of paraprofessional tasks are properly trained and competent to perform their assigned duties.

Item B: It is necessary that the training course include core training requirements to assure the health, safety, and well-being, and appropriate treatment of assisted living home care provider clients. It is reasonable that the training course include core training requirements to comply with Minnesota Statutes, section 144A.4605, subdivision 3(d). Those core training requirements, including either training or competency evaluation, are provided in subpart 3 of this part.

Item C: It is necessary that the training course include a competency evaluation to ensure that the training course imparts the requisite knowledge by measuring the student's mastery of the topics addressed in the course of study. Competency evaluation is a reasonable method to ensure the safe, consistent, and appropriate performance of these tasks.

Item D: It is necessary that the training course use a curriculum that meets the requirements of this chapter to ensure consistency among training courses. This item is a reasonable means to ensure that the training course imparts the information that unlicensed persons need to know to safely perform their duties.

Part 4668.0840 TRAINING AND COMPETENCY EVALUATION FOR UNLICENSED PERSONNEL, Subpart 3 Core training of unlicensed personnel.

Part 4668.0840, subpart 3 provides the core training topics that must be included in any training course or competency evaluation for unlicensed persons performing assisted living home care services for clients in a registered housing with services establishment. This subpart is necessary to implement Minnesota Statutes, section 144A.4605, subdivision 3(d), which enumerates the specific topics that must be included in this core training or competency evaluation. This subpart is reasonable because it ensures a basic level of consistency in training or competency among unlicensed persons providing assisted living home care services.

Item A: The subitems that must be included in the core training or competency evaluation are enumerated in Minnesota Statutes, section 144A.4605, subdivision 3(d). Subitems 1 to 6 are also listed in part 4668.0075, Orientation to Home Care Requirements. Subitems 7 to 12 are listed in part 4668.0130, Training and Competency Evaluation for Persons Who Perform Home Health Aide and Home Care Aide Tasks, subpart 2 Curriculum.

Item B: It is reasonable that the training and competency evaluation be performed by a registered nurse to ensure that the instructor possesses the level of knowledge and expertise necessary to properly instruct providers of assisted living home care services.

This item allows persons other than a registered nurse to conduct the training on: this chapter and Minnesota Statutes, sections 144A.43 to 144A.48; recognizing and handling emergencies and using emergency services; reporting maltreatment of vulnerable minors or adults under sections 626.556 and 626.557; the home care bill of rights, Minnesota Statutes, section 144A.44; handling clients' complaints and reporting complaints to the Office of Health Facility Complaints; the services of the ombudsman for older Minnesotans; and communication skills. This is reasonable because it requires training or competency evaluation on those items, but recognizes that some topics may be adequately addressed and taught by persons other than registered nurses. This flexibility is particularly helpful in parts of the state with shortages of registered nurses; if someone other than a registered nurse can conduct a portion of the core training requirements, the licensee can direct the available RN time for the training or competency evaluation to nursing topics. This may be a better, more efficient use of available dollars and registered nurse hours for some licensees.

Item C: It is reasonable to require that the curriculum or competency evaluation meets the requirements of this chapter and of the home care statutes to ensure that unlicensed persons are being trained or competency evaluated on accurate information and on the regulations they need to comply with in the performance of their duties.

Part 4668.0840 TRAINING AND COMPETENCY EVALUATION FOR UNLICENSED PERSONNEL, Subpart 4 Competency evaluation.

Part 4668.0840, subpart 4 provides the requirements for the competency evaluation for unlicensed personnel and who must perform it and is necessary to implement the provisions of Minnesota Statutes, section 144A.4605, subdivision 3(c). This subpart is reasonable because it clearly identifies what is required of and who must perform that competency evaluation to ensure that unlicensed persons are qualified to perform assisted living home care services. These requirements protect the health, safety, and well-being of assisted living home care provider clients by ensuring that providers of paraprofessional tasks are competent to perform their duties.

Item A: It is reasonable to require that each competency evaluation test meets the state home care regulations found in this chapter and in the home care licensing statutes to promote a uniformity of standards within the industry and to promote the awareness of those state regulations among providers, employees, and consumers.

Item B: It is necessary and reasonable to require that these competency evaluations are performed by a registered nurse to implement the authorizing statute.

Item C: This item incorporates language from the authorizing statute to describe how an unlicensed person demonstrates competency on the core training requirements and on each assisted living home care service that the person will perform.

Part 4668.0840 TRAINING AND COMPETENCY EVALUATION FOR UNLICENSED PERSONNEL, Subpart 5 Evidence of qualifications.

Part 4668.0840, subpart 5 requires documentation of the training or competency evaluation to be provided to the unlicensed person by the licensee that provides the training or competency evaluation. The proposed language is the same as part 4668.0130, subpart 4.

It is necessary to require that persons who have successfully completed all the required training requirements be provided with documentation attesting to this fact from the entity administering the program so those persons are able to verify that training. This is reasonable because it provides the unlicensed person with physical evidence that they are competent to provide assisted living home care services. It enables the unlicensed, trained persons to work for several licensees simultaneously or transfer from one licensee to another, without having to undergo duplicative training requirements.

Part 4668.0840 TRAINING AND COMPETENCY EVALUATION FOR UNLICENSED PERSONNEL, Subpart 6 Schedule of fines.

Part 4668.0840, subpart 6 contains the penalties for noncompliance with the other subparts of this part. This subpart is necessary to comply with the requirements in Minnesota Statutes, section 144.653, subdivision 6. The amounts of the fines are reasonable because they are consistent with the schedule of fines established for the entire home care rule chapter. See part 4668.0230, subpart 5, above for a discussion on the fining schedule established for Minnesota Rules, Chapter 4668.

Item A: The fine amount established for part 4668.0840, subpart 2 is \$300. The training required by this subpart is essential to provide assurance in the competency of unlicensed persons providing services, so the \$300 penalty level is appropriate.

Item B: The fine amount established for part 4668.0840, subpart 3 is \$300. The topics included in this subpart are necessary to assure that unlicensed personnel have had at least a basic introduction to the provision of assisted living home care services, so the \$300 penalty level is appropriate.

Item C: The fine amount established for part 4668.0840, subpart 4 is \$300. The competency evaluation required in this subpart is a common and reasonable method to assure the proper provision of services, so the \$300 penalty level is appropriate.

Item D: The fine amount established for part 4668.0840, subpart 5 is \$50. Subpart 5 requires the licensee to provide documentation of the successful completion of a training program or competency evaluation. Noncompliance with this part does not directly affect a client, so the \$50 penalty level is appropriate.

Part 4668.0845 PERIODIC SUPERVISION OF UNLICENSED PERSONNEL, Subpart 1 Scope.

Part 4668.0845, subpart 1 limits application of this rule part to those licensees that use unlicensed personnel to perform assisted living home care services. This subpart is necessary because not all assisted living home care providers will provide services through unlicensed personnel.

Part 4668.0845 PERIODIC SUPERVISION OF UNLICENSED PERSONNEL, Subpart 2 Services that require supervision by a registered nurse.

Part 4668.0845, subpart 2 addresses the frequency of supervision for those services that require supervision by a registered nurse. This proposed part implements Minnesota Statutes, sections 144A.45, subdivision 1(e) and 144A.4605, subdivision 2(c).

Minnesota Statutes, sections 148.171 to 148.285, the Nurse Practice Act, refers to supervision as an activity carried on by registered nurses and monitoring as a similar activity authorized for licensed practical nurses. Minnesota Rules, Chapter 6321 defines those terms:

6321.0100 DEFINITIONS.

Subp. 2. **Monitoring.** "Monitoring" means the periodic inspection by a registered nurse or licensed practical nurse of a directed function or activity and includes watching during performance, checking, and tracking progress, updating a supervisor of progress or accomplishment by the person monitored, and contacting a supervisor as needed for direction and consultation.

Subp. 3. **Supervision.** "Supervision" means the guidance by a registered nurse for the accomplishment of a function or activity. The guidance consists of the activities included in monitoring as well as establishing the initial direction, delegating, setting expectations, directing activities and courses of action, critical watching, overseeing, evaluating, and changing a course of action.

Item A: The basic supervision requirements for unlicensed personnel are necessary to implement revisions to Minnesota Statutes, section 144A.45, subdivision 1(e), that more accurately reflect the supervision mandate and increase the maximum time allowable between registered nurse supervision visits from 60 days to 62 days. This language is included in the current rules at part 4668.0100, subpart 9 and part 4668.0110, subpart 5.

Item B: Item B permits a licensed practical nurse to monitor an unlicensed person performing assisted living home care services delegated as tasks that require registered nurse supervision as long as a registered nurse supervises the client at least every other visit. This language is necessary to provide an optional method of supervision when supervision by a registered nurse is not necessary to provide cares to a client, or when using a licensed practical nurse is a more efficient or effective use of nurse hours. This item is reasonable because it is based on current rule part 4668.0100, subpart 9 and part 4668.0110, subpart 5 and is consistent with the Minnesota Nurse Practice Act (as cited in this rule part) and the rules developed to implement the Nurse Practice Act.

Part 4668.0845 PERIODIC SUPERVISION OF UNLICENSED PERSONNEL, Subpart 3 Services that do not require supervision by a registered nurse.

Part 4668.0845, subpart 3 provides the assurance that there will be nurse supervision of the assisted living home care services provided by unlicensed personnel. The proposed rule requires the licensee to address the appropriate person to supervise that service in the client's individualized service plan. This subpart is reasonable because it provides licensees with the flexibility to develop an appropriate schedule of supervision based on the services being provided and the client's needs. This requirement is necessary and reasonable to implement Minnesota Statutes, section 144A.45, subdivision 1(e) which allows for supervision of

unlicensed personnel by a registered nurse or "other appropriate health care professional," depending on the service being provided. This language is reasonable because it allows for a registered nurse to supervise those services that require professional nurse supervision, and for someone else to supervise other services on a different frequency than those nursing services. This allows for a much more individualized package of services to be provided to a client, in a more cost-effective and efficient and appropriate manner, and with the appropriate supervision of the persons providing those services.

**Part 4668.0845 PERIODIC SUPERVISION OF UNLICENSED PERSONNEL, Subpart 4
Schedule of fines.**

Part 4668.0845, subpart 4 contains the penalties for noncompliance with the other subparts of this part. This subpart is necessary to comply with the requirements in Minnesota Statutes, section 144.653, subdivision 6. The amounts of the fines are reasonable because they are consistent with the schedule of fines established for the entire home care rule chapter. See part 4668.0230, subpart 5, above for a discussion on the fining schedule established for Minnesota Rules, Chapter 4668.

Item A: The penalty assessment for part 4668.0845, subpart 2 is \$350. The \$350 penalty assessment has been assigned to those rules which relate to the direct provision of services to clients. The \$350 fine level is appropriate for this subpart because subpart 2 provides the supervision requirements for unlicensed personnel providing assisted living home care services that require supervision by a registered nurse.

Item B: The penalty assessment for part 4668.0845, subpart is \$300. The \$300 penalty assessment has been assigned to those rules that are necessary to assure that the service is properly provided. The \$300 penalty assessment is appropriate for this subpart because these supervision requirements are necessary to assure the proper provision of those services.

Part 4668.0855 MEDICATION ADMINISTRATION AND ASSISTANCE WITH SELF-ADMINISTRATION OF MEDICATION, Subpart 1 Scope.

Part 4668.0855, subpart 1 limits application of this rule part to assisted living home care provider licensees that provide medication administration or assistance with self-administration of medication by unlicensed personnel. This subpart is necessary because not all assisted living home care provider licensees will provide medication administration nor assistance with self-administration of medication.

Many comments and suggestions were provided to the Department regarding the proposed part 4668.0855. The Minnesota Pharmacists Association shared a draft of model state language for medication management in assisted living facilities that was developed by their national organization.

Part 4668.0855 MEDICATION ADMINISTRATION AND ASSISTANCE WITH SELF-ADMINISTRATION OF MEDICATION, Subpart 2 Clinical assessment and service plan.

Part 4668.0855, subpart 2 provides the basic framework for the provision of medication administration or assistance with self-administration of medication by an assisted living home care provider licensee. Because medication administration or assistance with self-administration of medication are nursing services that are delegated from a registered nurse to other persons, it is necessary to require a registered nurse to conduct an individualized clinical assessment of the client's needs and preferences and use the assessment information to develop a service plan for the provision of these services. Assessment is addressed in the state licensing rules for registered nurses, so it is reasonable that these rules are consistent with those other state regulations.

It is necessary and reasonable to require an assessment of a client's need for medication administration or assistance with self-administration of medication to ascertain the client's current status, needs, and preferences for those services. It is reasonable to require the development of a service plan based on the results of that assessment so that there is a written record of the service or services that the licensee will provide to satisfy the client's needs and preferences.

It is necessary that the service plan include the frequency of supervision for the unlicensed personnel who are providing medication administration or assistance with self-administration of medication because the registered nurse who delegated those tasks is responsible for the provision of those tasks. Since the service plan is an enforceable commercial agreement between the licensee and the client (or the client's responsible person), it is reasonable to address the frequency of supervision by a registered nurse so that consumers are informed about services to be provided. This subpart implements the Home Care Bill of Rights, section 144A.44, subdivision 1, items 1 through 3, and is reasonable because it is based on the service agreements rule, part 4668.0130.

Part 4668.0855 MEDICATION ADMINISTRATION AND ASSISTANCE WITH SELF-ADMINISTRATION OF MEDICATION, Subpart 3 Delegation by a registered nurse.

Part 4668.0855, subpart 3 permits a registered nurse to delegate medication administration and assistance with self-administration of medications to unlicensed persons who have completed required training, but only in accordance with the Nurse Practice Act. It is necessary to specify the basic requirements for unlicensed personnel to clarify how those requirements relate to the responsibilities of the registered nurse for those unlicensed persons and the performance of their duties. This subpart is reasonable because it is consistent with existing requirements at part 4668.0100, subpart 1, and with current standards of practice for nursing and for home health care.

Part 4668.0855 MEDICATION ADMINISTRATION AND ASSISTANCE WITH SELF-ADMINISTRATION OF MEDICATION, Subpart 4 Training for assistance with self-administration of medication or medication administration.

Part 4668.0855, subpart 4 specifies the training requirements for unlicensed personnel to whom the authority to provide medication administration or assistance with self-administration of medication may be delegated. It is necessary to require training to assure the health, treatment, safety, comfort, or well-being of clients. This subpart is reasonable because it is consistent with the training requirements at part 4668.0100, subpart and offers a method of training that relates to the specific task or tasks that the unlicensed person will provide. As with many sections of this proposed rule language, the training must be conducted by a registered nurse to ensure that each instructor possesses the level of knowledge and expertise necessary to properly instruct an unlicensed person in safe and appropriate methods and procedures for assistance with self-administration of medication and with medication administration. This requirement is reasonable because it implements Minnesota Statutes, section 144A.4605, subdivision 3, item (a).

Part 4668.0855 MEDICATION ADMINISTRATION AND ASSISTANCE WITH SELF-ADMINISTRATION OF MEDICATION, Subpart 5 Administration of medications.

Part 4668.0855, subpart 5 provides basic requirements for those unlicensed persons performing medication administration and assistance with self-administration of medications. It is necessary to establish some minimal standards for those services, to link together the training requirements and the delegation by the registered nurse. The subpart is reasonable because it is based on part 4668.0100, subpart 2, and provides basic protection of clients' health and safety.

One difference between this subpart and part 4668.0100, subpart 2 would include injectable medications in the list of medications that may be administered by an unlicensed person with appropriate training and delegation. This provision recognizes the wide variety of providers affected by these regulations. As defined in Minnesota Statutes, section 144D.01, subdivision 4:

"Housing with services establishment" or "establishment" means an establishment providing sleeping accommodations to one or more adult residents, at least 80 percent of which are 55 years of age or older, and offering or providing, for a fee, one or more regularly scheduled health-related services or two or more regularly scheduled supportive services, whether offered or provided directly by the establishment or by another entity arranged for by the establishment.

Among the providers included under the Housing With Services umbrella are corporate adult foster care providers. "Corporate adult foster care residences" are settings in which the setting is not the primary residence of the [adult foster care] license holder and the license holder

is not the primary caregiver.¹¹ The current adult foster care licensing regulations permit licensees to provide injections for their clients, in accordance with applicable statutes and rules, and after appropriate training and delegation from a registered nurse.

Traditionally, the home care rules have prohibited unlicensed persons from giving injections to home care clients. Those rules were developed to reflect standards of home care at the time of development; health care professionals and paraprofessionals went to a client's individual home to provide treatments or services. For many clients, home visits by a paraprofessional do not include supervision or monitoring of the services or the paraprofessional by a nurse. So, at the time of adoption of the original home care rules, the potential risks of allowing unlicensed persons to administer injections to home care clients outweighed any countervailing arguments.

The Nurse Practice Act (Minnesota Statutes, sections 148.171 to 148.285) does not specifically address the delegation of injections by a nurse. The Minnesota Board of Nursing has determined that the Nurse Practice Act does not prohibit an unlicensed person from giving injections if a registered nurse has trained that person or determined the person was competent to give injections, and the registered nurse has delegated that service for that client to that unlicensed person. The Nurse Practice Act (Minnesota Statutes, sections 148.171 to 148.285) defines "the practice of professional nursing" in section 148.171, item 3:

(3) The practice of professional nursing means the performance for compensation or personal profit of the professional interpersonal service of: (a) providing a nursing assessment of the actual or potential health needs of individuals, families, or communities; (b) providing nursing care supportive to or restorative of life by functions such as skilled ministrations of nursing care, supervising and teaching nursing personnel, health teaching and counseling, case finding, and referral to other health resources; and (c) evaluating these actions.

The practice of professional nursing includes both independent nursing functions and delegated medical functions which may be performed in collaboration with other health team members, or may be delegated by the professional nurse to other nursing personnel. Independent nursing function may also be performed autonomously. The practice of professional nursing requires that level of special education, knowledge, and skill ordinarily expected of an individual who has completed an approved professional nursing education program as described in section 148.211, subdivision 1.

¹¹Information Bulletin No. 96-3/ EHS-1, MDH Facility and Provider Compliance Division, July, 1996.

Minnesota Statutes, section 148.171, item 5, defines the practice of practical nursing as:

(5) The practice of practical nursing means the performance for compensation or personal profit of any of those services in observing and caring for the ill, injured, or infirm, in applying counsel and procedure to safeguard life and health, in administering medication and treatment prescribed by a licensed health professional, which are commonly performed by licensed practical nurses and which require specialized knowledge and skill such as are taught or acquired in an approved school of practical nursing, but which do not require the specialized education, knowledge, and skill of a registered nurse.

As with other services that a registered nurse can provide or can delegate, the delegation of the administration of injectable medication is a function of a registered nurse. As discussed above in the rule part on client evaluation, the Minnesota Board of Nursing has advised that:

“The decision of whether or not to delegate to other nursing personnel rests with the professional nurse. Both the status of the patient/client and the knowledge and skill of the person receiving the delegation (delegatee) must be considered. The delegator has the responsibility to make a proper act of delegation by giving clear, specific directions to a person who can perform safely and competently. And the delegatee has the responsibility of carrying out the delegated act or function correctly.”¹²

The registered nurse is authorized and responsible to determine whether, in each specific situation, it would be appropriate and safe to delegate the administration of injectable medications to that client. Delegation of injectables to an unlicensed person is not appropriate in every situation, depending on the client, the client's condition, the medication, possible effects of the medication, and the knowledge and skill of the unlicensed person that would be administering the medication. Delegation by a registered nurse does carry with it legal as well as professional accountability.

Part 4668.0855 MEDICATION ADMINISTRATION AND ASSISTANCE WITH SELF-ADMINISTRATION OF MEDICATION, Subpart 6 Limitations on administering medications.

Part 4668.0855, subpart 6 prohibits unlicensed personnel from drawing up injectables (getting liquid medication into a syringe in preparation of injection). This prohibition is necessary to ensure that only appropriately trained health care professionals are preparing the syringe for an injection. The potential risk to a client's health, safety, and well-being if an injectable were drawn up incorrectly is too great to permit persons not trained as health care professionals to perform that task. This subpart is reasonable because it is the same as part

¹²"Delegation in the Practice of Nursing," Joyce M. Schowalter, Executive Director, Minnesota Board of Nursing, FOR YOUR INFORMATION, May 1986.

4668.0100, subpart 3, except that part 4668.0100, subpart 3 has not allowed unlicensed personnel to administer injectable medications, as now is permitted in proposed part 4668.0855, subpart 5.

Part 4668.0855 MEDICATION ADMINISTRATION AND ASSISTANCE WITH SELF-ADMINISTRATION OF MEDICATION, Subpart 7 Performance of routine procedures.

Part 4668.0855, subpart 7 is the same as the current part 4668.0100, subpart 5, which addresses the orientation of the unlicensed person by the registered nurse prior to the provision of medication administration or assistance with self-administration of medication for that client. It is reasonable to require the registered nurse to determine how often the unlicensed person must be supervised and who should supervise the unlicensed person for each task that person is to perform because that registered nurse is responsible for the provision of those services by unlicensed personnel.

Items A and B: These items are reasonable because they assure that appropriately trained unlicensed persons receive specific instructions from the registered nurse on how to administer client medications. The registered nurse must document those instructions and verify the unlicensed person can demonstrate that the service can be performed competently. The manner and mode of physically administering medications to clients is a professional skill, necessitating the education and training of a registered nurse. Only a registered nurse, or the equivalent, is capable of determining how a client's particular condition affects the way in which his or her medication should be administered. It is both necessary and reasonable to require that a registered nurse individually instruct providers for each client in the procedure to administer medication or assist with self-administration of medication to ensure that a unlicensed person's judgment is not substituted for that of a registered nurse and to provide for the safe and appropriate administration of medications. This instruction has proven successful for nursing assistants, trained medication aides (TMAs), and home health aides as provided in Minnesota Rules, parts 4658.1325, 4658.1360, and 4668.0100.

Item C: To ensure that unlicensed personnel do in fact administer medication or assist with self-administration of medications in the manner prescribed by the physician and registered nurse, it is reasonable to require that unlicensed persons demonstrate to the registered nurse their ability to properly follow prescribed procedures. This enables the registered nurse to evaluate the person's techniques and competencies and make appropriate changes in these techniques before clients are injured or suffer other adverse effects.

Item D: Item D addresses the documentation requirements when medication administration or assistance with self-administration of medications is performed by unlicensed personnel. It is reasonable to require documentation in the client's records because it ensures that a set of instructions is readily available to staff at the housing with services establishment, should there be a need to verify the procedures. This is necessary to ensure the safe and appropriate administration of medication or assistance with self-administration of medications, and to enable the Department to more readily verify compliance with the requirements of this chapter.

Item E: Item E requires the licensee to retain documentation that the unlicensed person has demonstrated competency to the registered nurse in administering a client's medication or assisting with self-administration of that client's medication. This item is reasonable because it provides the licensee a method of verifying compliance with the training and competency requirements for unlicensed persons who administer medications or assist with self-administration of medication, and ensures the safe and appropriate administration of medication or assistance with self-administration of medication.

4668.0855 MEDICATION ADMINISTRATION AND ASSISTANCE WITH SELF-ADMINISTRATION OF MEDICATION, Subpart 8 Documentation.

Part 4668.0855, subpart 8 requires the licensee to keep documentation in the personnel records to verify which staff have completed the training required to administer medication or to assist clients with self-administration of their medication. Employers are, as a rule, responsible for the actions of their employees. Documenting this information provides ready access by the Department and enables the Department to verify compliance with these requirements.

4668.0855 MEDICATION ADMINISTRATION AND ASSISTANCE WITH SELF-ADMINISTRATION OF MEDICATION, Subpart 9 Medication records.

Part 4668.0855, subpart 9 addresses the records that are to be maintained regarding medication administration and assistance with self-administration of medication. This subpart is similar to regulations controlling other settings where these services are provided which is necessary for consistent expectations among various health care settings, and which, in turn, allows for consistency in staff training programs, regardless of where those staff are employed. The requirements for what must be included in the medication records are based on standards of practice in nursing and in pharmacy and are necessary to ensure the safe and appropriate administration of medication or assistance with self-administration of medication.

Part 4668.0855 MEDICATION ADMINISTRATION AND ASSISTANCE WITH SELF-ADMINISTRATION OF MEDICATION, Subpart 10 Schedule of fines.

Part 4668.0855, subpart 10 contains the penalties for noncompliance with the other subparts of this part. This subpart is necessary to comply with the requirements in Minnesota Statutes, section 144.653, subdivision 6. The amounts of the fines are reasonable because they are consistent with the schedule of fines established for the entire home care rule chapter. See part 4668.0230, subpart 5, above for a discussion on the fining schedule established for Minnesota Rules, Chapter 4668.

Item A: The penalty for noncompliance with a correction order for part 4668.0855, subpart 2, is \$350. Subpart 2 addresses the requirement for a clinical assessment and development of a service plan for those clients needing medication administration or assistance with self-administration, which specifies what services are to be provided to the client. The \$350 penalty level, therefore, is appropriate.

Item B: The penalty for noncompliance with a correction order for part 4668.0855, subpart 3, is \$350. Subpart 3 allows a registered nurse to delegate medication administration or assistance with self-administration of medications to a person who has met the training requirements in pat 4668.0835, subpart 2, and according to the Nurse Practice Act. The act of delegation, and the outcome of that delegation, relates to the direct provision of services, so the \$350 penalty level is appropriate.

Item C: The penalty for noncompliance with a correction order for part 4668.0855, subpart 4, is \$300. Subpart 4 describes the training requirements for unlicensed personnel to provide medication administration or assistance with self-administration of medications. Training is necessary to assure those services are provided properly, so the \$300 penalty level is appropriate.

Item D: The penalty for noncompliance with a correction order for part 4668.0855, subpart 5, is \$350. Subpart 5 addresses administration of medication, which is a direct provision of a service, so the \$350 penalty level is appropriate for this subpart.

Item E: The penalty for noncompliance with a correction order for part 4668.0855, subpart 6, is \$500. The maximum penalty assessment of \$500 is assigned to those rules and statutes for which noncompliance with a correction order would present an imminent risk of harm to the health, treatment, comfort, safety, or well-being of clients, and for violations interfering with the regulatory process. Subpart 6 prohibits an unlicensed person from drawing up injectable medication into a syringe. This is a task which is the responsibility of a licensed nurse who has had the appropriate education and training. The risk of harm to the client should a medication be drawn up incorrectly is so strong that the \$500 penalty for noncompliance with this subpart is appropriate.

Item F: The penalty for noncompliance with a correction order for part 4668.0855, subpart 7, is \$350. Subpart 7 requires the registered nurse to instruct and document instructions for routine procedures, which is necessary to assure those procedures are properly performed. The \$350 penalty, therefore, is appropriate.

Item G: The penalty for noncompliance with a correction order for part 4668.0855, subpart 8, is \$50. The minimum fine of \$50 is assigned to those rules, such as this which requires the retention of training records, that do not directly jeopardize the health, safety, treatment, comfort or well-being of clients.

Item H: The penalty for noncompliance with a correction order for part 4668.0855, subpart 9, is \$300, which is appropriate where, as here, failure to document that medications were received as needed, compromises the proper provision of service.

Part 4668.0860 MEDICATION AND TREATMENT ORDERS, Subpart 1 Scope.

Part 4668.0860, subpart 1, limits application of this rule to situations when an authorized prescriber orders a medication or treatment to be administered by the assisted living home care licensee. The language is similar to that found in part 4668.0150, subpart 1. It is necessary and reasonable to include this language for the licensee that will administer medications, assist with self-administration of medications, or provide delegated medical treatments, so the licensee is aware of how to deal with orders for medications and treatments. This subpart is necessary because not all assisted living home care providers will provide medication administration or assistance with self-administration of medication.

4668.0860 MEDICATION AND TREATMENT ORDERS, Subpart 2 Prescriber's orders required.

Part 4668.0860, subpart 2, requires orders for those drugs that either are administered by the licensee (or staff of the licensee) or are self-administered with assistance by the licensee (or staff of the licensee), including an over-the-counter drug. This is necessary to ensure that the physician or other authorized prescriber is aware of drugs that the licensee is administering or providing assistance with self-administration, whether prescription drugs or not. This is reasonable to lessen the risk of drug interactions and misuse by the client and to ensure that a medical professional is aware of the client's medication use. The nursing home rules, in part 4658.1330, also require that there be orders for all medications administered by the licensee. It is reasonable to revise the home care rules to provide consistency in regulation between different licensure types.

Part 4668.0860 MEDICATION AND TREATMENT ORDERS, Subpart 3 Medication and treatment orders.

Part 4668.0860, subpart 3, requires that medications and treatments must be administered by a nurse or someone trained and supervised by a nurse. This language is necessary and reasonable to be consistent with the Minnesota Nurse Practice Act. It is also reasonable to ensure that the provision of medication administration or assistance with self-administration is done by persons who have had appropriate training for that service.

Part 4668.0860 MEDICATION AND TREATMENT ORDERS, Subpart 4 Authorizations.

Part 4668.0860, subpart 4, requires that orders for medication or treatments be dated and signed by the prescriber, be current, and be consistent with the clinical assessment of the client. It is necessary and reasonable that orders be dated and signed by the prescriber to ensure the order is applicable to the client's current condition and valid according to state regulations for physicians and other authorized prescribers. This is also reasonable because it makes assisted living home care licensees, aware of their responsibilities and the responsibilities of other health

professionals. The requirement that the order be current is necessary and reasonable to ensure that the client is receiving care and services that are appropriate to that client's condition and preferences at the time the care or services are provided.

Part 4668.0860 MEDICATION AND TREATMENT ORDERS, Subpart 5 Content of medication orders.

Part 4668.0860, subpart 5, lists items that must be in a medication order. This language is the same as part 4668.0150, subpart 4. The language is necessary and reasonable to ensure that orders are written appropriately and in compliance with regulations administered by the Minnesota Board of Pharmacy. It is necessary and reasonable to repeat that language for this group of licensees to ensure consistency in regulations and consumer protections among the various home care licensure classes.

Part 4668.0860 MEDICATION AND TREATMENT ORDERS, Subpart 6 Verbal orders.

Part 4668.0860, subpart 6, provides a procedure for receiving and verifying a verbal order from an authorized prescriber. The language is the same as in the current part 4668.0150, subpart 5. It is necessary and reasonable to repeat that language for this group of licensees to ensure consistency in regulations and consumer protections among the various home care licensure classes.

Part 4668.0860 MEDICATION AND TREATMENT ORDERS, Subpart 7 Electronically transmitted orders.

Part 4668.0860, subpart 7, addresses the receipt and security of electronically transmitted orders. This language is consistent with that found in part 4658.0455 for licensed nursing homes. When the original home care licensing rules were promulgated, technology had not advanced to the level it is at today, and the rules did not contemplate a congregate housing setting where home care services are to be delivered. It is necessary and reasonable to include rules that address situations that may occur when multiple home care recipients reside in the same location, to provide for efficiency and economy in service provision.

Item A: Item A is necessary to clarify that these orders, whether received by telephone, facsimile machine, or other electronic means, are covered by existing state laws on the confidentiality of client health information. This is reasonable because it provides a link between the relatively new mode of electronically transmitted orders and existing laws covering confidentiality of client records.

Item B: Item B is necessary to ensure that the supervising registered nurse is made aware of the new order within one hour of its receipt by electronic means (which includes telephone orders, faxed orders, and orders received by other electronic means such as via E-mail). This is necessary and reasonable to ensure that the order is implemented in a timely manner for the protection, the health, and the safety of the client.

Item C: Item C requires that an electronically received order, except for orders received over a facsimile machine, must be immediately recorded or placed in the client's record by a nurse and must be countersigned by the prescriber within 62 days of its receipt by the licensee. This is necessary to ensure that a licensed nurse is aware of new orders so that reasonable efforts can be made to implement them consistent with existing laws and rules. Countersignature is necessary to ensure that the order was received correctly by the licensee or a nurse employed by the licensee. This requirement is reasonable to protect the health, safety, and well-being of the client because an incorrectly received order can have adverse effects on the client's condition. The 62-day time frame is reasonable and should allow ample time for the prescriber to countersign the order, thus verifying its correctness and authenticity.

Item D: Item D requires orders received via facsimile machine to be signed by the prescriber and immediately be recorded or a durable copy placed in the client's record. Faxed orders do not need to be countersigned by the prescriber because the prescriber signed the original order. Because some facsimile machines produce documents that fade fairly rapidly over time, either a "durable" copy of that fax must be made to be placed in the client's record or that information in the faxed order must be recorded in the client's record. This is necessary and reasonable to ensure that the faxed order can be implemented in a timely manner, thus protecting the health and safety of the client.

Part 4668.0860 MEDICATION AND TREATMENT ORDERS, Subpart 8 Implementation of order.

Part 4668.0860, subpart 8, requires orders to be implemented by the licensee, or an employee of the licensee, within 24 hours of receipt of the order. This is a new requirement of the home care licensing rules, and it is necessary to ensure the protection of the health and safety of the clients. The home care licensing rules have not addressed the timing of implementation, which has been problematic for client safety and enforcement of the rules. This subpart is necessary to ensure the protection of the health and safety of clients that are dependent on receiving appropriate home care services. It is reasonable to require that the order be implemented within 24 hours of receipt of the order by the licensee

Part 4668.0860 MEDICATION AND TREATMENT ORDERS, Subpart 9 Renewal of orders.

Part 4668.0860, subpart 9 requires that a medication or treatment order be renewed at least every 12 months or more frequently if indicated in the clinical assessment required under part 4668.0855, subpart 2. This subpart is necessary and reasonable to implement Minnesota Statutes, section 144A.4605, subdivision 2, item (e), which reads:

"(e) medication and treatment orders, if any, are included in the client record and are renewed at least every 12 months, or more frequently when indicated by a clinical assessment."

This subpart is reasonable to protect the client's health and safety by ensuring a minimal level of physician involvement with the client. It is consistent with current standards of practice for medicine and pharmacy, including Minnesota Rules, part 6800.3510, which reads:

6800.3510 REFILL LIMITATIONS.

No prescription may be filled or refilled more than 12 months after the date on which the prescription was issued.

Refills originally authorized in excess of 12 months are void 12 months after the original date of issuance of the prescription.

After 12 months from the date of issuance of a prescription, no additional authorizations may be accepted for that prescription. If the prescriber desires continued therapy, a new prescription must be generated and a new prescription number assigned.

Part 4668.0860 MEDICATION AND TREATMENT ORDERS, Subpart 10 Schedule of fines.

Part 4668.0860, subpart 10 contains the penalties for noncompliance with the other subparts of this part. This subpart is necessary to comply with the requirements in Minnesota Statutes, section 144.653, subdivision 6. The amounts of the fines are reasonable because they are consistent with the schedule of fines established for the entire home care rule chapter. See part 4668.0230, subpart 5, above for a discussion on the fining schedule established for Minnesota Rules, Chapter 4668.

Item A: The penalty for noncompliance with part 4668.0860, subpart 2 is \$350. Subpart 2 requires prescriber's orders for drugs administered to clients or drugs with which assistance with self-administration is provided, which are the direct provision of a service. The \$350 penalty level is appropriate for this rule.

Item B: The penalty for noncompliance with part 4668.0860, subpart 3 is \$350. Subpart 3 requires medications or treatments to be administered by a nurse or an unlicensed person under the direction of a nurse and supervision of a registered nurse. The \$350 penalty assessment level is appropriate because this subpart relates to the direct provision of services.

Item C: The penalty for noncompliance with part 4668.0860, subpart 4 is \$350. This penalty is reasonable because administering medications or treatments that are unauthorized or out of date relates to the direct provision of services to clients.

Item D: The penalty for noncompliance with part 4668.0860, subpart 5 is \$350. Subpart 5 addresses the content of medication orders, which relates to the direct provision of services, so the \$350 penalty level is appropriate.

Item E: The penalty for noncompliance with part 4668.0860, subpart 6 is \$350. Subpart 6 addresses the documentation and verification of verbal orders received by a nurse. This

subpart relates to the safe and appropriate direct provision of services, so the \$350 penalty level for noncompliance is necessary and reasonable.

Item F: The penalty for noncompliance with part 4668.0860, subpart 7, item A, is \$250. Subpart 7, item A, addresses the confidentiality of orders, which is guaranteed under the Home Care Bill of Rights, so the \$250 penalty for noncompliance with this item is appropriate.

Item G: The penalty for noncompliance with part 4668.0860 subpart 7, item B, is \$300. Subpart 7, item B, requires that orders received by phone or electronically must be communicated to the registered nurse within one hour of receipt. This requirement is necessary to ensure that new orders for medication or treatments are implemented promptly and correctly, so the \$300 penalty level is appropriate for noncompliance with this item.

Item H: The penalty for noncompliance with part 4668.0860, subpart 7, item C, is \$300. Subpart 7, item C, requires that orders received electronically, but not over a facsimile machine, must be countersigned by the prescriber within 62 days. Requiring written verification of the order is necessary to assure that the order was received correctly, and so could be implemented properly, so the \$300 penalty level is appropriate.

Item I: The penalty for noncompliance with part 4668.0860, subpart 7, item D, is \$300. Subpart 7, item D, requires that orders received by fax machine must have been signed by the prescriber and must immediately be recorded or a durable copy placed in the client's record. The prescriber's signature is necessary to assure that the order is correct, so the service can be properly provided, so the \$300 penalty level is appropriate for noncompliance with this item.

Item J: The penalty for noncompliance with part 4668.0860, subpart 8 is \$500. The maximum penalty assessment of \$500 is assigned to those rules and statutes for which noncompliance with a correction order would present an imminent risk of harm to the health, treatment, comfort, safety, or well-being of clients, and for violations interfering with the regulatory process. Subpart 8 requires action to be taken to implement orders no later than 24 hours after receipt of those orders. This requirement directly relates to the provision of services safely and appropriately, and noncompliance with this requirement will present an imminent risk of harm to the health, treatment, comfort, safety, or well-being of the client, so the \$500 penalty level is appropriate.

Item K: The penalty for noncompliance with part 4668.0860, subpart 9 is \$100. The \$100 fine is assigned to violations of rules which only indirectly affect the health, safety, or well-being of clients, and to violations involving regulatory compliance issues. Subpart 9 requires that orders be renewed at least every 12 months or more frequently as needed. Renewing orders that have been in place for a number of months or up to a year only indirectly affects the client, so the \$100 penalty level is appropriate for noncompliance with this subpart.

Part 4668.0865 CENTRAL STORAGE OF MEDICATION, Subpart 1 Scope.

Part 4668.0865, subpart 1, limits applicability of this rule part to those assisted living home care licensees that provide central storage of medications. This subpart is necessary and reasonable to inform licensees that will centrally store medications of requirements for a system for central storage of medications.

It is necessary and reasonable to create part 4668.0865 to implement statutory requirements and language that defines what an "assisted living home care provider" is, as found in Minnesota Statutes, section 144A.4605:

144A.4605 ASSISTED LIVING HOME CARE PROVIDER.

Subdivision 1. **Definitions.** For purposes of this section, the term "assisted living home care provider" means a home care provider who provides nursing services, delegated nursing services, other services performed by unlicensed personnel or central storage of medications solely for residents of one or more housing with services establishments registered under chapter 144D.

Part 4668.0865 CENTRAL STORAGE OF MEDICATION, Subpart 2 Clinical assessment and service plan.

Part 4668.0865, subpart 2, which requires a registered nurse to complete a clinical assessment and to develop a service plan for each client for whom the licensee provides central storage of medication, is necessary because central storage of medication is a nursing service that can be delegated from a registered nurse to other persons. The registered nurse uses the assessment information to develop a service plan for the provision of these services. "Assessment" is a defined duty in the Nurse Practice Act, so these rules are reasonable to provide consistency with other state regulations.

Assessment of a client's need for central storage of medication is necessary and reasonable to ascertain the client's current status, needs, and preferences for those services. It is reasonable to require the development of a service plan based on the results of that assessment so that there is a written record of the service or services that the licensee will provide to meet the client's needs and to reflect the client's preferences, which were documented during the clinical assessment.

It is necessary that service plan address the frequency of supervision for the unlicensed personnel who are providing central storage of medication, because the registered nurse who delegates that task is responsible for the provision of the task. Since the service plan is a standard commercial agreement between the licensee and the client (or the client's responsible person), it is reasonable to address how often a service will be supervised by a registered nurse, and how often the unlicensed person will be supervised by a registered nurse. It is reasonable to have that service plan include information on services and on supervision and monitoring of unlicensed persons so that a consumer has been provided information on what services are to be

provided. This language implements language in the Home Care Bill of Rights, in section 144A.44, subdivision 1, items 1 through 3, and other language in that statute.

Part 4668.0865 CENTRAL STORAGE OF MEDICATION, Subpart 3 Control of medications.

Part 4668.0865, subpart 3 requires that a registered nurse establish and maintain a system for central storage of medications and lists the elements that system must include. This part is necessary to implement Minnesota Statutes, section 144A.45, which includes the requirement that:

144A.45 REGULATION OF HOME CARE SERVICES.

Subdivision 1. **Rules.** The commissioner shall adopt rules for the regulation of home care providers pursuant to sections 144A.43 to 144A.49. The rules shall include the following:

(d) standards for medication management which may vary according to the nature of the services provided, the setting in which the services are provided or the status of the consumer. Medication management includes the central storage, handling, distribution, and administration of medications;

Item A: This subpart is necessary and reasonable to implement Minnesota Statutes, section 144A.4605, which is the basis for the proposed rule language:

144A.4605 ASSISTED LIVING HOME CARE PROVIDER.

Subd. 2. **Assisted living home care license established.** A home care provider license category entitled assisted living home care provider is hereby established. A home care provider may obtain an assisted living license if the program meets the following requirements:

(a) nursing services, delegated nursing services, other services performed by unlicensed personnel, or central storage of medications under the assisted living license are provided solely for residents of one or more housing with services establishments registered under chapter 144D;

(f) the central storage of medications in a housing with services establishment registered under chapter 144D is managed under a system that is established by a registered nurse and addresses the control of medications, handling of medications, medication containers, medication records, and disposition of medications.

Item B: Part 4668.0865, subpart 3, item B is necessary to implement Minnesota Statutes, section 144A.4065, subdivision 2(f). The home care licensing statutes and rules have not previously addressed central storage of medication, so the rule advisory committee, state agency staff, and other interested persons developed the proposed language. Many of the people who contributed to the draft rule proposed specific language because of the nature of the service and the potential for harm to the client if the medication is not stored or administered appropriately.

There is no requirement that a nurse be present at housing with services establishments at all times; the presence of a nurse is dependent on the services offered and provided by the establishment and the needs of the clients. Because the registered nurse who is responsible for developing and maintaining the central storage of medication system is not required to be present at the establishment, it is necessary that the details of the system be documented to ensure consistent and safe central storage of medication. The language is reasonable because it is consistent with existing rule language for other license types. The language is reasonable because it is consistent with language in existing waivers for home care licensees that have been providing central storage of medication.

Part 4668.0865 CENTRAL STORAGE OF MEDICATION, Subpart 4 Over-the-counter drugs.

Part 4668.0865, subpart 4, allows the assisted living home care licensee to retain over-the-counter drugs in stock supply and requires that they be kept in the original labeled container. This language is necessary to allow the licensee to retain over-the-counter drugs. For example, the licensee might keep a stock supply of aspirin, acetaminophen, ibuprofen, or antacid, that could be administered to any client with prescribers' orders for that item. It is reasonable to require that those stock supply drugs be kept in the original labeled container to ensure that what is administered to a client or what is provided through assistance with self-administration is the over-the-counter drug that was intended for that client. The proposed language is reasonable because it is consistent with other similar requirements for legend drugs.

Part 4668.0865 CENTRAL STORAGE OF MEDICATION, Subpart 5 Legend drugs.

Part 4668.0865, subpart 5, requires legend drugs (which need a prescription to be dispensed) to be kept in their original containers with the original label. The language is necessary to ensure protection of the health and safety of the clients that receive central storage of medications. Without the original labels, it would be easy for medications to be administered to the wrong person or in the wrong dose, or for some other medication error to occur. This proposed language is consistent with state and federal regulations for pharmacy services, including Minnesota Rules, part 6800.4150, which reads as follows:

6800.4150 LABELING OF CONTROLLED SUBSTANCES AND CERTAIN OTHER DRUGS.

Drugs administered systemically as controlled substances under Minnesota Statutes, chapter 152, and parts 6800.4200 to 6800.4250, and other drugs deemed appropriate in the professional judgment of the pharmacist and dispensed to or for an adult patient, other than an inpatient of a hospital or nursing home, shall be labeled according to the requirements of part 6800.3400 and in addition shall contain the following:

"Caution: Taking this drug alone or with alcohol may impair your ability to drive."

Controlled substances shall also be labeled:

"Caution: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed."

Part 4668.0865 CENTRAL STORAGE OF MEDICATION, Subpart 6 Medication samples.

Part 4668.0865, subpart 6, addresses medication samples for an assisted living home care provider licensee. This subpart is necessary because an authorized prescriber may provide a person who is a client of an assisted living home care provider licensee with medication samples, and the licensee needs to know how to handle them if the licensee is providing central storage of medications or assistance with medications.

The Minnesota Board of Pharmacy statutes provides:

151.26 EXCEPTIONS.

Subdivision 1. ... Except for the provisions of section 151.37, nothing in this chapter applies to or interferes with the dispensing, in its original package and at no charge to the patient, of a legend drug, other than a controlled substance, that was packaged by a manufacturer and provided to the dispenser for distribution as a professional sample...

This subpart is reasonable because it provides clear, concise direction on the appropriate storage of medication samples and ensures the protection of the client's health and safety by requiring the original labels with legible directions for use. It is necessary and reasonable to require, when the licensee provides medication administration or assistance with self-administration of medication, that the use of a medication sample be addressed in the client's plan of care so that the existence and use of the sample is documented by the registered nurse to provide instruction to other nurses and unlicensed staff on the appropriate use of the medication. That documentation is necessary so that the registered nurse, licensee, or other staff of the licensee can readily verify administration procedures, intended outcomes from the medication sample, and possible side effects to watch for, to ensure the protection of the health and safety of the client. Addressing the use of a medication sample in the plan of care will verify that the registered nurse is aware of the use of the medication sample, and that it is consistent and appropriate in conjunction with other medications, treatments, and services provided to the client.

Part 4668.0865 CENTRAL STORAGE OF MEDICATION, Subpart 7 Prohibitions.

Part 4668.0865, subpart 7, prohibits the use of a legend drug supply for a person other than that it was prescribed for. This is necessary to provide specific direction to licensees to ensure the health and safety of the client. The language is reasonable because it is consistent with federal regulations and other state rules regarding pharmacy services.

Part 4668.0865 CENTRAL STORAGE OF MEDICATION, Subpart 8 Storage of drugs.

Part 4668.0865, subpart 8, requires that licensees providing central storage of medications must store those medications in locked compartments at proper temperatures and permits only authorized nursing personnel to have access to keys to those locked compartments. It is necessary that medications be kept in locked compartments to ensure the security of those medications, which are the property of the client and which are needed to ensure the health of the client. It is necessary and reasonable to specify that medications be kept at appropriate temperatures so the licensee is aware that certain medications need to be maintained within specific temperatures ranges to ensure their efficacy. It is necessary and reasonable to require that only authorized nursing personnel have access to keys to the locked compartments to ensure the safety and security of the medications, which are necessary to ensure the health of the clients.

Part 4668.0865 CENTRAL STORAGE OF MEDICATION, Subpart 9 Storage of Schedule II drugs.

Part 4668.0865, subpart 9, provides direction on the storage of Schedule II drugs. Schedule II drugs are controlled substances, and are called "Schedule II" because they are included in Schedule II of the Federal Controlled Substances Act and in the laws and rules of the Minnesota Board of Pharmacy. It is necessary and reasonable to provide direction in these assisted living home care provider licensing rules on the appropriate storage of Schedule II drugs to ensure the health and safety of clients who are taking those drugs and to ensure the health and safety of other clients in the housing with services establishment by limiting access to those controlled substances.

Part 4668.0865 CENTRAL STORAGE OF MEDICATION, Subpart 10 Schedule of fines.

Part 4668.0865, subpart 10 contains the penalties for noncompliance with the other subparts of this part. This subpart is necessary to comply with the requirements in Minnesota Statutes, section 144.653, subdivision 6. The amounts of the fines are reasonable because they are consistent with the schedule of fines established for the entire home care rule chapter. See part 4668.0230, subpart 5, above for a discussion on the fining schedule established for Minnesota Rules, Chapter 4668.

Item A: The penalty for noncompliance with part 4668.0865, subpart 2 is \$350. The \$350 penalty assessment has been assigned to those rules which relate to the direct provision of services to clients. Subpart 2 addresses the clinical assessment and plan of care for central medication storage, which are services directly provided to clients, so the \$350 penalty level is necessary and reasonable.

Item B: The penalty for noncompliance with part 4668.0865, subpart 3 is \$300. Subpart 3 addresses the system for control of medications, which is necessary to assure proper provision of central medication storage, so the \$300 penalty level is appropriate.

Item C: The penalty for noncompliance with part 4668.0865, subpart 4 is \$300. Subpart 4 assures that central storage of medication is provided properly, so the \$300 penalty level for noncompliance is appropriate.

Item D: The penalty for noncompliance with part 4668.0865, subpart 5 is \$300. Subpart 5 assures that central storage of medication is provided properly, so the \$300 penalty level for noncompliance is appropriate.

Item E: The penalty for noncompliance with part 4668.0865, subpart 6 is \$300. Subpart 6 addresses the use of medication samples by an assisted living home care provider licensee providing central storage of medications. This subpart is necessary to assure that central storage of medication is provided properly, so the \$300 penalty level for noncompliance is appropriate.

Item F: The penalty for noncompliance with part 4668.0865, subpart 7 is \$300. Subpart 7 prohibits using one client's medication for another client, which is necessary to assure that central storage of medication is provided properly, so the \$300 penalty level for noncompliance is appropriate.

Item G: The penalty for noncompliance with part 4668.0865, subpart 8 is \$300. Subpart 8 assures that central storage of medication is provided properly, so the \$300 penalty level for noncompliance is appropriate.

Item H: The penalty for noncompliance with part 4668.0865, subpart 9 is \$300. Subpart 9 discusses the storage of Schedule II drugs. This subpart is necessary to assure that central storage of medication is provided properly, so the \$300 penalty level for noncompliance is appropriate.

Part 4668.0870 DISPOSITION OF MEDICATIONS, Subpart 1 Scope.

Part 4668.0870, subpart 1, limits application of this rule part to assisted living home care provider licensees that provide central storage of medication. It is necessary and reasonable to include this language for the licensee that will store medications for its clients so that the licensee is aware of how to provide that service safely and appropriately, including knowing that there are ways to appropriately dispose of medications. It is also necessary to include the language so it is clear that this part does not automatically apply to all assisted living home care licensees - only to those licensees that provide central storage of medications.

Part 4668.0870 DISPOSITION OF MEDICATIONS, Subpart 2 Drugs given to discharged clients.

Part 4668.0870, subpart 2 addresses disposition of client medications when clients are discharged or move from the housing with services establishment. It is necessary to include this subpart in rule so that the licensee is aware that the client's current medications must be given to the client (or the client's responsible person) when the person is no longer an assisted living

home care client or no longer resides in the housing with services establishment. Those medications belong to the client, so it is reasonable that the licensee give them to the client. It is necessary to require that the licensee document in the client's record who received the medications to ensure there is a record to trace those medications if it becomes necessary to do so. This documentation is reasonable to verify the licensee's actions as well as the client's (or client's responsible person's) receipt of the medication in the event there is any question over where that medication went.

Part 4668.0870 DISPOSITION OF MEDICATIONS, Subpart 3 Disposition of medications.

Part 4668.0870, subpart 3 describes how to dispose of medications that are left in the housing with services establishment after the death or discharge of a client, that are unused or discontinued. This subpart is necessary and reasonable to protect the health and safety of clients as well as to comply with existing regulations for drugs. The language provided in these proposed rules is reasonable because it will provide clear guidance to licensees on the appropriate way to dispose of medications that are no longer needed by the client. The language is reasonable because it is based on language in rules from the Minnesota Board of Pharmacy, found in Minnesota Rules, part 6800.6500, that work for other types of licensees, and that comply with standards of practice in pharmacy services:

6800.6500 CONSULTING SERVICES TO LICENSED NURSING HOMES.

Subp. 3. **Unused portions.** Unused portions of controlled substances shall be handled by contacting the Minnesota Board of Pharmacy who shall furnish the necessary instructions and forms, a copy of which shall be kept on file in the facility for two years.

Any unused portion of other prescribed drugs remaining in the facility after the death or discharge of the patient or resident for whom they were prescribed or any prescriptions permanently discontinued shall be destroyed by the facility in the presence of a pharmacist or registered nurse who shall witness such destruction or shall be handled in accordance with part 6800.2700.

Part 4668.0870 DISPOSITION OF MEDICATIONS, Subpart 4 Loss or spillage.

Part 4668.0870, subpart 4, describes what to do when there is a loss or spillage of a Schedule II drug. Schedule II drugs require special documentation and tracking. It is necessary, therefore, to require documentation in the client's record when there is loss or spillage of a Schedule II drug. It is reasonable that licensees be made aware of methods to comply with state and federal laws and rules regarding the appropriate use and possession of controlled substances.

Part 4668.0870 DISPOSITION OF MEDICATIONS, Subpart 5 Schedule of fines.

Part 4668.0870, subpart 5 contains the penalties for noncompliance with the other subparts of this part. This subpart is necessary to comply with the requirements in Minnesota Statutes, section 144.653, subdivision 6. The amounts of the fines are reasonable because they are consistent with the schedule of fines established for the entire home care rule chapter. See part

4668.0230, subpart 5, above for a discussion on the fining schedule established for Minnesota Rules, Chapter 4668.

Item A: The penalty assessment for noncompliance with a correction order for part 4668.0870, subpart 2, is \$300. The \$300 penalty assessment has been assigned to those rules that are necessary to assure that the service is properly provided. Part 4668.0870, subpart 2, addresses the return of clients' drugs when they are discharged from the licensee or move from the housing with services establishment. The proposed rule is necessary to assure that disposition of medications is properly provided, so the \$300 penalty level is appropriate for part 4668.0870, subpart 2.

Item B: The penalty assessment for noncompliance with a correction order for part 4668.0870, subpart 3, is \$300. Subpart 3 addresses the disposition of unused medications and is necessary to assure that is done appropriately, so the \$300 penalty level is appropriate.

Item C: The penalty assessment for noncompliance with a correction order for part 4668.0870, subpart 4, is \$300. Subpart 4 addresses the loss or spillage of Schedule II drugs, which is necessary to include in rule to assure that those situations are handled appropriately, so the \$300 penalty level is appropriate.

VI. ADDITIONAL NOTICE

The Department has initiated numerous efforts to provide additional notification of the development of the proposed rules.

Articles describing the rule revision process and its status have been published regularly in *The Resource*, the publication of the MDH Facility and Provider Compliance Division, which is distributed to all licensed nursing homes, boarding care homes, provider and consumer organizations, and other interested persons. The major provider organizations and many professional organizations, including the Minnesota Health and Housing Alliance and Care Providers of Minnesota, have published articles on the home care rule revision process in their newsletters. State agency staff have presented information on the project at many meetings of members of those organizations, and have thereby received many helpful comments and suggestions from persons who are actually providing what will be licensed as assisted living home care services.

Public meetings have been conducted at various points throughout the process to assure that all possible viewpoints are being received. The Department is in the process of revising Minnesota Rules, Chapter 4668 Home Care and Hospice Licensure rules. The Home Care and Hospice Licensure Rule Advisory Committee met in June and September of 1996 to discuss possible revisions to the existing home care rules to accommodate what was then called the "Elderly Housing With Services Act." The charge of that rule advisory committee is to provide

suggestions for rule language and revisions to the existing home care rules.

Because of the specificity in Minnesota Statutes, section 144A.4605, another rule advisory committee was formed to provide suggestions for rules to implement the assisted living home care provider license class. Some of the persons on this rule advisory committee are also members of the Home Care and Hospice Rule Advisory Committee. Rule advisory committee meetings are always open to the public.

Staff at the department have attended many other meetings of interested persons, businesses, and professional organizations to provide information and answer questions on the rule revision process. Presentations have been made at annual conferences and other gatherings of provider organizations and professional organizations. Often, information gathered from persons at these meetings was used by the department and the rule advisory committee as discussion points regarding potential changes, including additions and deletions, to the rules.

The basis for much of the proposed language for the assisted living home care provider licensure standards is Minnesota Statutes, section 144A.4065. Draft legislation was proposed in 1996, but did not get passed into law. The 1997 Legislature made amendments to the statutes addressing home care licensure standards and those addressing Housing with Services registration. Much of the proposed rule language is based directly on those legislative changes. The 1996 bill was widely circulated among the industry and state agencies, and was provided to the rule advisory committee. Draft rule language had been created in 1996 based on that bill, and was refined and developed to match the 1997 legislation.

Public Advisory Committees

A Rule Advisory Committee, consisting of 22 members from the public and private sectors, provides oversight to the Department on the home care rule revision process. This rule advisory committee is charged with sharing information on the rule revision process with their constituents. The members of this Rule Advisory Committee have been:

Sherilyn Moe, Minnesota Home Care Ombudsman
Mary Rippke, R.N., MDH CHS Division, Public Health Nursing
Phyllis King, Arrowhead Health Care Center, Care Providers of Minnesota
Kathy Wick, R.N., Dakota County Public Health
Anne Ringquist, R.N., Minnesota Board of Nursing
Joanne Sylvander, MN Professional Direct Caregivers Assn.
Val Barnes, MN Professional Direct Caregivers Assn
Dan Holst, MN Hospice Organization
Joann Susens, People Inc. Home Health Agency
Mary Rodenberg-Roberts, ARRM
Sally Smaida, MN Hospital and Healthcare Partnership
Mary Youle, MN Health & Housing Alliance
Karen Holmes, MDH Environmental Health Division

Deb Kildahl, MN Home Care Association
Cate DeVaan, MN Home Care Association
Susan Lynx, MN Nurses Association
Dianne Hansen, MN Nurses Association
Pam Erkel, DHS - Home & Community Based Services
Adele Spavin, AARP
Jeannette Lindgren, R.N.
Linda Sutherland, MDH F&PC Division Director
Mary Absolon, R.N., MDH F&PC, Licensing & Certification Program Manager
Mary Cahill, MDH F&PC Division
Maggie Friend MDH F&PC Division

The Home Care Rule Advisory Committee was notified of meetings scheduled to discuss rule language for the assisted living home care provider class. If requested, Home Care Rule Advisory Committee members received copies of drafts of proposed revisions when they were created. The rule advisory committee is responsible to share information from those drafts with their constituents and to relay comments and suggestions from their constituents to the committee and department. Such widespread dissemination of information to interested persons and groups has provided a "bigger picture" of the public's responses to drafts of proposed rules.

The Assisted Living Home Care Provider Rule Advisory Committee, an offshoot of the Home Care Rule Advisory Committee, met four times to discuss Minnesota Statutes, section 144A.4605 and how best to implement it through rules. The charge provided to this committee was to "advise the Minnesota Department of Health of suggestions for rule language for the new license class and of reasons for the suggested language. Additional persons attended these rule advisory committee meetings to discuss the development of the "assisted living home care provider" licensure class rules. Representatives of the Minnesota Department of Health, Minnesota Department of Human Services, Care Providers of Minnesota, and the Minnesota Health and Housing Alliance met on July 2, 1997, to determine the major areas of concern which the new license class should address. The Assisted Living Home Care Provider Rule Advisory Committee met on August 6, August 20, September 3, and October 8, 1997, to discuss drafts of proposed rule language. Persons attending these meetings and involved in the development of these proposed rules include:

Barb Case, Anoka County Social Services
Beth Lang, Otter Tail County Social Services
Carole Lohman, St. Paul Ramsey County Public Health
Jane Heaton, Hennepin County
Joanne Thomas, Anoka County Public Health Nursing
Kathy Wick, Dakota County Public Health
Marge Wherley, Hennepin County
Maryon Kellar, Hennepin County Community Health Services
Sarah VanWinkle, Hennepin County
Toni Baker, Ramsey County Human Services

Beckie Conway, Presbyterian Homes, Roseville
 Cheryl Kroeber, South Central SAIL
 Dianne Hansen, RN, LiveWell (until 1997: MN Nurses Association)
 Joanne Sylvander, MN Professional Direct Caregivers Assn.
 Karen Beard, Spring of Water Home Care
 Linda Ernst, Agape
 Marcine McLeran, MN Home Care Inc.
 Maureen Sop, Seniors Agenda for Independent Living (SAIL), Mankato
 Nan Just, East Metro SAIL
 Sue Stout, MN Nurses Association
 Val Barnes, MN Professional Direct Caregivers Assn
 Cate DeVaan, MN Home Care Association
 Dan Peterson, MN Home Care Association
 Debra Kildahl, MN Home Care Association
 Mary Youle, MN Health & Housing Alliance
 Duane Elg, MN Health & Housing Alliance
 Glenn Silloway, Care Providers of Minnesota
 Anne Ringquist, R.N., Minnesota Board of Nursing
 Bev Archer, MN Department of Human Services
 Deb Wesley, MN Department of Human Services
 Donna Wen, MN Department of Human Services
 Jane Vujovich, MN Department of Human Services
 John Fillbrandt, MN Department of Human Services
 John Hastings, MN Department of Human Services
 Karen Holmes, MDH Environmental Health Division
 Karen Kieffer, DHS Licensing Division
 Maura Dower, MN Board of Nursing
 Pat James, MN Department of Human Services
 Renee Fredericksen, MN Department of Human Services, SAIL Project
 Sherilyn Moe, Minnesota Home Care Ombudsman
 Linda Sutherland, MDH F&PC Division Director
 Mary Absolon, R.N., MDH F&PC, Licensing & Certification Program Manager
 Marci Martinson, MDH F&PC Division, Licensing & Certification
 Mary Cahill, MDH F&PC Division
 Maggie Friend, MDH F&PC Division

In addition to persons who have attended meetings to review and discuss proposed rule language, a mailing list of interested persons has been developed and maintained. Persons on the mailing list have received drafts of proposed revisions to the rules and have been encouraged to submit written comments on the draft language. Drafts were sent to the mailing list on October 3, 1997, November 14, 1997, February 6, 1998, and March 19, 1998. In addition, once a more finalized version was returned from the Office of the Revisor of Statutes, a draft dated April 30, 1998 was provided to interested persons.

Notice Plan

The dual notice of proposed rulemaking as it appears in the *State Register* will be sent to all licensed home care providers, all registered housing with services establishments (504 as of 9/23/98), the discretionary mailing list for this rulemaking project, and the official department rulemaking mailing list. The discretionary mailing list contains over 180 names of persons and organizations that have expressed an interest in this rulemaking project, and includes the major provider organizations and professional organizations affected by this rule.

VII. COMMISSIONER OF FINANCE REVIEW OF CHARGES

Minnesota Statutes, section 16A.1285, does not apply because the rules do not set or adjust fees or charges. The licensure fees for this category of home care license are established in Minnesota Statutes, section 144A.4605, subdivision 5. The penalty assessments in the proposed rules are based on a schedule of fines developed according to Minnesota Statutes, section 144.653, subdivision 6. Penalty assessments are not considered to be fees or charges since they do not automatically apply to a licensee. Penalty assessments only apply when a licensee does not comply with a correction order and remains out of compliance with a rule.

VIII. PERFORMANCE-BASED REGULATORY SYSTEMS

The 1998 Legislature added a section to the laws regarding rule promulgation. That section reads:

14.002 STATE REGULATORY POLICY.

The legislature recognizes the important and sensitive role for administrative rules in implementing policies and programs created by the legislature. However, the legislature finds that some regulatory rules and programs have become overly prescriptive and inflexible, thereby increasing costs to the state, local governments, and the regulated community and decreasing the effectiveness of the regulatory program. Therefore, whenever feasible, state agencies must develop rules and regulatory programs that emphasize superior achievement in meeting the agency's regulatory objectives and maximum flexibility for the regulated party and the agency in meeting those goals.

The regulatory program that includes these proposed rules has been designed to emphasize superior achievement in meeting MDH's regulatory objectives by providing a variety of licensing options for providers to pick and choose from, depending on their business plan and the services they choose to provide. Providers have licensure options to choose from within the

home care regulatory program, so they can tailor their operations to serve the client base they wish to choose, and then have regulations that are specific to their service delivery situation. In addition, the home care licensing rules allow for providers to request and be granted waivers from specific rules when they demonstrate an alternative method to achieve the regulatory objectives in that rule. This allows for customizing of the regulations for a specific licensee, which should emphasize superior achievement in meeting regulatory objectives if they can have an input on how they can meet those objectives.

When the two major provider organizations in this state were working with the legislature to develop and enact the Housing With Services Act and the changes to the home care licensing statutes, one of their intended outcomes of the new regulatory program for places that provide assisted living was the least restrictive method of regulation possible. There are some basic portions of the regulatory program that apply to all regulated parties. In these assisted living home care provider rules, a licensee chooses what services they will deliver, and then follows the rules for the provision of those services. For example, if the licensee is providing delegated nursing services, the licensee follows the rule parts that address the provision of delegated nursing services. If the licensee provides central storage of medication, the licensee then follows the rule parts that address central storage of medications. Similarly, if the licensee does not provide central storage of medications, then those parts of these rules do not apply to that licensee.

These proposed rules have been designed to provide maximum flexibility for the regulated party. Throughout the proposed rules, the language is constructed to allow the licensees to make decisions on the organization and operation of their business. These proposed rules are a regulatory option for establishments that provide both housing and services to an older population. A housing with services establishment, registered as such under Chapter 144D, that provides health related services, must provide those services under a home care license - these proposed rules are an additional option for which type of home care license is appropriate to the business and the clients to be served.

IX. EFFECTIVE DATE OF THE RULES

These proposed rules will be effective five working days after the notice of adoption is published in the State Register. Housing with Services establishments that already have a home care license will be able to continue with that license class until their annual renewal date. New home care applicants that are registered housing with services establishments will have the option to apply for the home care license that best suits their service delivery plan.

X. LIST OF WITNESSES

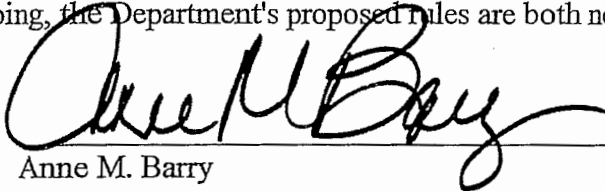
If these rules go to a public hearing, the Department anticipates having the following witnesses testify in support of the need for and reasonableness of the rules:

1. Ms. Mary Cahill will testify on behalf of the Department about the development and content of the rules.
2. Ms. Maggie Friend will testify on behalf of the Department about the development and content of the rules.
3. The witnesses will be available to answer questions about the development and the content of the rules. Other staff may testify or be available to answer questions about specific aspects of the proposed rule. Other staff may substitute for those named above.

X. CONCLUSION

Based on the foregoing, the Department's proposed rules are both needed and reasonable.

Dated: 10/2/98



Anne M. Barry
Commissioner
Minnesota Department of Health

